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FEDERAL REGISTER

Vol. 78 Tuesday,
No. 209 October 29, 2013

Pages 64389–64872

OFFICE OF THE FEDERAL REGISTER

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Printed on recycled paper.

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BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Chapter X

[Docket No. CFPB–2012–0046]

Policy To Encourage Trial Disclosure Programs; Information Collection

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of policy.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is issuing its Policy to Encourage Trial Disclosure Programs (Policy), which is intended to carry out the Bureau's authority under of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act).

DATES: The Policy is effective on October 29, 2013.

FOR FURTHER INFORMATION CONTACT: For additional information about the Policy, contact Will Wade-Gery, Division of Research, Markets and Regulations, Consumer Financial Protection Bureau, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Overview

In subsection 1032(e) of the Dodd-Frank Act, 12 U.S.C. 5532(e), Congress gave the Bureau authority to provide certain legal protections to companies to conduct trial disclosure programs. This authority can be used to help further the Bureau's statutory objective, stated in subsection 1021(b)(5) of the Act, to ''facilitate access and innovation'' in the ''markets for consumer financial products and services.''

In line with this authority, the Bureau is publishing the Policy that is laid out in full in the final section of this Notice. Under its terms, if the Bureau approves a specific trial, then, for the duration of an agreed testing period, the Bureau will deem a testing company's disclosure, to the extent that it is used in accordance with the terms and conditions approved by the Bureau, to be in compliance with, or hold it exempt from, applicable federal disclosure requirements. The Bureau believes that there may be significant opportunities to enhance consumer protection by facilitating innovation in financial products and services and enabling companies to research informative, cost-effective disclosures. The Bureau also recognizes that in-market testing, involving companies and consumers in real world situations, may offer particularly valuable information with which to improve disclosure rules and model forms.

II. Overview of Public Comments

On December 17, 2012, the Bureau published a notice inviting the general public and other Federal agencies to comment on any aspect of its proposed Policy to Encourage Trial Disclosure Programs (the Proposed Policy).[1] The Bureau received eighteen formal comments on the Proposed Policy. Industry trade associations and other industry groups submitted nine comment letters. Financial services providers submitted three comment letters. There were three comment letters from consumer groups. Individuals also submitted a further three comments.

All commenters supported the stated goals of the Proposed Policy. Most comments asked for clarification or further detailing around specific parts of the Proposed Policy. Some urged changes to the Proposed Policy either to create more incentives for the regulated community to participate in trial disclosure programs or to provide for additional consumer protections in approved tests. One comment opposed implementation of the Proposed Policy, at least in its current form; this commenter also disputed the Bureau's legal authority for certain aspects of the Proposed Policy.

III. Summary of Comments, Bureau Response, and Resulting Policy Changes

This section provides a summary of the comments received by subject matter. It also summarizes the Bureau's assessment of the comments by subject matter and, where applicable, describes the resulting changes that the Bureau is making in the final Policy. With some specific exceptions, the Bureau has not made changes to the substance of the Policy. In response to certain comments, however, it has revised the Policy to provide additional clarity and elaboration around a number of specific points.

A. Legal Authority

As noted in the Proposed Policy, Section 1032(e) of the Dodd-Frank Act gives the Bureau authority to permit trial programs that are designed to ''improve upon'' existing disclosures. One consumer group contended that the Proposed Policy exceeds the Bureau's legal authority in two respects: (1) By not requiring trial disclosure programs to meet the criteria for model forms prescribed by the Bureau under Section 5532(b) of the Act, 12 U.S.C. 5532(b); and (2) by potentially permitting trial disclosure programs that are designed to test cost savings alone. The Bureau believes both contentions lack legal merit.

Section 5532(b)(1) authorizes the Bureau to issue model forms that ''may be used at the option of a covered person.'' Section 5532(b)(2) sets forth three ''minimum'' features such model forms must possess. These provisions do not limit the trial disclosures that the Bureau may approve under Section 5532(e). In that provision, Congress gave the Bureau authority to permit testing of disclosures that violate disclosure requirements imposed directly on covered persons by the Bureau. There is no textual or other reason to think that Congress intended the Bureau's authority under Section 5532(e) to be circumscribed by Section 5532(b).

Indeed, adding the Section 5532(b)(2) criteria to the Policy arguably would frustrate Congress' purposes in enacting Section 5532(e). Thus, a proposal to change a delivery mechanism, as opposed to the content of the disclosure, would not track against the criteria for a model form. Yet there is nothing in Section 1032(e) to suggest that Congress intended to exclude changed delivery mechanisms from the list of potential improvements. As a matter of policy, however, to the extent a proposal includes revised disclosures, the Bureau believes those should meet the stated 1032(b)(2) criteria of plain language, clear format and design, and

[1] 77 FR 74625 (Dec. 17, 2012).

succinctness. The Policy has been revised to make that point.

The Bureau also sees no legal or policy reason to eliminate cost-effectiveness as a sufficient criterion for an ''improved'' disclosure. In the Bureau's view, a trial disclosure that is intended to maintain the same level of consumer understanding but in a more cost effective manner counts as an improved disclosure. Under the Policy, however, the Bureau will not approve any trial disclosure that it believes will weaken consumer understanding of valuable information that is the focus of a regulatory obligation. That outcome is not one that the Policy is intended to enable, and the Bureau has revised the Policy to make that clear.

B. Approval Process

Most comments concerned the approval process for trial disclosure programs. Comments focused on the areas identified below.

1. Cost-Sharing

Several trade associations and financial services companies questioned whether, in light of the costs involved in designing and implementing trial disclosure programs, companies will have sufficient incentive to use the Policy. For the most part, however, these commenters did not urge more streamlined application or participation procedures. Instead, they requested a clear indication from the Bureau that several covered persons—potentially facilitated by a trade organization—may properly spread the costs of participation among themselves, thereby improving the incentive to participate. Some trade associations noted that absent such collaboration, industry participants would lack the resources to conduct a trial program.

The Bureau would welcome collaboration and cost-sharing, and it has clarified the final Policy to this effect. To help ensure adequate protection for consumers, however, the Bureau must know the identity of each specific in-market tester before approving that entity's participation. As a result, the Bureau will not give final approval to any proposed trial disclosure unless the entities involved are specifically identified. At the same time, however, the Bureau sees no reason why a single trial disclosure program may not properly be proposed and implemented by more than one covered person. In fact, as both industry and consumer commenters noted, multi-party tests may offer more robust and reliable results. By the same token, the Policy should not be read to prevent a trade association—or indeed any other entity, including non-profit groups or third-party vendors—from helping to facilitate cost-spreading.

In addition, the Policy does not rule out the possibility of the Bureau conditionally approving a particular disclosure for testing without at that point requiring the specific identity of all participants. In this kind of staggered approval arrangement, there would be a follow-on process for specific testers to secure approval to use the disclosure. But even if the Bureau were to stage approval in this manner, the Policy would still not permit a particular tester to claim the benefit of a waiver unless the Bureau ultimately approves it *by name* as a test participant.

2. Development Costs

Citing the costs of developing a proposal and implementing a trial disclosure program, several commenters urged the Bureau to permit covered persons to contact the Bureau to discuss a proposal before they submit complete applications. This initial contact could help companies avoid the costs of developing proposals that are unlikely to meet with the Bureau's approval, whether because of the merits of the proposal or because the Bureau is close to approving a duplicative proposal. The Policy is not intended to limit this kind of initial contact. The present Policy is one component part of the Bureau's Project Catalyst initiative, which invites companies to bring innovation-related concerns to the Bureau's attention at *ProjectCatalyst@cfpb.gov*. Disclosure innovators, therefore, may use that point of contact to request a preliminary discussion of a potential trial disclosure proposal.

3. Iterative Testing

Several commenters, including industry and consumer group commenters, suggested that the Policy accommodate iterative testing of disclosures. The Bureau acknowledges that in some cases, iterative testing, using relatively small test populations, may help refine and improve disclosure concepts. Instead of a single, larger test, of a preset disclosure, this kind of approach involves a sequence of smaller tests that enable ongoing improvements to a test disclosure concept. Both forms of testing may serve well in different contexts, and the Bureau intends for the Policy to support both approaches.

In cases where iterative testing is appropriate, therefore, the Bureau will follow a staggered approach to waiver approval. At an initial stage, an iterative proposal should follow all the normal terms of the Policy, with the exception that it may not include all forms of the disclosure to be tested, to the extent that these are unknown at the point of initial submission. Any such proposal should explain why iterative testing is the more effective means of proceeding with respect to the particular disclosure. If the Bureau approves the program, an initial waiver will then cover the first test disclosure, and the Bureau will commit in the Terms and Conditions document governing that waiver to consider later iterations of the test disclosure for follow-on waivers on a defined fast-track basis. The Policy thereby enables iterative testing, where it is appropriate, while also ensuring that each tested disclosure is specifically authorized.

4. Additional Safeguards

Notice and Comment

Several consumer groups asked that the Policy require that all proposed disclosures be subject to full notice and comment. In contrast, a financial service provider cautioned that such a procedure would dissuade companies from proposing trial disclosure programs because it would add considerable time and expense to the process. In the Bureau's assessment, requiring notice and comment for each proposed disclosure would conflict with Congress's instruction to issue standards and procedures ''designed to encourage covered persons to conduct trial disclosure programs.'' (12 U.S.C. 5532(e)(2).) The Bureau believes that it is highly unlikely that covered persons would be willing to subject proposals to full notice and comment, not least because of the extended time period involved. In addition, a test disclosure does not represent a proposed Bureau rule. Test results could help the Bureau to put forward proposed rule changes, but full notice and comment would then apply at that point.

Other Safeguards

Consumer groups also proposed that tests be approved only when there is no statutory liability associated with the disclosure process. In addition, they proposed that no in-market tests proceed until after ''lab-based'' qualitative testing of each proposed disclosure.

The Bureau does not agree that tests should be limited to disclosures for which non-compliance carries no statutory liability. Section 1032(e) authorizes the Bureau to apply a time-limited safe harbor with respect to disclosure requirements under ''a rule or an enumerated consumer law.'' [2] It does not limit this authority to statutes

[2] 12 U.S.C. 5532(e)(2); *see also* n.17 *infra.*

(or rules) that impose no liability. In addition, while statutory liability may well indicate that a disclosure is intended to prevent severe consumer harm, as the commenters reasonably contend, that does not argue against testing for disclosure improvement. The more important the role of disclosure in preventing harm, the more important it is to improve disclosures as much as possible. If 1032(e) were used only where disclosure does not matter to consumer welfare, its purpose would go unrealized.

The Bureau agrees with commenters that qualitative testing will often be a useful means of showing that a disclosure is worth testing. That is not a compelling reason, however, to make qualitative testing an absolute requirement for test approval. The approval process calls for reasonable grounds to expect the revised disclosures to represent an improvement. In many cases, those grounds will consist—at least in part—of qualitative test results. But that need not always be the case. Other grounds could certainly supply a sufficient basis for expecting improved outcomes. Similar disclosures may have been used and shown to be effective for related consumer financial products, or prior research may offer reasonable grounds to believe the revised disclosure will be an improvement.

5. Guidance on Bureau Disclosure Priorities

Some commenters asked the Bureau to identity priority areas for potential tests. The Bureau does not rule out taking this step at some point in the future. In considering ways to improve disclosure policy, the Bureau may in the future identify one or more areas as particularly appropriate for testing.

C. Legal Protection

1. Waiver Scope

Several trade associations and industry participants asked the Bureau to clarify the scope of the safe harbor that will be provided to approved participants. In particular, they asked whether the waivers would shield participants from (i) private litigation by consumers and (ii) enforcement or other proceedings by other regulators.

The Bureau recognizes that Section 1032(e) will not provide the incentive to test new disclosures that Congress intended unless the scope of any approved waivers is clear. Entities that the Bureau approves for a waiver—so long as their conduct accords with the terms of approval—should not face private liability exposure for violating those provisions of a federal disclosure statute or rule that the Bureau identifies as being within the scope of the waiver. Because such a waiver deems the trial disclosure to be in compliance with or exempt it from the provisions identified by the Bureau, there is no basis under those provisions for a private suit based on the company's use of the disclosure. The same rationale applies to other federal and state regulators even if they have enforcement or supervisory authority as to the ''enumerated consumer laws'' for which the Bureau has rulemaking authority. When a Bureau-issued waiver is in effect, there can be no predicate for an enforcement or supervisory action by such a regulator that is both based on statutory or regulatory provisions that are within the scope of the waiver and against a company with an approved program in compliance with the terms of the wavier.

It is true that certain other federal regulators may, in certain circumstances, issue rules that overlap with the Bureau's rules. (*See, e.g.,* 12 U.S.C. 5581(b)(5))(D).) When considering a waiver, therefore, the Bureau will confer, as appropriate, with other federal regulators. Similarly, although the Bureau lacks authority to waive state disclosure requirements, the Bureau will endeavor to work with state regulators, as appropriate, to secure their support for a particular trial disclosure program. The Bureau also encourages participants to confer with other federal and state regulators where a proposed disclosure implicates requirements administered by such regulators. In addition, submissions may properly indicate whether other regulators have indicated support or opposition to the proposal.

2. Affirmative Bureau Statements

Finally, several commenters asked the Bureau to state that disclosures approved under the Policy are not deceptive. The Bureau does not intend to approve test disclosures that it considers deceptive. As a result, the Bureau anticipates being able to make this kind of statement when it publishes notice of a waiver. In either case, however, the Bureau's determination would be provisional. Unless and until otherwise indicated, the Bureau's statement or waiver would apply only to disclosures that an approved party made under the terms of that particular approved trial disclosure program.

3. Waiver Revocation

The Proposed Policy specified that if the Bureau decides to revoke or partially revoke a waiver for failure to follow the waiver's terms, it: (i) Will do so in writing, specifying the reason or reasons for its action; and (ii) may offer an opportunity to correct any such failure before revoking a waiver. Several commenters found these procedural protections insufficient and requested that they be enhanced in various ways.

The Bureau acknowledges that entities may reasonably request some opportunity to dispute grounds for a potential revocation. Before determining to issue a revocation, therefore, the Bureau will notify the company of its grounds for its potential revocation, and permit the company an opportunity to respond, consistent with the terms of this Policy. The Policy has been clarified to this effect.

D. Public Disclosure

Commenters raised two public disclosure concerns.

1. Consumer Awareness of Tests

Citing protocols for conducting research on human subjects, consumer groups urged that consumers be given the chance to opt out of test participation. They also requested that test disclosures be clearly identified as such. One industry submission suggested that the Bureau inform consumers after the fact of their participation in a test.

The Bureau does not agree that standard practice argues for requiring consumer consent in this context. In-market testing of consumer behavior and reactions to new products or new ways of delivering services is a constant of modern life. Companies routinely carry out such tests using their customer base, without consumer consent or awareness. The fact that companies must share test results with the Bureau does not compel a different outcome here. As the statute makes clear, 1032(e) tests are still conducted *by covered persons*.

Furthermore, there is very good reason not to identify test disclosures at the time of delivery. As one commenter observed, disclosures only work to the extent consumers read them. A critical test of any disclosure's effectiveness, therefore, is whether consumers decide to read it in any given case. As a result, if consumers are told that a disclosure is for a test, it will no longer be possible to test for the most basic and controlling component of disclosure effectiveness. Moreover, requiring such disclosure would be in tension with Congress's recognition in section 1032 that public disclosure of programs may appropriately be limited in order to

encourage the conduct of ''effective'' tests.[3]

The Bureau has considered requiring companies to alert consumers that they are in a test population—regardless of whether the consumers are in a control group or in the group to receive a test disclosure.[4] This type of notification, potentially supplemented by an opt-out option, would create equivalency between the two groups. At the same time, however, it would prevent effective testing in many cases. All consumers would be alerted to the fact of disclosure testing, and their conduct upon receiving disclosures would likely change as a result. In the Bureau's assessment, the benefit of this direct notice, weighed against the cost of preventing effective testing and associated disclosure improvements, does not warrant a categorical rule requiring direct disclosure of testing to test populations. To the extent that companies can find ways to provide notice or an opt-out option that do not risk the effectiveness of potential tests, however, the Bureau encourages them to do so.

2. Disclosure of Test Results

Several consumer groups urged that all test results be made public. After careful consideration, the Bureau has decided not to revise the Proposed Policy to this effect. Congress has directed that public disclosure be limited as necessary to encourage covered persons to conduct effective tests. (*See* 12 U.S.C. 5532(e)(3).) In the Bureau's assessment, requiring testing companies to commit, *a priori,* to complete public disclosure of test results may unproductively discourage valuable potential programs that stand to benefit consumers. Some of the information provided to the Bureau may comprise trade secrets or other confidential business information. Testing companies will ultimately need to permit public use of test results if those results are to enable regulatory change. An incentive to public disclosure, therefore, is built into the structure of the program. Particularly against that background, additional categorical rules could reduce the incentive to propose potentially valuable trial disclosure programs. In addition, the absence of a categorical rule does not preclude the Bureau from seeking a particular level of disclosure in connection with any particular proposal.

[3] 12 U.S.C. 5532(e)(3).

[4] Indirect notice that consumers may receive a test disclosure will already be provided by the Bureau's Web site publication of approved test disclosures.

E. Other Considerations

Commenters also requested clarification on a number of discrete issues.

1. Delivery Form

The Bureau confirms that disclosure improvements may properly consist of revised forms of delivery, not simply changes to the content of disclosures. This was already covered at footnote 7 of the Proposed Policy. It is now reflected in the eligibility criteria listed in Section A of the final Policy.

2. Electronic Submission

Submissions for approval can be made via electronic means. Submitters can use the Project Catalyst email address. The Policy has been revised accordingly.

3. Bureau Monitoring of Consumer Harm

Several consumer groups requested that the Bureau monitor tests for potential harm to consumers. The Proposed Policy already called for proposals to include plans to mitigate any harm identified. To further address the concern raised, however, the Bureau has amended the eligibility criteria to include both an identification of any risks of consumer harm that may be associated with the proposed program and a description of how the program mitigates any such risks.

IV. Final Policy

The text of the final Policy is as follows.

Consumers need timely and understandable information to make the financial decisions that they believe are best for themselves and their families. Much federal consumer protection law, therefore, rests on the assumption that accurate and effective disclosures will help Americans understand the costs, benefits, and risks of different consumer financial products and services. In Section 1032 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), Congress gave the Consumer Financial Protection Bureau (Bureau) authority to develop rules to ensure that consumers receive such disclosures, as well as model forms to help companies comply with those rules.[5]

In subsection 1032(e) of the Dodd-Frank Act, Congress also gave the Bureau authority to approve ''trial disclosure programs.''[6] This authority can be used to help further the Bureau's statutory objective, stated in subsection 1021(b)(5) of the Dodd-Frank Act, to ''facilitate access and innovation'' in the ''markets for consumer financial products and services.'' In particular, Congress empowered the Bureau to provide a legal ''safe harbor'' to companies testing revised disclosures. For disclosure trials it approves, therefore, the Bureau will, for a defined period, ''deem'' a participating company ''to be in compliance with,'' or ''exempt'' from identified federal disclosure requirements.[7] The Bureau believes that there may be significant opportunities to enhance consumer protection by facilitating innovation in financial products and services through enabling responsible companies to research informative, cost-effective disclosures in test programs. We also recognize that ''in-market'' testing, involving companies and consumers in real world situations, may offer particularly valuable information with which to improve disclosure rules and model forms.

Accordingly, the Bureau is issuing its Policy on trial disclosure programs.[8] Our intent is for the Policy to encourage banks, thrifts, credit unions, and other financial services companies to innovate by proposing and conducting such programs, consistent with the protections for consumers that are described in this Policy.[9] The information that companies generate by such programs may then help the Bureau to establish more effective disclosure rules and practices.[10]

The policy has four sections:

[5] *See* 12 U.S.C. 5532(a)–(d).

[6] 12 U.S.C. 5532(e).

[7] 12 U.S.C. 5532(e)(2). For convenience, this statutory authority to deem companies in compliance with or to exempt them from disclosure requirements—in each case for a limited period of time—is hereinafter referred to as the authority to issue ''waivers'' for approved programs.

[8] The Bureau may permit a covered person or covered persons to conduct a trial disclosure program ''subject to specified standards and procedures.'' 12 U.S.C. 5532(e)(1).

[9] The Policy is not intended to nor should it be construed to: (1) Restrict or limit in any way the CFPB's discretion in exercising its authorities; (2) constitute an interpretation of law; or (3) create or confer upon any covered person (including one who is the subject of CFPB supervisory, investigation or enforcement activity) or consumer, any substantive or procedural rights or defenses that are enforceable in any manner. Of course, if the Bureau approves a waiver in connection with a trial disclosure program, the terms of its approval will specify certain legal rights granted to the recipient or recipients of the waiver with respect to that program. Those rights, however, are based on the approval notice, and not on the present policy guidance.

[10] The Policy should not be viewed as substituting for the normal process of rulemaking. In the event that information learned from trial disclosure programs triggers or otherwise informs follow-on rulemaking, the Bureau would follow the standard rulemaking process, which affords the public the opportunity of submitting comments on a proposed regulation.

• Section A describes which proposed programs will be considered eligible for a temporary waiver;
• Section B lists factors the Bureau will consider in deciding which eligible programs to approve for such a waiver;
• Section C describes the Bureau's procedures for issuing waivers; and
• Section D describes how we will disclose information about these programs.

Paperwork Reduction Act

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The information that should be submitted to demonstrate eligibility, as described further in Section A below, has been deemed to be a collection of information for these purposes. The OMB control number for this collection is 3170–0039. It expires on 09/30/2016. The time required to complete this information collection is estimated to average between 2 and 10 hours per response, including the time for reviewing any instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The obligation to respond to this collection of information is required to obtain a benefit to the extent that the information is to establish eligibility for a temporary waiver, as described in this policy. Comments regarding this collection of information, including the estimated response time, suggestions for improving the usefulness of the information, or suggestions for reducing the burden to respond to this collection should be submitted to Bureau at the Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, or by email to *CFPB_Public_PRA@cfpb.gov*.

A. Eligibility

To be considered eligible for a waiver, a proposal should:

1. Identify the testing company or companies; [11]

2. Describe the new disclosures or delivery methods that are to be tested; [12]

3. Describe how these changes are expected to improve upon existing disclosures,[13] particularly with respect to consumer use, consumer understanding, and/or cost-effectiveness; [14]

4. Provide a reasonable basis for expecting these improvements, and metrics for testing whether such improvements are realized;

5. Identify the duration of the test and the size, location, and nature of the consumer population involved in the test, and explain why that duration and scope are reasonably necessary for sound testing;

6. Identify any risks of consumer harm that may be associated with the proposed program, describe how the program mitigates such risks, and explain the testing procedures that will be used to assess for potential consumer harm during the course of the test;

7. Identify with particularity which provisions of current rules or enumerated consumer laws are to be temporarily waived in connection with the trial disclosure program; [15]

8. Identify any third-party vendors to be used in connection with the proposed program and describe their proposed role;

9. Contain a commitment to and schedule for sharing test result data [16] with the Bureau;

10. Acknowledge that the Bureau may revoke any approved waiver if the program violates the terms and conditions under which the Bureau approves the program; and

11. Explain how the testing company will address disclosure requirements for the test population at the conclusion of the test period.

All proposals should be submitted via email to *ProjectCatalyst@cfpb.gov*.[17] Submitted proposals may be withdrawn at any time.

B. Approval of Proposals for Waivers

To decide whether to approve a proposed program for a waiver,[18] the Bureau will consider a variety of factors, including:

1. The extent to which the program may help the Bureau develop disclosure rules or policies that better enable consumers to understand the costs, benefits, and risks associated with consumer financial products or services;

2. The extent to which the program may help the Bureau develop more cost-effective disclosure rules or policies;

[11] The Bureau will accept proposals that involve testing by more than one company. Each testing company must be approved by name and must be a signatory to specific waiver terms, as described further in Section C below. Although not every testing company need be identified in an initial application, no company can test subject to a waiver unless and until it has obtained—and become a signatory to—specific Bureau approval to test a given disclosure. The Bureau will not provide that approval unless it is satisfied, in its sole discretion, that a company has met all eligibility requirements for approval and should be approved for the applicable testing program under the terms of this Policy.

[12] So long as otherwise consistent with the minimum eligibility standards, a proposal could include modifications to an existing model form or other disclosures, changed delivery mechanisms, replacement of a model form or existing disclosure requirements with new disclosure or forms, and/or the elimination of select disclosure requirements. All proposals should include a copy of the trial disclosures to be tested, a description of what they would replace, and a clear statement of how they would be provided to consumers. When proposals consist of revised disclosure content—as opposed to revised or streamlined delivery mechanisms—that content should be in plain language, reflect a clear format and design, and be succinct.

If a proposal is for iterative testing, it should include copies of all forms of the disclosure that are known at the time of initial submission. It should explain why iterative testing is the more effective means of proceeding with respect to the particular disclosure concept. In addition, it should include a proposal for a streamlined approval process for different iterations of the disclosure. Again, no disclosure can be subject to a waiver under Section 1032(e) unless the specific tester has been approved to test that specific disclosure.

[13] The relevant existing disclosures are those made in accordance with disclosure rules issued either under the authority of Section 1032 or to implement an enumerated statute. *See* 12 U.S.C. 5532(e)(1).

[14] Trial disclosures should be ''designed to improve upon'' existing disclosures. 12 U.S.C. 5532(e)(1). Intended improvements may go to consumer use and understanding of the relevant product or service and/or to the cost-effectiveness of disclosures. The Bureau anticipates approving trial disclosure programs that are intended to improve both consumer use and understanding, and cost-effectiveness. Although the Bureau considers cost-effectiveness an appropriate metric of disclosure improvement, it will not approve a trial disclosure that it believes will weaken consumer understanding of valuable information that is the focus of a regulatory obligation, no matter the cost savings obtained.

[15] Under subsection 1032(e)(2), the Bureau has authority to waive ''a requirement of a rule or an enumerated consumer law,'' as that term is defined in the Dodd-Frank Act. *See* 12 U.S.C. 5481(12). As used in subsection 1032(e)(2), the term ''rule'' includes: (i) Rules implementing an enumerated consumer law; and (ii) rules implementing the Consumer Financial Protection Act of 2010, including rules promulgated by the Bureau under its authority to prevent unfair, abusive, or deceptive acts or practices, or to enable full, accurate and effective disclosure.

[16] The proposal should commit to sharing test result data with the Bureau within a reasonable period following the end of the program. In addition, it should contain either (1) a commitment to sharing with the Bureau interim data on test results during the course of the program, or (2) an explanation for why such interim data cannot reasonably be provided.

[17] The email subject line should begin ''Trial Disclosure Program.'' The present Policy is one component part of the Bureau's Project Catalyst initiative, which invites companies to bring innovation-related concerns to the Bureau's attention at *ProjectCatalyst@cfpb.gov*. Disclosure innovators may use the same Project Catalyst point of contact to request a preliminary discussion of a potential trial disclosure proposal. There are no formal submission requirements to request such a preliminary discussion.

[18] The decision whether to approve a proposed program for a waiver will be within the Bureau's sole discretion. The Bureau will review reasonable requests to reconsider its position on programs for which it has not approved a waiver.

3. The extent to which the program anticipates, controls for, and mitigates risks to consumers; [19]

4. The strength and record of the company's compliance management system relative to the size, nature, and complexity of the company's consumer business;

5. How effectively and efficiently the program will test for potential improvements to consumer understanding and/or the cost-effectiveness of disclosures, and how narrowly the program is tailored to the testing objectives;

6. The extent to which existing data or other evidence indicate that the proposed changes will realize the intended improvements; and

7. The extent to which the company intends to permit public disclosure of test results.

In reviewing and approving applications, the Bureau will also take into consideration the scope and nature of programs currently underway as well as the Bureau's available resources.

C. Waiver Procedures for Approved Programs

When the Bureau approves a waiver, it will provide the company or companies that receive the waiver with the specific terms and conditions of its approval.[20] Waivers will require companies to certify, and document or otherwise demonstrate to the Bureau, their compliance with these approved terms and conditions. If a company does not follow the terms and conditions of the waiver, the Bureau may revoke the waiver in whole or in part.[21]

Waiver terms and conditions will be in writing in an integrated document entitled ''1032(e) Trial Disclosure Waiver: Terms and Conditions.'' This document will be signed by the Director of the Bureau or by his or her designee, and by an officer of each company approved for a waiver in connection with the program.

In addition, the document will:

1. Identify the company or companies that are receiving a waiver;

2. Specify the new disclosure(s) or delivery methods to be used by that company or companies under the terms of the waiver;

3. Specify the rules and statutory provisions that the Bureau will waive during the test period for the testing company or companies;

4. Specify the temporary duration of the waiver;

5. Describe and delineate the test population(s); and

6. Specify any other conditions on the effectiveness of the waiver, such as the terms of testing, data sharing, certification of compliance with the terms of the waiver, and/or public disclosure.

D. Bureau Disclosure of Information Regarding Trial Programs

The Bureau will publish notice on its Web site of any trial disclosure program that it approves for a waiver. The notice will: (i) Identify the company or companies conducting the trial disclosure program; (ii) summarize the changed disclosures to be used, their intended purpose, and the duration of their intended use; (iii) summarize the scope of the waiver and the Bureau's reasons for granting it; and (iv) state that the waiver only applies to the testing company or companies in accordance with the approved terms of use.

Public disclosure of any other information regarding trial programs is governed by the Bureau's Rule on Disclosure of Records and Information.[22] For example, the rule requires the Bureau to make available records requested by the public unless they are subject to a FOIA exemption or exclusion.[23] To the extent the Bureau wishes to disclose information regarding trial programs, the terms of such disclosure will be included in the 1032(e) Trial Disclosure Waiver: Terms and Conditions document. Consistent with applicable law and its own rules, the Bureau will not seek to disclose any test data that would conflict with consumers' privacy interests.

Dated: October 23, 2013.

Christopher D'Angelo,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2013–25580 Filed 10–28–13; 8:45 am]

BILLING CODE 4810–AM–P

[19] This includes the extent to which a proposal contains reasonable contingency plans for addressing unanticipated consumer harms that arise during the duration of the test.

[20] If the Bureau determines not to approve a proposed trial program, it will inform the company of its determination.

[21] Before determining to issue a revocation, the Bureau will notify the affected company (or companies) of the grounds for revocation, and permit an opportunity to respond. If the Bureau nonetheless determines that the company failed to follow the terms of the waiver, it may offer an opportunity to correct any such failure before revoking the waiver. If the Bureau revokes or partially revokes a waiver for failure to follow the waiver's terms, it will do so in writing and it will specify the reason or reasons for its action.

[22] *See* 12 CFR 1070 *et seq.*

[23] *See* 12 CFR 1070.14.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–1245; Directorate Identifier 2012–NE–41–AD; Amendment 39–17626; AD 2013–21–02]

RIN 2120–AA64

Airworthiness Directives; Lycoming Engines and Continental Motors, Inc. Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are superseding airworthiness directive (AD) 2012–24–09 for Lycoming Engines TIO–540–AK1A, and Continental Motors, Inc. (CMI) TSIO–360–MB, TSIO–360–SB, and TSIO–360–RB reciprocating engines, with certain Hartzell Engine Technologies (HET) turbochargers, model TA0411, installed. AD 2012–24–09 required removing certain HET turbochargers from service before further flight. This AD also requires removing certain HET turbochargers from service before further flight. This AD was prompted by a report that an additional engine, the CMI LTSIO–360–RB, has the affected HET turbochargers installed. We are issuing this AD to prevent turbocharger turbine wheel failure, reduction or complete loss of engine power, loss of engine oil, oil fire, and damage to the airplane.

DATES: This AD is effective November 13, 2013.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 20, 2012 (77 FR 72203, December 5, 2012).

We must receive any comments on this AD by December 13, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m.

and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Hartzell Engine Technologies, LLC, 2900 Selma Highway, Montgomery, AL 36108, phone: 334–386–5400; fax: 334–386–5450; Internet: *http://www.hartzellenginetech.com.* You may view this service information at the FAA, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Christopher Richards, Aerospace Engineer, Chicago Aircraft Certification Office, FAA, 2300 E. Devon Ave., Des Plaines, IL 60018; phone: 847–294–7156; fax: 847–294–7834; email: *christopher.j.richards@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On November 29, 2012, we issued AD 2012–24–09, Amendment 39–17279 (77 FR 72203, December 5, 2012), for Lycoming Engines TSIO–540–AK1A, and CMI TSIO–360–MB, TSIO–360–SB, and TSIO–360–RB reciprocating engines, with certain HET turbochargers, model TA0411, part numbers 466642–0001; 466642–0002; 466642–0006; 466642–9001; 466642–9002; or 466642–9006, or with certain HET model TA0411 turbochargers overhauled or repaired since August 29, 2012. On January 7, 2013, we issued a correction to AD 2012–24–09 (78 FR 2615, January 14, 2013), which corrected the affected Lycoming Engines engine model from ''TSIO–540–AK1A'' to ''TIO–540–AK1A.'' AD 2012–24–09 required removing the affected turbochargers from service before further flight. AD 2012–24–09 resulted from a report of a turbocharger turbine wheel that failed a static strength test at the manufacturing facility. We issued AD 2012–24–09 to prevent turbocharger turbine wheel failure, reduction or complete loss of engine power, loss of engine oil, oil fire, and damage to the airplane.

Actions Since AD 2012–24–09 Was Issued

Since we issued AD 2012–24–09 (77 FR 72203, December 5, 2012; corrected January 14, 2013 (78 FR 2615)), we received a report that an additional engine, the CMI LTSIO–360–RB, has the affected HET turbochargers installed.

FAA's Determination

We are issuing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

AD Requirements

This AD requires removing the affected turbochargers from service before further flight.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because the AD requires removal of the affected turbochargers before further flight. Therefore, we find that notice and opportunity for prior public comment are impracticable and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–1245; Directorate Identifier 2012–NE–41–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Costs of Compliance

We estimate that this AD affects 56 engines of U.S. registry with affected turbochargers installed. We also estimate that it will take about 4 hours to remove a turbocharger from service. The average labor rate is $85 per hour. Based on these figures, we estimate the total cost of this AD to U.S. operators to be $19,040.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2012–24–09, Amendment 39–17279 (77 FR 72203, December 5, 2012; corrected January 14, 2013 (78 FR 2615)) and adding the following new AD:

2013–21–02 Lycoming Engines and Continental Motors, Inc.: Amendment 39–17626; Docket No. FAA–2012–1245; Directorate Identifier 2012–NE–41–AD.

(a) Effective Date

This AD is effective November 13, 2013.

(b) Affected ADs

This AD supersedes AD 2012–24–09, Amendment 39–17279 (77 FR 72203, December 5, 2012; corrected January 14, 2013 (78 FR 2615)).

(c) Applicability

This AD applies to certain Lycoming Engines TIO–540–AK1A, and Continental Motors, Inc. (CMI) LTSIO–360–RB, TSIO–360–MB, TSIO–360–SB, and TSIO–360–RB reciprocating engines with a Hartzell Engine Technologies (HET) turbocharger installed that has a model number, part number, and serial number identified in Tables 1 and 2 of HET Alert Service Bulletin (ASB) No. 048, dated November 16, 2012.

(d) Unsafe Condition

This AD was prompted by a report that an additional engine, the CMI LTSIO–360–RB, has the affected HET turbochargers installed. We are issuing this AD to prevent turbocharger turbine wheel failure, reduction or complete loss of engine power, loss of engine oil, oil fire, and damage to the airplane.

(e) Compliance

(1) Comply with this AD within the compliance times specified, unless already done.

(2) After the effective date of this AD and before further flight, remove from service any turbocharger identified in Tables 1 and 2 of HET ASB No. 048, dated November 16, 2012.

(f) Prohibitions

After the effective date of this AD, do not return to service, and do not operate without a special flight permit, any engine with an HET turbocharger installed that is identified in Tables 1 and 2 of HET ASB No. 048, dated November 16, 2012.

(g) Special Flight Permits

Special flight permits are limited to when:

(1) Ferry flights do not exceed three hours duration;

(2) The turbocharger boost is set to ''Off'' in the cockpit (if equipped); and

(3) The wastegate for the turbocharger is safety wired in the locked open position.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago Aircraft Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(2) AMOCs approved for AD 2012–24–09 (77 FR 72203, December 5, 2012; corrected January 14, 2013 (78 FR 2615)) remain in effect for this AD.

(i) Related Information

For more information about this AD, contact Christopher Richards, Aerospace Engineer, Chicago Aircraft Certification Office, FAA, 2300 E. Devon Ave., Des Plaines, IL 60018; phone: 847–294–7156; fax: 847–294–7834; email: *christopher.j.richards@faa.gov.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on December 20, 2012 (77 FR 72203, December 5, 2012; corrected January 14, 2013 (78 FR 2615)).

(i) Hartzell Engine Technologies Alert Service Bulletin No. 048, dated November 16, 2012.

(ii) Reserved.

(4) For service information identified in this AD, contact Hartzell Engine Technologies, LLC, 2900 Selma Highway, Montgomery, AL 36108, phone: 334–386–5400; fax: 334–386–5450; Internet: *http://www.hartzellenginetech.com.*

(5) You may view this service information at the FAA, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(6) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202 741 6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr_locations.html.*

Issued in Burlington, Massachusetts, on October 8, 2013.

Colleen M. D'Alessandro,

Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–25342 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9627]

RIN 1545–BL04

Mixed Straddles; Straddle-by-Straddle Identification Under Section 1092(b)(2)(A)(i)(I); Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations; correcting amendments.

SUMMARY: This document contains amendments to temporary regulations relating to guidance for taxpayers electing to establish a mixed straddle using straddle-by-straddle identification. These amendments include a change to the applicability date of the temporary regulations pursuant to which the temporary regulations apply to transactions established after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. The amendments to the temporary regulations will affect taxpayers who elect to establish a mixed straddle using straddle-by-straddle identification.

DATES: *Effective Date:* These amendments are effective on October 29, 2013.

Applicability Date: As corrected, § 1.1092(b)-6T applies to identified mixed straddles established after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Pamela Lew or Robert B. Williams at (202) 622–3950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of these amendments are under section 1092 of the Internal Revenue Code (Code). The temporary regulations (TD 9627) were published in the **Federal Register** on Friday, August 2, 2013 (78 FR 46807). The temporary regulations applied to all identified mixed straddles established after the date of filing, August 1, 2013.

Need for Amendments

The Treasury Department and the IRS received comments raising concerns about the immediate applicability date of the temporary regulations. In response to those comments, this document amends the temporary

regulations to limit the application of the identified mixed straddle transaction rules in § 1.1092(b)–6T to section 1092(b)(2) identified mixed straddles established after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. This document also amends the examples in the temporary regulations to reflect the change in the applicability date and to clarify the determination of a holding period. The Treasury Department and the IRS anticipate finalizing the regulations no later than the end of the current Priority Guidance Plan year on June 30, 2014, and will as part of that process consider all comments received.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.1092(b)–6T also issued under 26 U.S.C. 1092(b)(1).

Section 1.1092(b)–6T also issued under 26 U.S.C. 1092(b)(2).* * *

■ **Par. 2.** Section 1.1092(b)–3T is amended by:

■ 1. Revising the heading of paragraph (b)(6).

■ 2. Revising the first sentence of paragraph (b)(6).

The amendments read as follows:

§ 1.1092(b)–3T Mixed straddles; straddle-by-straddle identification under section 1092(b)(2)(A)(i)(I) (Temporary).

* * * * *

(b)(6) *Accrued gain and loss with respect to positions of a section 1092(b)(2) identified mixed straddle established on or before the applicability date of § 1.1092(b)–6T.* The rules of this paragraph (b)(6) apply to all section 1092(b)(2) identified mixed straddles established on or before the applicability date of § 1.1092(b)–6T; see § 1.1092(b)–6T for section 1092(b)(2) identified mixed straddles established after the applicability date of § 1.1092(b)–6T.* * *

* * * * *

■ **Par. 3.** Section 1.1092(b)–6T is amended as follows:

■ 1. Revising the heading of § 1.1092(b)–6T.

■ 2. Adding a sentence at the end of the introductory text of paragraph (b) and revising *Example 1* and *Example 2* of paragraph (b).

■ 3. Revising paragraph (c).

The amendments read as follows:

§ 1.1092(b)–6T Mixed straddles; accrued gain and loss associated with a position that becomes part of a section 1092(b)(2) identified mixed straddle.

* * *

(b) * * * The following examples assume that this section applies to identified mixed straddles established after August 1, Year 2.

Example 1. On August 13, Year 2, A enters into a section 1256 contract. As of the close of the day on August 15, Year 2, there is $500 of unrealized loss on the section 1256 contract. On August 16, Year 2, A enters into an offsetting non-section 1256 position and makes a valid election to treat the straddle as a section 1092(b)(2) identified mixed straddle. A continues to hold both positions of the section 1092(b)(2) identified mixed straddle on January 1, Year 3. Under these circumstances, A will recognize the $500 loss on the section 1256 contract that existed prior to establishing the section 1092(b)(2) identified mixed straddle on the last business day of Year 2 because the section 1256 contract would be treated as sold on December 31, Year 2, (the last business day of the taxable year) under section 1256(a). The loss recognized in Year 2 will be treated as 60% long-term capital loss and 40% short-term capital loss. All gains and losses occurring after the section 1092(b)(2) identified mixed straddle is established are accounted for under the applicable provisions in § 1.1092(b)–3T.

Example 2. On September 3, Year 1, A enters into a non-section 1256 position. As of the close of the day on August 22, Year 2, there is $400 of unrealized short-term capital gain on the non-section 1256 position. On August 23, Year 2, A enters into an offsetting section 1256 contract and makes a valid election to treat the straddle as a section 1092(b)(2) identified mixed straddle. On September 10, Year 2, A closes out the section 1256 contract at a $500 loss and disposes of the non-section 1256 position, realizing an $875 gain. Under these circumstances, A has $400 of short-term capital gain attributable to the non-section 1256 position prior to the day the section 1092(b)(2) identified mixed straddle was established. The $400 unrealized gain earned on the non-section 1256 position will be recognized on September 10, Year 2, when the non-section 1256 position is disposed of. The gain will be short-term capital gain. See § 1.1092(b)–2T for rules concerning holding period. On September 10, Year 2, the gain of $875 on the non-section 1256 position will be reduced to $475 to take into account the $400 of unrealized gain when the section 1092(b)(2) identified mixed straddle was established. The $475 gain on the non-section 1256 position will be offset by the $500 loss on the section 1256 contract. The net loss of $25 from the straddle will be treated as 60% long-term capital loss and 40% short-term capital loss because it is attributable to the section 1256 contract.

(c) *Effective/applicability date.* The rules of this section apply to all section 1092(b)(2) identified mixed straddles established after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

Martin Franks,

Branch Chief, Publications & Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure & Administration).

[FR Doc. 2013–25361 Filed 10–25–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 924

[SATS No. MS–023–FOR; Docket No. OSM–2012–0018; S1D1SSS08011000SX066A00067F134S180110; S2D2SSS08011000SX066A00033F13XS501520]

Mississippi Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Mississippi regulatory program (Mississippi Program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Mississippi proposed revisions to its regulations regarding: definitions; identification of interests; lands eligible for remining; permit eligibility determination; review of permit applications; eligibility for provisionally issued permits; criteria for permit approval or denial; initial review and finding requirements for improvidently issued permits; notice requirements for improvidently issued permits; suspension or rescission requirements for improvidently issued permits; unanticipated events or conditions at remining sites; verification of ownership or control application information; who may challenge ownership or control listings and findings; how to challenge an ownership or control listing or finding; burden of proof for ownership or control challenges; written agency decision on challenges to ownership or control listings or findings; post-permit issuance requirements for regulatory authorities and other actions based on

ownership, control, and violation information; post-permit issuance requirements for permittees; backfilling and grading: previously mined areas; and alternative enforcement. Mississippi intends to revise its program to be no less effective than corresponding Federal regulations, to clarify ambiguities, and to improve operational efficiency.

DATES: *Effective Date:* October 29, 2013.

FOR FURTHER INFORMATION CONTACT: Sherry Wilson, Director, Birmingham Field Office. Telephone: (205) 290–7282 Email: *swilson@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Mississippi Program
II. Submission of the Amendment
III. OSM's Findings
IV. Summary and Disposition of Comments
V. OSM's Decision
VI. Procedural Determinations

I. Background on the Mississippi Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''. . . a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act . . .; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Mississippi program effective September 4, 1980. You can find background information on the Mississippi program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Mississippi program in the September 4, 1980, **Federal Register** (45 FR 58520). You can also find later actions concerning the Mississippi program and program amendments at 30 CFR 924.10, 924.15, 924.16, and 924.17.

II. Submission of the Amendment

By email dated July 26, 2012 (Administrative Record No. MS–0423), the Mississippi Department of Environmental Quality (Mississippi or the Department) sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Mississippi submitted the proposed amendment in response to a September 30, 2009, letter (Administrative Record No. MS–0420–02) that OSM sent to Mississippi in accordance with 30 CFR 732.17(c), concerning multiple changes to ownership and control requirements. Mississippi also made additional changes to its regulations on its own initiative. The specific sections in the Mississippi program are discussed in Part III OSM's Findings. Mississippi intends to revise its program to be no less effective than the Federal regulations, to clarify ambiguities, and to improve operational efficiency.

We announced receipt of the proposed amendment in the September 19, 2012, **Federal Register** (23 FR 58056). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because none were requested one. The public comment period ended on October 19, 2012. We did not receive any public comments.

By email dated March 4, 2013 (Administrative Record No. MS–0423–03), Mississippi requested that we suspend processing of their proposed amendment while they made some administrative corrections to their submission. Mississippi submitted their administratively revised proposed rule by email dated June 28, 2013 (Administrative Record No. MS–0423–04). We did not reopen the comment period for the additional changes because they were entirely administrative in nature and did not substantively affect the Mississippi Program.

III. OSM's Findings

We are approving the amendment as described below. The following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are also approving the administrative changes made by Mississippi throughout their proposed rule, which primarily consisted of changing the word ''chapter'' to ''rule'' and ''subpart'' to ''chapter.'' Statutory references were added at the end of each chapter and rule. Any revisions that we do not specifically discuss below concerning non-substantive wording or editorial changes can be found in the full text of the program amendment available at *www.regulations.gov.*

A. Mississippi Surface Coal Mining Regulations § 105. Definitions

Mississippi proposed to add new definitions for ''Previously Mined Area'' and ''Violation''; and revised the definitions for ''Applicant Violator System or AVS''; ''Knowing or Knowingly''; ''Slope''; and ''Willfully.'' Mississippi's new definitions and revised definitions are substantively the same as counterpart Federal regulations at 30 CFR 701.5. Mississippi also corrected a reference to a regulatory citation within its definition of ''Ownership or Control Link,'' which has no Federal counterpart. Revision of this previously approved definition does not make Mississippi's program less effective than the Federal regulation. Therefore, we approve Mississippi's new and revised definitions.

B. Mississippi Surface Coal Mining Regulations § 2305. Identification of Interests

Mississippi proposed to add additional language clarifying the requirements for information to be included in a permit application concerning the identification of interests for the applicant and operator and for the entry of the applicant's information into the Applicant Violator System (AVS). We find that Mississippi's new language is substantively the same as counterpart Federal regulations at 30 CFR 778.8, 778.9, and 778.11. Therefore, we approve Mississippi's revisions.

C. Mississippi Surface Coal Mining Regulations § 2902. Lands Eligible for Remining

Mississippi proposed to add new § 2902 regarding lands eligible for remining. The regulation requires that any person who submits a permit application to conduct a surface coal mining operation on lands eligible for remining must comply with all the requirements of the regulations; including the permitting requirements of § 3130, which concerns unanticipated events or conditions at remining sites. We find that Mississippi's new regulation is substantively the same as the counterpart Federal regulation at 30 CFR 785.25. Therefore, we approve Mississippi's new regulation.

D. Mississippi Surface Coal Mining Regulations § 3102. Permit Eligibility Determination; § 3112. Review of Permit Applications; § 3113. Eligibility for Provisionally Issued Permits; and § 3115. Criteria for Permit Approval or Denial

Mississippi proposed to add new § 3102 which explains the roles and responsibilities of the Department and the Permit Board on whether the applicant is eligible to receive a permit. We find that Mississippi's new regulation is substantively the same as the counterpart Federal regulation at 30 CFR 773.12. Therefore, we are approving Mississippi's new regulation.

Mississippi proposed renumbering § 3113 Review of Permit Applications, to § 3112 Review of Permit Applications. This change allows Mississippi's regulations to remain in compliance with other portions of its regulations. We find that these revisions make Mississippi's regulations no less effective than the Federal regulations. Therefore, we approve Mississippi's revision.

Mississippi proposed to add new § 3113 regarding the applicant's eligibility for a provisionally issued permit. This applies to any applicant that applies for a permit or who owns or controls a surface coal mining and reclamation operation with outstanding permit violations. We find that Mississippi's new regulation is substantively the same as the counterpart Federal regulation at 30 CFR 773.14. Therefore, we approve Mississippi's new regulation.

Mississippi proposed to revise its citations in § 3115(m) to require compliance with new § 3102(d) regarding update of compliance information prior to permit issuance. Mississippi added new paragraphs (n) and (o) to clarify the requirements regarding permit approval criteria for proposed remining operations. We find that Mississippi's revised citations and new paragraphs (n) and (o) are substantively the same as counterpart Federal regulations at 30 CFR 773.15(k)(1) and (m)(i), (ii), and (iii). Therefore, we approve Mississippi's revisions.

E. Mississippi Surface Coal Mining Regulations. § 3127. Initial Review and Finding Requirements for Improvidently Issued Permits; § 3128. Notice Requirements for Improvidently Issued Permits; and § 3129. Suspension or Rescission Requirements for Improvidently Issued Permits

Mississippi proposed to delete old language in § 3127 regarding general procedures for improvidently issued permits. Mississippi replaced its old language with new language regarding what the Permit Board must do when it has reason to believe that a permit has been improvidently issued. The revision describes the written permit findings the Permit Board must make regarding improvidently issued permits and how a permittee can challenge those findings. We find that Mississippi's newly added language is substantively the same as the counterpart Federal regulation at 30 CFR 773.21. Therefore, we approve Mississippi's revisions.

Mississippi proposed to add new § 3128 regarding the responsibilities of the Department in serving the notice of suspension or rescission of improvidently issued permits. We find that Mississippi's new regulation is substantively the same as the counterpart Federal regulation at 30 CFR 773.22. Therefore, we approve Mississippi's new regulation.

Mississippi proposed to delete old language in § 3129 regarding revocation or suspension procedures for improvidently issued permits. Mississippi replaced this old language with new language regarding the Permit Board's responsibilities for: (1) Suspension or rescission of improvidently issued permits; (2) evaluation of permittee evidence; (3) administrative review of the findings; and (4) terms of the notice of cessation of operations. We find that Mississippi's revisions are substantively the same as counterpart Federal regulations at 30 CFR 773.21 and 773.23. Therefore, we approve Mississippi's revisions.

F. Mississippi Surface Coal Mining Regulations § 3130. Unanticipated Events or Conditions at Remining Sites

Mississippi proposed to add new § 3130 regarding an applicant's eligibility for a permit if he has on record an unabated violation resulting from unanticipated events or conditions at an existing or past permit on lands eligible for remining. We find that Mississippi's new regulation is substantively the same as the counterpart Federal regulation at 30 CFR 773.13. Therefore, we approve Mississippi's new regulation.

G. Mississippi Surface Coal Mining Regulations § 3131. Verification of Ownership or Control Application Information

Mississippi proposed revisions to § 3131 regarding what Mississippi must do when it receives an application and it appears that neither the applicant nor the operator has any mining experience. Specifically, it requires the Department to investigate to determine whether there may be additional owners or controllers. If additional owners or controllers are identified, Mississippi requires such persons to disclose their identity and make certifications, and requires their identification information be entered into AVS. We find that these revisions allow Mississippi to fully meet the Federal requirements of 30 CFR 773.10 and 773.11 regarding review of permit history and review of compliance history, thereby making Mississippi's regulation no less effective than the Federal regulations. Therefore, we approve Mississippi's revisions.

H. Mississippi Surface Coal Mining Regulations § 3133. Who May Challenge Ownership or Control Listings and Findings; § 3135. How To Challenge an Ownership or Control Listing or Finding; § 3136. Burden of Proof for Ownership or Control Challenges; and § 3137. Written Agency Decision on Challenges to Ownership or Control Listings or Findings

Mississippi proposed to delete old language in § 3133 regarding the review of ownership or control and violation information and add new language regarding who may challenge an ownership or control listing or finding. We find that the new language is substantively the same as the counterpart Federal regulation at 30 CFR 773.25. Therefore, we approve Mississippi's revisions.

Mississippi proposed to delete old language in § 3135 regarding procedures for challenging ownership or control listings or findings, and replaced it with new language regarding how to challenge an ownership or control listing or finding. It explains that to challenge an ownership or control listing or finding, the person making the challenge must submit a written explanation of the basis for the challenge, along with evidence or explanatory material that a person wishes to provide. We find that this new language is substantively the same as the counterpart Federal regulation at 30 CFR 773.26. Therefore, we approve Mississippi's revisions.

Mississippi proposed to delete old language in § 3136 regarding written agency decisions on challenges to ownership or control listings or findings and replaced it with new language regarding the burden of proof for ownership or control challenges. This applies to anyone who challenges a listing of ownership or control, or a finding of ownership or control made under § 3138(g). It requires anyone who challenges an ownership or control listing or finding to prove by a preponderance of evidence that they either do not or did not own or control the relevant portion of a surface coal mining operation. We find that Mississippi's new language is substantively the same as the counterpart Federal regulation at 30 CFR 773.27. Therefore, we approve Mississippi's revisions.

Mississippi proposed to delete old language in § 3137 regarding standards for challenging ownership or control links and the status of violations, and replaced it with new language regarding written agency decisions on challenges to ownership or control listings or

findings. Mississippi explains that the Permit Board will promptly provide the person making the challenge with a copy of its decision by any means consistent with the rules governing services of summons and complaints under Rule 4 of the Mississippi Rule of Civil Procedures. We find that this new language is substantively the same as the counterpart Federal regulation at 30 CFR 773.28. Therefore, we approve Mississippi's revisions.

I. Mississippi Surface Coal Mining Regulations § 3138. Post-Permit Issuance Requirements for Regulatory Authorities and Other Actions Based on Ownership, Control, and Violation Information

Mississippi proposed to add new § 3138 regarding the Department's responsibilities after permit issuance related to ownership, control, and violation information. It also allows the permittee to request a preliminary hearing related to such actions. We find that Mississippi's new section is substantively the same as the counterpart Federal regulation at 30 CFR 774.11. Therefore, we approve Mississippi's new regulation.

J. Mississippi Surface Coal Mining Regulations § 3139. Post-Permit Issuance Requirements for Permittees

Mississippi proposed to add new § 3139 regarding the responsibilities of permittees for providing information following a cessation order after a permit has been issued. We find that Mississippi's new section is substantively the same as the counterpart Federal regulation at 30 CFR 774.12. Therefore, we are approving Mississippi's new regulation.

K. Mississippi Surface Coal Mining Regulations § 5396. Backfilling and Grading: Previously Mined Areas

Mississippi proposed to add new § 5396 regarding backfilling and grading requirements on previously mined areas with preexisting highwalls. The regulation states that the requirements of § 5391(a)(1) and (2) requiring elimination of highwalls will not apply to remining operations where the volume of all reasonably available spoil is insufficient to completely backfill the highwall. Instead, the highwall is to be backfilled to the maximum extent practical in accordance with a set of criteria articulated in the regulation. We find that Mississippi's new section is substantively the same as the counterpart Federal regulation at 30 CFR 816.106. Therefore, we approve Mississippi's new regulation.

L. Mississippi Surface Coal Mining Regulations Chapter 73. Alternative Enforcement

Mississippi proposed to add a new chapter to its regulations regarding alternative enforcement that provides for criminal penalties and civil actions to compel compliance with provisions of the Act by adding § 7301 Scope, § 7303 General Provisions, § 7305 Criminal Penalties, and § 7307 Civil Actions for Relief. We find that Mississippi's new Chapter 73 Alternative Enforcement is substantively the same as counterpart Federal regulations at 30 CFR Part 847. Therefore, we approve Mississippi's new Chapter 73.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendments, but did not receive any.

Federal Agency Comments

On August 1, 2012, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendments from various Federal agencies with an actual or potential interest in the Mississippi program (Administrative Record No. MS–0423–01). We did not receive any comments.

Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to get a written concurrence from the EPA for those provisions of the program amendments that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Mississippi proposed to make in these amendments pertained to air or water quality standards. Therefore, we did not ask EPA to concur on the amendments. However, on August 1, 2012, under 30 CFR 732.17(h)(11)(i), we requested comments on the amendments from the EPA (Administrative Record No. MS–0423–01). The EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On August 1, 2012, we requested comments on Mississippi's amendments (Administrative Record No. MS–0423–01), but neither the SHPO nor ACHP responded to our request.

V. OSM's Decision

Based on the above findings, we approve the amendments Mississippi sent us on July 26, 2012, as revised June 28, 2013.

To implement this decision, we are amending the Federal regulations at 30 CFR Part 924 that codify decisions concerning the Mississippi program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this rule effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of sections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10) decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the

regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on federally recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. This determination is based on the fact that the Mississippi program does not regulate coal exploration and surface coal mining and reclamation operations on Indian lands. Therefore, the Mississippi program has no effect on federally recognized Indian tribes.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 924

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 3, 2013.

William L. Joseph,

Acting Regional Director, Mid-Continent Region.

For the reasons set out in the preamble, 30 CFR part 924 is amended as set forth below:

PART 924—MISSISSIPPI

■ 1. The authority citation for Part 924 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 924.15 is amended in the table by adding a new entry in chronological order by ''Date of final publication'' to read as follows:

§ 924.15 Approval of Mississippi regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	* * * * *
July 26, 2012	October 29, 2013	MSCMR Sections: 105; 1106; 2305; 2902; 3102; 3112; 3113; 3115(m), (n) and (o); 3127; 3128; 3129; 3130; 3131; 3133; 3135; 3136; 3137; 3138; 3139; 5396; 7301; 7303; 7305; and 7307.

[FR Doc. 2013–25575 Filed 10–28–13; 8:45 am]
BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2013–0384; FRL–9901–77–Region 9]

Approval and Promulgation of Implementation Plans; California; South Coast; Contingency Measures for 1997 $PM_{2.5}$ Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State implementation plan (SIP) revision submitted by California to address Clean Air Act (CAA) contingency measure requirements for the 1997 annual and 24-hour national ambient air quality standard (NAAQS) for fine particulate matter ($PM_{2.5}$) in the Los Angeles-South Coast Air Basin (South Coast). Approval of this SIP revision terminates the sanctions clocks and a federal implementation plan (FIP) clock that were triggered by EPA's partial disapproval of a related SIP submission on November 5, 2011.

DATES: This rule is effective on November 29, 2013.

ADDRESSES: You may inspect the supporting information for this action, identified by docket number EPA–R09–OAR–2013–0384, by one of the following methods:

1. Federal eRulemaking portal, *http://www.regulations.gov,* please follow the online instructions; or,
2. Visit our regional office at, U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Docket: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* voluminous records, large maps, copyrighted material), and some may not be publicly available in either location (*e.g.,* Confidential Business Information). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed directly below.

FOR FURTHER INFORMATION CONTACT: Doris Lo, EPA Region IX, (415) 972–3959, *lo.doris@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

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I. Summary of Proposed Action
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I. Summary of Proposed Action

On June 24, 2013 (78 FR 37741), EPA proposed to approve the ''South Coast Air Quality Management District Proposed Contingency Measures for the 2007 $PM_{2.5}$ SIP'' (dated October 2011), which the California Air Resources Board (CARB) submitted on November 14, 2011 and supplemented on April 24, 2013 (collectively the ''Contingency Measures SIP''). EPA proposed to approve the Contingency Measures SIP as satisfying the attainment contingency measure requirement in CAA section 172(c)(9) for the 1997 $PM_{2.5}$ NAAQS and to conclude that the reasonable further progress (RFP) contingency measure requirement in CAA section 172(c)(9) for the 2012 milestone year is moot because the South Coast area has achieved the emission reduction benchmarks for the 2012 RFP year. Our June 24, 2013 proposed rule provides the rationale for this action.

II. Public Comment and EPA Response

EPA provided a 30-day public comment period on our proposed action. The comment period ended on July 24, 2013. We received one public comment and respond to that comment below.

Comment: A private citizen asserted that there has been no attempt to address methane outgassing and the many oil fields in the South Coast area. The commenter also stated that train maintenance, promotion of bicycles and rail, automobile and truck lane reductions, digital signage, outdoor wood burning and landfills are not being adequately addressed, that health risk assessments should be required, that there are cancer clusters in the area, and that ''the political handling of [the] air quality problem does not change the quality of life and health of'' South Coast area residents.

Response: The commenter's submission contained only general observations and conclusions that are outside the scope of EPA's rulemaking action. While expressing a broad range of environmental concerns, the commenter failed to identify any specific issue relevant to EPA's proposed action on the Contingency Measures SIP, and did not address the basis for EPA's approval of the South Coast's contingency measures. To the extent the commenter intended to encourage additional review and evaluation of air pollution sources in the South Coast area, and additional potential transportation and control measures that may reduce air pollution, EPA encourages the commenter to participate in the regulatory processes carried out by the South Coast Air Quality Management District (SCAQMD), CARB, and other State/local agencies involved in the development of air quality management plans for the South Coast area. EPA finds no basis in the comment to change its views on the approvability of the specific contingency measures at issue in this rulemaking.

III. EPA's Final Action

We are finalizing our proposal to conclude that the Contingency Measures SIP submitted by CARB on November 14, 2011, as supplemented on April 24, 2013, satisfies the attainment contingency measure requirement in CAA section 172(c)(9) for the 1997 $PM_{2.5}$ NAAQS in the South Coast nonattainment area. We therefore fully approve this submission into the California SIP. This final action is based in part on EPA's final rule approving SCAQMD Rule 444 and Rule 445, which was signed by Jared Blumenfeld, Regional Administrator, Region IX, on August 22, 2013. See ''Revisions to Implementation Plan, South Coast Air Quality Management District'' Final Rule, signed August 22, 2013 (pre-publication copy).[1]

We are also finalizing our proposal to conclude that the RFP contingency measure requirement in CAA section 172(c)(9) for the 2012 milestone year is moot as applied to the South Coast because the area achieved its SIP-approved emission reduction benchmarks for the 2012 RFP year.

Today's final approval corrects deficiencies that were the basis for EPA's partial disapproval of the South Coast $PM_{2.5}$ SIP on November 9, 2011 (76 FR 69928) and therefore terminates the CAA section 179(b) sanctions clocks triggered by that action and the obligation on EPA to promulgate a FIP within two years of that action.

[1] EPA's proposal to approve the Contingency Measures SIP relied in part on a simultaneous proposal to approve Rule 444 and Rule 445, which we stated would provide SIP-creditable $PM_{2.5}$ emission reductions upon final EPA approval of these rules into the SIP. *See* 78 FR at 37745–37746 and 37751, Table 4.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it does not apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 30, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*see* section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Incorporation by reference, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 25, 2013.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(432) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(432) The following plan was submitted on November 14, 2011, by the Governor's Designee.

(i) [Reserved].

(ii) Additional materials.

(A) South Coast Air Quality Management District.

(*1*) South Coast Air Quality Management District Proposed Contingency Measures for the 2007 $PM_{2.5}$ SIP (dated October 2011) (''Contingency Measures SIP''), adopted October 7, 2011.

(*2*) SCAQMD Resolution No. 11–24, dated October 7, 2011, adopting the Contingency Measures SIP.

(*3*) Letter dated April 24, 2013 from Elaine Chang, Deputy Executive Officer, SCAQMD, to Deborah Jordan, Director, Air Division, EPA Region 9, Re: ''Update of the 2012 RFP Emissions and 2015 Reductions from Contingency Measures for the 2007 Annual $PM_{2.5}$ Air Quality Management Plan for the South Coast Air Basin,'' including attachments.

(B) State of California Air Resources Board.

(*1*) CARB Executive Order S–11–023, dated November 14, 2011, adopting the Contingency Measures SIP.

[FR Doc. 2013–25182 Filed 10–28–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 312

[EPA–HQ–SFUND–2013–0513; FRL–9902–22–OSWER]

Amendment to Standards and Practices for All Appropriate Inquiries

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Because EPA received adverse comment, we are withdrawing the direct final rule for the Amendment to Standards and Practices for All Appropriate Inquiries published on August 15, 2013.

DATES: Effective October 29, 2013, EPA withdraws the direct final rule published at 78 FR 49690, on August 15 2013.

FOR FURTHER INFORMATION CONTACT: Rachel Lentz, Office of Brownfields and Land Revitalization (5105–T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0002; telephone number: 202–566–2745; fax number: 202–566–

1476; email address: *lentz.rachel@epa.gov.*

SUPPLEMENTARY INFORMATION: Because EPA received adverse comment, we are withdrawing the direct final rule for the Amendment to Standards and Practices for All Appropriate Inquiries published on August 15, 2013 (78 FR 49690). We stated in that direct final rule that if we received adverse comment by September 16, 2013, the direct final rule would not take effect and we would publish a timely withdrawal in the **Federal Register**. We subsequently received adverse comment on that direct final rule. We will address the comments received in any subsequent final action. As stated in the direct final rule and the parallel proposed rule, we will not institute a second comment period on the parallel proposed rule published on August 15, 2013 (78 FR 49714).

List of Subjects in 40 CFR Part 312

Administrative practice and procedure, Hazardous substances.

Dated: October 22, 2013.

Mathy Stanislaus,

Assistant Administrator, Office of Solid Waste and Emergency Response.

Accordingly, EPA withdraws the amendments to 40 CFR 312.11(c), published in the **Federal Register** on August 15, 2013 (78 FR 49690), as of October 29, 2013.

[FR Doc. 2013–25592 Filed 10–28–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[PS Docket Nos. 11–153 and 10–255; FCC 13–127]

Next Generation 911; Text-to-911; Next Generation 911 Applications

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) amends the text-to-911 ''bounce-back'' requirement as it applies to Commercial Mobile Radio Service (CMRS) providers when consumers are roaming. In the May 2013 *Bounce-Back Order,* FCC 13–64, the Commission required all CMRS providers and providers of interconnected text messaging services to provide an automatic ''bounce-back'' text message in situations where a consumer attempts to send a text message to 911 in a location where text-to-911 is not available. This document amends the rule to specify that when a consumer attempts to send a text to 911 while roaming on a CMRS network, the CMRS provider offering roaming service (host provider) satisfies its bounce-back obligation provided that it does not impede the consumer's text to the consumer's home network provider (home provider) or impede any bounce-back message generated by the home provider back to the consumer.

DATES: Effective October 29, 2013.

FOR FURTHER INFORMATION CONTACT: Nicole McGinnis, Federal Communications Commission, Public Safety and Homeland Security Bureau, 445 12th Street SW., Room 7–A814, Washington, DC 20554. Telephone: (202) 418–2877, email: *nicole.mcginnis@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Order on Reconsideration,* PS Docket Nos. 11–153, 10–255; FCC 13–127, adopted September 27, 2013 and released September 30, 2013. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC 20554. This document will also be available via ECFS (*http://fjallfoss.fcc.gov/ecfs/*) or on the Commission's Web site at *http://www.fcc.gov/document/text-911-bounce-back-message-order.* This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via the company's Web site, *http://www.bcpiweb.com.*

I. Background

1. *Bounce-Back Order.* In the *Bounce-Back Order,* the Commission required ''all CMRS providers to provide an automatic bounce-back message when a consumer roaming on a network initiates a text-to-911 in an area where text-to-911 service is not available.'' Given the important public safety implications of the bounce-back requirement, the Commission stated that ''carriers should make automatic bounce-back messages available to consumers roaming on their network to the same extent they provide such messages to their own subscribers.'' Accordingly, the bounce-back rule in § 20.18(n) of the Commission's rules contains a specific subsection relating to roaming. Section 20.18(n)(7) currently provides that: ''A CMRS provider subject to § 20.12 shall provide an automatic bounce-back message to any consumer roaming on its network who sends a text message to 911 when (i) the consumer is located in an area where text-to-911 service is unavailable, or (ii) the CMRS provider does not support text-to-911 service at the time.''

2. *CTIA Petition.* On June 28, 2013, CTIA filed a petition for reconsideration, or in the alternative, for clarification, of the roaming provision of the *Bounce-Back Order.* CTIA's core concern is that in a situation where a wireless consumer attempts to send a text to 911 while roaming on a CMRS provider's network, § 20.18(n)(7) could be read to impose an obligation on the host provider to originate a bounce-back message, which CTIA contends is technically infeasible for the host provider. CTIA claims that in current network architecture for Short Message Service (SMS) texting, only the consumer's home provider has the technical ability to initiate a bounce-back message when the consumer is roaming on another network. CTIA also contends that § 20.18(n)(7) was adopted ''with minimal discussion of the rule's practicality or technical feasibility.'' CTIA therefore requests that the Commission either eliminate § 20.18(n)(7) or, in the alternative, clarify that § 20.18(n)(7) ''applies only to home network operators.'' CTIA further suggests that the clarification could be accomplished by deleting § 20.18(n)(7) and adding language to § 20.18(n)(3), which specifies the circumstances under which a covered text provider must provide an automatic bounce-back message, to state that the bounce-back requirement applies where the consumer is roaming on the network of another CMRS provider. CTIA states that ''the relief it requests will not prevent wireless subscribers who are roaming from receiving a bounce-back message'' but merely seeks to ''allocate carrier responsibilities in a way that aligns with technical realities.''

3. *Responsive Pleadings.* On July 11, 2013, the Commission released a *Public Notice* seeking comment on the Petition. Several parties filed in support of the CTIA petition. AT&T supports the Commission ''clarifying that, while covered text providers must send a bounce-back message alerting end users that text-to-911 is unavailable, it is the Home Carrier (and not the Host Carrier) that is responsible for sending that bounce-back message when the end user is texting while roaming on another carrier's network.'' T-Mobile similarly contends that, in a roaming scenario, the host provider will automatically pass an

attempted text to 911 to the consumer's home provider, which will then generate a bounce-back message that will be delivered, via the roaming network, to the consumer. Changes to this architecture, T-Mobile argues, are ''simply not feasible.'' T-Mobile opines that ''the Commission did not intend to create a mandate for serving carriers in § 20.18(n)(7) but rather intended to ensure that serving carriers do not prevent home carriers from generating bounce-back messages for their roaming subscribers.'' Therefore, T-Mobile urges the Commission to ''either issue an erratum correcting the rule or clarify that § 20.18(n)(7) does not apply to serving [i.e., roaming] carriers.''

4. Two other commenting parties, Blooston Rural Carriers (Blooston) and NCTA, support not requiring host providers to provide a bounce-back message to a roaming consumer at this time, based on current technical considerations. Blooston agrees with CTIA that origination of a bounce-back message by a roaming provider is technically infeasible. Blooston further argues that the Commission should not require home providers to originate a bounce-back message in this scenario because the home provider cannot determine the location of the consumer on the host provider's network, and therefore cannot determine whether the PSAP serving the consumer's location supports text-to-911. Thus, Blooston argues that the bounce-back rule should not apply to consumers while roaming until a technological solution can be worked out by industry standard-setting bodies that would enable the home provider to determine the consumer's location on the host provider's network. NCTA similarly argues that implementation of the roaming portion of the bounce-back rule should be delayed until a technical solution is developed by standards-setting bodies and implemented.

5. APCO filed an opposition to the Petition, arguing that CTIA has failed to demonstrate that complying with the Commission's rule is not technically feasible. APCO objects that CTIA's proposal would result in all roaming customers receiving a bounce-back message even in situations where the roaming consumer is located in an area where the local PSAP accepts text-to-911. APCO contends that if a roaming consumer is in an area where the PSAP supports text-to-911, the home and host providers should be required to deliver the consumer's text to the PSAP rather than sending a bounce-back message. APCO argues that delivery of a text-to-911 from a roaming customer to the PSAP serving the customer's area is technically feasible under existing standards. In reply, CTIA disputes APCO's contention that a technical solution exists to support routing of 911 texts from roaming customers to PSAPs. CTIA also argues that the issues APCO raises regarding the feasibility of text-to-9-1-1 while roaming ''are directed at the second part of the NPRM, which is still pending before the Commission.''

6. In an *ex parte* filing, NENA states that it does not oppose CTIA's petition. While NENA supports implementation of a ''ubiquitous'' text-to-911 solution that works ''regardless of whether the subscriber is attached to a home or a roaming network,'' it agrees that CTIA's position with respect to the ''limited question of which party should be responsible for delivering a bounce-back message'' in a roaming scenario is consistent with current technology and the understanding reached by NENA, APCO, and the four major wireless carriers in their December 2012 voluntary text-to-911 agreement. CTIA also provides further clarification in an ex parte filing, noting the technical infeasibility of a host network provider to '' 'transmit' the text-to-911 of a consumer roaming on the host network to the covered text provider home network and the home network's responding 'bounce[-]back' message due to the store-and-forward nature of CMRS provided SMS services.'' CTIA also notes that ''a covered home network text provider's obligation to provide any bounce back message should account for whether the home network operates 'in the area' that a consumer initiates the text-to-911, and not only whether the covered home network text provider supports text-to-911 services at that time.''

II. Discussion

7. In the *Bounce-Back Order,* the Commission sought to ensure that the carrier with direct control of a consumer's attempted text message to 911 would be responsible for delivering the bounce-back message in circumstances where text-to-911 is unavailable. The Commission is persuaded by the technical representations made in the record that under the current technical standard developed for SMS-based texting to 911, the home provider alone has control over sending a consumer a required bounce-back message. Current network architecture is such that, when a roaming consumer sends an SMS message, that message is routed first to the home provider, which has control over the further routing of that SMS message to its intended recipient. It is therefore the home provider that has direct control over the delivery of the SMS message to its intended recipient. Thus, the Commission agrees with CTIA that based on current network architecture, it would be technically challenging for a host provider to originate a bounce-back message to a roaming consumer.

8. Accordingly, the Commission amends § 20.18(n)(7) to reflect that the host provider must not impede the consumer's text message to 911 to the consumer's home provider and/or any bounce-back message generated by the home provider back to the consumer. The host provider is not under any obligation to originate a bounce-back message to the consumer or otherwise ensure that the home provider generates a bounce-back message in response to the consumer's text to 911.

9. As revised, § 20.18(n)(7) specifies that a host provider shall not impede the text message to 911 of a consumer roaming on its network and/or impede any bounce-back message originated by the home provider to that roaming consumer. It is the home provider's responsibility to generate the bounce-back message. This apportionment of responsibility between the roaming and home providers assures that consumers receive potentially lifesaving bounce-back messages, while taking into account the technical realities of current network architecture. The revised language also accounts for whether the home provider is supporting text-to-911 in the area where the consumer initiates a text message to 911.

10. The Commission denies CTIA's petition to the extent it seeks elimination of § 20.18(n)(7) of the bounce-back rule. In light of its amendment of the rule, the Commission finds that compliance with the rule is technically feasible and does not raise the concerns referenced in CTIA's petition. The Commission finds that there was adequate notice to adopt the rule and that, as amended, the rule is consistent with the record in the underlying proceeding. The Commission does not agree with Blooston that it should eliminate the roaming portion of the bounce-back rule in its entirety or otherwise defer implementation of the rule. The bounce-back requirement addresses an important public safety interest in providing consumers immediate notification of non-delivery of their text to the PSAP. To eliminate bounce-back messaging in roaming situations would risk leaving roaming consumers without information as to whether their text reached the appropriate PSAP, potentially endangering them by preventing or delaying their attempt to

reach 911 through another means. The Commission's amendment of the rule provides for a technically and economically feasible apportionment of responsibilities for roaming and home providers, while preserving the important public safety interests of the original rule.

11. With respect to APCO's argument that host providers should be able to route consumer texts to 911 to the appropriate PSAP, the Commission notes that the questions APCO raises about the technical feasibility of requiring host providers to route texts to 911 are part of the broader and still-pending portion of the Commission's rulemaking proceeding. Therefore, the Commission does not address these issues in this order, but reserves them for consideration in the next phase of the proceeding. Today's order is limited in scope to the limited issue of how responsibility is apportioned for delivering bounce-back messages to consumers when those consumers are roaming.

12. Finally, in order to effectuate the modifications described herein, the Commission waives § 20.18(n)(7) on its own motion, pending the effective date of the amended rule. In light of the potential technical difficulties associated with complying with § 20.18(n)(7) as originally drafted, the Commission concludes there is good cause to waive application of this portion of the bounce-back rule until the effective date of the amendments adopted in this order. The remainder of § 20.18(n), which was published in the **Federal Register** and took effect on June 28, 2013, remains in full force and effect. Accordingly, except as provided in this order, covered text providers must begin providing bounce-back messages in accordance with the rule no later than September 30, 2013. In addition, as discussed below, the Commission determines that amended version of § 20.18(n)(7) will take effect on publication in the **Federal Register.** Therefore, covered text providers must begin complying with § 20.18(n)(7) as of that date.

III. Procedural Matters

A. Effective Date

13. The Commission concludes that good cause exists to make the effective date of the modifications adopted in this *Order on Reconsideration* effective October 29, 2013, pursuant to section 553(d)(3) of the Administrative Procedure Act, 5 U.S.C. 553(d)(3). Agencies determining whether there is good cause to make a rule revision take effect less than 30 days after **Federal Register** publication must balance the necessity for immediate implementation against principles of fundamental fairness that require that all affected persons be afforded a reasonable time to prepare for the effective date of a new rule. Given the public safety need for bounce-back messaging and the relative lack of any additional burden imposed by this *Order on Reconsideration,* there is good cause to make these amendments effective immediately upon **Federal Register** publication. Indeed, given that covered text providers must begin generating automatic bounce-back messages outside of the roaming context beginning no later than September 30, 2013, and given that no party has argued that the modifications to the § 20.18(n)(7) requirement raised by the CTIA Petition would require additional time to comply with, the Commission finds that good cause exists to make the modifications to § 20.18(n)(7) effective immediately upon their publication in the **Federal Register**.

B. Paperwork Reduction Act

14. This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA). Therefore the Order on Reconsideration does not contain any new or modified information collection burdens for small businesses with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002.

C. Final Regulatory Flexibility Analysis

15. The Regulatory Flexibility Act (RFA) requires that agencies prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that ''the rule will not have a significant economic impact on a substantial number of small entities.'' The RFA defines ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

16. The Commission hereby certifies that this *Order on Reconsideration* will not have a significant economic impact on a substantial number of small entities. The Commission will send a copy of this *Order on Reconsideration,* including this certification, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the *Order on Reconsideration* (or a summary thereof) and certification will be published in the **Federal Register**.

D. Congressional Review Act

17. The Commission will send a copy of this *Order on Reconsideration* to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

E. Accessible Formats

18. Accessible formats of this *Order on Reconsideration* (Braille, large print, electronic files, audio format) are available to persons with disabilities by sending an email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice) 202–418–0432 (TTY). This *Order on Reconsideration* can also be downloaded at *http://www.fcc.gov.*

IV. Ordering Clause

19. Accordingly, *it is ordered* pursuant to sections 1, 4(i), 301, 303(b), 303(f), 303(g), 303(r), 307, 316, 319, 324, 332, 333, 405, 615a, 615a–1, and 615b of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 301, 303(b), 303(f), 303(g), 303(r), 307, 316, 319, 324, 332, 333, 405(a), 615a, 615a–1, and 615b, and §§ 1.2 and 1.429(a) of the Commission's rules, 47 CFR 1.2, 1.429(a), that Petition for Reconsideration, or in the Alternative, for Clarification filed by CTIA—the Wireless Association, PS Docket Nos. 11–153 and 10–255 on June 28, 2013 *is granted* to the extent provided herein and otherwise *denied.*

20. *It is further ordered* that the modifications to 47 CFR 20.18(n)(7) specified in this Order on Reconsideration *shall be effective* immediately upon publication in the **Federal Register**.

21. *It is further ordered* that, pursuant to §§ 1.3, 1.4, 1.103, and 1.427 of the Commission's rules, 47 CFR 1.3, 1.4, 1.103, and 1.427, the requirements of 47 CFR 20.18(n)(7) are *waived* to the extent and for the time period specified herein.

22. *It is further ordered* that, pursuant to §§ 1.3, 1.4, 1.103, and 1.427 of the Commission's rules, 47 CFR 1.3, 1.4, 1.103, and 1.427, the waiver of 47 CFR 20.18(n)(7) specified herein is *effective immediately upon release* of this Order on Reconsideration.

23. *It is further ordered* that the Commission *shall send* a copy of the Order on Reconsideration to Congress and the Government Accountability Office pursuant to the Congressional Review Act.

24. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Order on Reconsideration to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 20

Communications common carriers, Communications equipment, Radio.

Federal Communications Commission.

Sheryl D Todd,

Deputy Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 20 as follows:

PART 20—COMMERCIAL MOBILE SERVICES

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 47 U.S.C. 151, 154, 160, 201, 251–254, 301, 303, 303(b), 303(r), 307, 309, 316, 319, 324, 332, 333, 615a, 615a–1, 615b, and 615c unless otherwise noted. Section 20.12 is also issued under 47 U.S.C. 1302.

■ 2. Section 20.18 is amended by revising paragraph (n)(7) to read as follows:

§ 20.18 911 Service.

* * * * *

(n) * * *

(7) Notwithstanding any other provisions in this section, when a consumer is roaming on a covered text provider's host network pursuant to § 20.12, the covered text provider operating the consumer's home network shall have the obligation to originate an automatic bounce-back message to such consumer when the consumer is located in an area where text-to-911 service is unavailable, or the home provider does not support text-to-911 service in that area at the time. The host provider shall not impede the consumer's 911 text message to the home provider and/or any automatic bounce-back message originated by the home provider to the consumer roaming on the host network.

* * * * *

[FR Doc. 2013–25274 Filed 10–28–13; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register

Vol. 78, No. 209

Tuesday, October 29, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1210

[Document Number AMS–FV–11–0031]

Watermelon Research and Promotion Plan; Importer Membership Requirements and Referendum Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and referendum order.

SUMMARY: This proposed rule would amend the Watermelon Research and Promotion Plan (Plan) importer membership requirements to serve on the National Watermelon Promotion Board (Board). The Board recommended eliminating the requirement that an importer import more than 50 percent of the total volume handled and imported in order to qualify as an importer member. This change would allow for additional parties to qualify as an importer member. This proposed rule also announces that the U.S. Department of Agriculture (USDA or Department) will conduct a referendum among eligible producers, handlers, and importers of watermelons to determine whether they favor the amendment to the Plan.

DATES: The voting period for the referendum will be from January 13, 2014 through January 27, 2014. To be eligible to vote, persons must have produced, handled, or imported watermelons during the representative period from January 1, through December 31, 2012, and must currently be a producer, handler, or importer of watermelons. Additionally, producers must be engaged in the growing of 10 acres or more of watermelons and importers must import 150,000 or more pounds of watermelons annually. Importers who import less than 150,000 pounds of watermelons annually and did not apply for and receive reimbursements of assessments during the representative period are eligible to vote in the referendum. The referendum will be conducted by mail ballot. Ballots must be received by the referendum agents no later than the close of business 4:30 p.m., Eastern daylight-standard time, January 27, 2014, to be counted.

ADDRESSES: Copies of the proposed amendment may be obtained from: Referendum Agent, Promotion and Economics Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., Stop 0244, Room 1406–S, Washington, DC 20250–0244; telephone: (888) 720–9917 (toll free); fax: (202) 205–2800; or it can be viewed at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Jeanette Palmer, Marketing Specialist, Promotion and Economics Division, Fruit and Vegetable Program, AMS, U.S. Department of Agriculture, Stop 0244, 1400 Independence Avenue SW., Room 1406–S, Washington, DC 20250–0244; telephone: (888) 720–9917 (toll free); Direct line: 202–720–9915; facsimile: (202) 205–2800; or electronic mail: *Jeanette.Palmer@ams.usda.gov*.

SUPPLEMENTARY INFORMATION: This rule is issued under the Watermelon Research and Promotion Plan [7 CFR part 1210]. The Plan is authorized under the Watermelon Research and Promotion Act (Act) [7 U.S.C. 4901–4916].

A proposed rule was published in the **Federal Register** on February 13, 2013 [78 FR 10104], with a thirty-day comment period which closed on March 15, 2013.

Pursuant to section 1655 of the Act, a referendum will be conducted among watermelon producers, handlers, and importers to determine whether they favor amending the Plan to eliminate the requirement that an importer import more than 50 percent of the total volume handled and imported in order to qualify as an importer member.

The representative period for establishing voter eligibility for the referendum shall be the period from January 1 through December 31, 2012. Section 1653(b) of the Act requires that the amendment be approved by a majority of watermelon producers, handlers, and importers voting in the referendum. Only producers of 10 acres or more of watermelons, watermelon handlers, and importers of 150,000 or more pounds of watermelons annually, and importers who import less than 150,000 pounds of watermelons annually and who did not apply for and receive reimbursements of assessments during the representative period will be eligible to vote in the referendum. The referendum shall be conducted by mail ballot from January 13, 2014 through January 27, 2014. Ballots must be received by the referendum agents no later than the close of business 4:30 p.m., Eastern daylight-standard time, January 27, 2014, to be counted.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as a ''non-significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has waived the review process.

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review revealed that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Order 12988

In addition, this rule has been reviewed under Executive Order 12988, Civil Justice Reform. The rule is not intended to have retroactive effect.

The Act allows producers, producer-packers, handlers, and importers to file a written petition with the Secretary of Agriculture (Secretary) if they believe that the Plan, any provision of the Plan, or any obligation imposed in connection with the Plan, is not established in accordance with the law. In any petition, the person may request a modification of the Plan or an

exemption from the Plan. The petitioner will have the opportunity for a hearing on the petition. Afterwards, an Administrative Law Judge (ALJ) will issue a decision. If the petitioner disagrees with the ALJ's ruling, the petitioner has 30 days to appeal to the Judicial Officer, who will issue a ruling on behalf of the Secretary. If the petitioner disagrees with the Secretary's ruling, the petitioner may file, within 20 days, an appeal in the U.S. District Court for the district where the petitioner resides or conducts business.

Regulatory Flexibility Act and Paperwork Reduction Act

In accordance with the Regulatory Flexibility Act (RFA) [5 U.S.C. 601–612], AMS has examined the economic impact of this rule on the small producers, handlers, and importers that would be affected by this rule. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (handlers and importers) as those having annual receipts of no more than $7 million. Under these definitions, the majority of the producers, handlers, and importers that would be affected by this rule would be considered small entities. Producers of less than 10 acres of watermelons are exempt from this program. Importers of less than 150,000 pounds of watermelons per year are also exempt.

USDA's National Agricultural Statistics Service (NASS) data for the 2012 crop year indicates that about 306 hundredweight (cwt.) of watermelons were produced per acre within the United States. The 2012 grower price published by NASS was $13.30 per hundredweight. Thus, the value of watermelon production per acre in 2012 averaged about $4,070 (306 cwt. x $13.30). At that average price, a producer would have to farm over 184 acres to receive an annual income from watermelons of $750,000 ($750,000 divided by $4,070 per acre equals 184). Accordingly, as previously noted, a majority of the watermelon producers would be classified as small businesses.

Based on the Board's data, using an average of the free on board (f.o.b.) price of $.181 per pound and the number of pounds handled in 2012, none of the watermelon handlers had receipts over the $7 million threshold. Therefore, the watermelon handlers would all be considered small businesses. A handler would have to ship over 38 million pounds of watermelons to be considered large (38,674,033 times $.181 f.o.b. equals $7 million).

According to the Board, there are approximately 950 producers, 230 handlers, and 137 importers who are required to pay assessments under the program.

Based on the watermelon import assessments received for the year 2012, the United States imported watermelons worth over $237 million. The largest volume of watermelon imports came from Mexico which accounted for 86 percent of the total volume in 2012. Other suppliers of imported watermelons are Guatemala at 9 percent and Honduras at 2 percent. The remaining 3 percent of imported watermelons came from Costa Rica, Nicaragua, Canada, Dominican Republic, and Panama.

Based on the U.S. Customs and Border Protection (Customs) and Board data, it is estimated that there are about 201 importers of watermelon. Not all of these importers are required to pay assessments under the program. Using 2012 Customs data, all of the importers import less than $7.0 million worth of watermelon annually. Therefore, all of the watermelon importers would be considered small entities.

The Board's audit records show import assessments for the calendar years 2010, 2011, and 2012 at $746,043, $855,890, and $824,897 respectively. Based on this data, the three-year average of import assessments for watermelon totals $808,943 ($2,426,830 divided by 3). This represents approximately 30 percent of the total assessments paid to the Board. Currently, the Board membership distribution consists of 14 producers, 14 handlers, 8 importers, and 1 public member. A final rule that increased the number of importers on the Board was published in the July 18, 2011, **Federal Register** [76 FR 42009].

The Watermelon Research and Promotion Improvement Act of 1993 amended the Watermelon Research and Promotion Act by adding importer members to the Board, among other things. At that time the industry recommended that, in order to qualify as an importer member on the Board, an individual that both handles and imports watermelons may vote for importer members and serve as an importer member if that person imports 50 percent or more of the combined total volume of watermelons handled and imported by that person. A final rule was published in the **Federal Register** on February 28, 1995 [60 FR 10795] containing this and other amendments to the program.

At the time of this amendment there was a more clear division of roles among producers, handlers, and importers. In other words, those individuals that imported watermelons did not cross over into handling or producing watermelons as much as they do now. Since then, the industry has become more consolidated and of the 137 importers required to pay assessments, 42 also handle watermelons and would be eligible to serve as either handler or importer member.

At its February 26, 2011, meeting, the Board voted unanimously, to modify the importer eligibility requirements to serve on the Board. The Board is having difficulty finding eligible importers to serve on the Board because of the requirement in the Plan that a person who both imports and handles watermelons will be counted as an importer only if that person imports 50 percent or more of the combined total volume of watermelons handled and imported by that person. The Board voted to eliminate the 50 percent or more requirement of the combined total volume of watermelons handled and imported by a person to allow more individuals to become eligible to serve on the Board as an importer. Individuals that both handle and import would be allowed to decide which part of the industry they would prefer to represent regardless of the volume handled or imported. The industry believes that this change would increase the importer representation on the Board by allowing more individuals to be eligible to serve. This action may also increase diversity on the Board.

The Board considered a second alternative to change the 50 percent or more of the combined total volume of watermelons handled and imported by the person to 25 percent or more of the combined total volume of watermelons handled and imported by the person. However, the Board did not choose this option because they wanted to allow more importers to be eligible for nomination on the Board and found this purpose better served if they eliminated the percentage requirement altogether. By eliminating the percentage requirement for the importer member, this will allow for smaller importer businesses to become eligible to serve as an importer member on the Board.

Section 1655 of the Act provides for referenda to be conducted to ascertain approval of changes to the Plan prior to going into effect. In order to implement the amendment to the Plan, the Secretary must determine that the

amendment to the Plan has been approved by a majority of the producers, handlers, and importers of watermelons voting in the referendum. Accordingly, before this amendment is made to the Plan, a referendum will be conducted among eligible producers, handlers, and importers of watermelons.

In accordance with the Office of Management and Budget (OMB) regulation [5 CFR part 1320] which implements the Paperwork Reduction Act of 1995 [44 U.S.C. Chapter 35], the information collection and recordkeeping requirements that are imposed by the Plan have been approved previously and assigned OMB number 0581–0093, except that the background form, has been approved under OMB number 0505–0001.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other programs.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

We have performed this Regulatory Flexibility Analysis regarding the impact of this amendment to the Plan on small entities, and we did not receive any comments on the analysis. Additionally, the estimated numbers in the RFA represents the total universe of watermelon producers, handlers, and importers and not those who may be eligible to vote in the referendum.

Background

Under the Plan, the Board administers a nationally coordinated program of research, development, advertising, and promotion designed to strengthen the watermelon's position in the market place and to establish, maintain, and expand markets for watermelons. This program is financed by assessments on producers growing 10 acres or more of watermelons, handlers of watermelons, and importers of 150,000 pounds of watermelons or more per year. The Plan specifies that handlers are responsible for collecting and submitting both the producer and handler assessments to the Board, reporting their handling of watermelons, and maintaining records necessary to verify their reports. Importers are responsible for payment of assessments to the Board on watermelons imported into the United States through the U.S. Customs and Border Protection. This action would not have any impact on the assessment rates paid by producers, handlers, and importers.

Membership on the Board consists of two producers and two handlers for each of the seven districts established by the Plan, at least one importer, and one public member. The Board currently consists of 37 members: 14 producers, 14 handlers, 8 importers, and 1 public member. A final rule to increase the number of importers on the Board was published in the July 18, 2011, **Federal Register** [76 FR 42009].

The Watermelon Research and Promotion Improvement Act of 1993 amended the Watermelon Research and Promotion Act by adding importer members to the Board, among other things. At that time the industry recommended that, in order to qualify as an importer member on the Board, an individual that both handles and imports watermelons may vote for importer members and serve as an importer member if that person imports 50 percent or more of the combined total volume of watermelons handled and imported by that person. A final rule was published in the **Federal Register** on February 28, 1995 [60 FR 10795] containing this and other amendments to the program. At the time of this amendment there was a more clear division of roles among producers, handlers, and importers. In other words, those individuals that imported watermelons did not cross over into handling or producing watermelons as much as they do now. Since then, the industry has become more consolidated and of the 137 importers required to pay assessments 42 also handle watermelons and would be eligible to serve as either a handler or importer member.

At its February 26, 2011, meeting, the Board voted unanimously to modify the importer eligibility requirements to serve on the Board. The Board is having difficulty finding eligible importers to serve on the Board because of the requirement in the Plan that a person who both imports and handles watermelon will be counted as an importer if that person imports 50 percent or more of the combined total volume of watermelons handled and imported by that person. The Board voted to eliminate the 50 percent or more requirement of the combined total volume of watermelons handled and imported by a person to allow more individuals to become eligible to serve on the Board as an importer. Individuals that both handle and import would be allowed to decide which part of the industry they would prefer to represent regardless of the volume handled or imported. The industry believes that this change would increase the importer representation on the Board by allowing more individuals to be eligible to serve. This action may also increase diversity on the Board.

Accordingly, the proposed rule would amend sections 1210.321(d) and 1210.404(g) which reference importer eligibility requirements to be nominated to the Board. These sections would be revised to specify that a person who both imports and handles watermelons may participate in the nomination process and serve on the Board as either an importer or handler, but not both.

Also, sections 1210.363(b) and 1210.602(a) as published in the proposed rule have been modified to remove unnecessary language. These sections pertain to referenda; the language removed does not affect the way the referendum will be conducted or how the results will be determined. Thus, the changes to sections 1210.363(b) and 1210.602(a) will not be voted on in the referendum.

For the changes to sections 1210.321(d) and 1210.404(g) of the Plan to become effective, the proposed amendment must be approved by a majority of eligible producers, handlers, and importers of watermelons voting in a referendum. Only producers of 10 acres or more of watermelons; watermelon handlers, and importers of 150,000 or more pounds of watermelons annually, and importers who import less than 150,000 pounds of watermelons annually and did not apply for and receive reimbursements of assessments during the representative period will be eligible to vote in the referendum. Accordingly, a referendum will be conducted among eligible producers, handlers, and importers of watermelons. The referendum will be conducted by mail ballot from January 13, 2014 through January 27, 2014. Ballots must be received by the referendum agents no later than the close of business 4:30 p.m., Eastern daylight-standard time, January 27, 2014, to be counted.

A thirty-day comment period was provided to allow interested persons to respond to this proposal which was published in the **Federal Register** on February 13, 2013 [78 FR 10104]. Copies of the rule were made available through the Internet by the Department and the Office of the Federal Register. Additionally, the Board prepared a PowerPoint presentation on the proposed rule that was distributed through electronic mail to several watermelon State associations (Florida, North Carolina, South Carolina, Delaware, Maryland, Indiana and Illinois) and sent to the producers, handlers, and importers in its database. Also, the proposed rule was available on the Board's Web site and it was

published on a news Web site. The comment period ended March 13, 2013. Sixteen comments were received by the deadline.

Summary of Comments

Of the 16 comments received, 14 comments supported the proposed amendment. One comment was opposed to the watermelon program in general and was not within the scope of this rulemaking action. One comment discussed how the amendments were presented and made recommendations on writing the regulation so it is easier for the public to understand.

In general, commenters supporting the amendment stated the change would allow more importers to be eligible to serve on the Board. One commenter stated this would allow the Board to fill vacant seats on the Board with qualified individuals who are interested in serving the watermelon industry.

One commenter who supported the importer requirement change recommended adding a clause that the eligible importer should not import less than 10 percent of their total combined volume imported and handled. As previously mentioned, the Board considered reducing the 50 percent requirement to a lower level such as 25 percent, so that persons who import and handle watermelons could serve on the Board as an importer if 25 percent of their combined volume was imported. However, the Board wants to allow more individuals to serve on the Board and thus recommended eliminating the percentage requirement altogether. No changes have been made to the proposed rule based on this comment.

Another commenter who supported the proposed change suggested adding a clause to prevent a board member who imports less than 10 percent of watermelons to use their position to steer or direct the research and promotion activities to suit their personal needs. There are 37 Board members, and each member may vote on all budgets, marketing, research, and promotional activities as described in sections 1210.325 and 1210.328 of the Plan. Further, any action of the Board requires the concurring votes of a majority of those present and voting. No changes have been made to the proposed rule based on this comment.

As mentioned above, one commenter recommended writing the regulation so that it is easier for the public to understand. The Department reviewed the recommendations and adopted some of them as discussed in the following paragraphs.

The commenter suggested that section 1210.321(d) of the Plan regarding nominations and selections be revised to be more informative and easier to understand. The Department agrees and has simplified the last portion of this section as published in the proposed rule to specify that all importers may participate in the nomination process. A person who both imports and handles watermelons may participate in the nomination process and serve on the Board as either an importer or handler, but not both.

The commenter also suggested that section 1210.363(b) of the Plan which discusses suspension and termination be clarified. The Department agrees and has simplified the section to remove unnecessary language. The language removed does not affect the way the referendum will be conducted or how the results will be determined. Thus, the change to section 1210.363(b) will not be voted on in the referendum.

The commenter also recommended revising the language of section 1210.404(g) of the Plan which discussed the importer member nomination and selection. The Department agrees the language should be clarified and has revised the language to specify that a person who both imports and handles watermelons may participate in the nomination process and serve on the Board as either an importer or handler, but not both.

The commenter also recommended revising section 1210.602(a) of the Plan regarding voting in a referendum. The Department agrees and has simplified the section to remove language that is not necessary. The language removed does not affect the way the referendum will be conducted or how the results will be determined. Thus, the change to section 1210.602(b) will not be voted on in the referendum.

The commenter suggested changing the headings in sections 1210.321, 1210.363, 1210.404 and 1210.602 to a question format to be more useful and easier for the public to understand. Regulations for research and promotion programs are used primarily by a sector of the public who are industry members familiar with the program or persons who administer the program's day-to-day operations. Each program begins with an index that lists the sections of each program for ease of reference. Industry members and program administrators have found the format useful. Changing the format in the manner suggested would cause confusion. Thus, no changes to the proposed rule have been made based on this comment.

The commenter also made suggestions to sections that were not included in the first proposed rule published in February 2013. The commenter recommended replacing the term ''Secretary'' with the name of the office or official who takes action on the program. Section 1210.301 of the Plan defines Secretary to mean not only the Secretary of Agriculture, but also any person to whom the Secretary has delegated authority. Names of offices and titles change periodically within the Department and it would be inefficient and costly to engage in rulemaking to revise the terms in the Plan each time. Thus, no changes have been made to the proposed rule based on this comment.

The commenter also recommended using the term ''marketer'' and defining it within the regulation to avoid repeating the terms ''producer,'' ''handler,'' and ''importer.'' The commenter believes using the term marketer would be easier for the reader to understand. Producers, handlers, and importers perform different roles in the industry which are defined in sections 1210.306, 1210.307, and 1210.314 respectively in the Plan. Producers grow watermelons. Handlers perform functions like grading, packing, or processing and placing watermelons in channels of commerce. Importers import watermelons into the United States. In the field of agriculture, marketers are typically persons who sell product into channels of trade. Producers, handlers and importers do not all market watermelons, and categorizing all three as marketers would likely create confusion in the industry. The terms are also consistent with the Watermelon Research and Promotion Act. Thus, no changes have been made to the proposed rule based on this comment.

For the proposed amendments to the Plan and to become effective, they must be approved by a majority of the eligible producers, handlers, and importers voting in the referendum. The proposed changes to the regulations will be made effective, if the proposed amendments to the Plan are approved in referendum.

While the proposal set forth below has not received the approval of USDA, it is determined that the proposed amendment is consistent with and would effectuate the purposes of the Act.

Referendum Order

It is hereby directed that a referendum be conducted among eligible watermelon producers, handlers, and importers to determine whether they favor amending the Watermelon Research and Promotion Plan to eliminate the requirement that an importer import more than 50 percent of the total volume handled and imported in order to qualify as an importer

member to serve on the National Watermelon Promotion Board.

The referendum shall be conducted from January 13, 2014 through January 27, 2014. The referendum agents will mail the ballots to be cast in the referendum and voting instructions to all known eligible watermelon producers, handlers, and importers prior to the first day of the voting period. Only producers of 10 acres or more of watermelon; watermelon handlers, and importers of 150,000 or more pounds of watermelons annually, and importers who import less than 150,000 pounds of watermelons annually and did not apply for and receive reimbursements of assessments annually during the representative period will be eligible to vote in the referendum. Any eligible watermelon producers, handlers, and importers who do not receive a ballot should contact the referendum agent no later than one week before the end of the voting period. Ballots must be received by the referendum agents no later than the close of business 4:30 p.m., Eastern daylight-standard time, January 27, 2014, to be counted.

Jeanette Palmer, Sonia Jimenez and Marlene Betts, PED, FVP, AMS, USDA, Stop 0244, Room 1406–S, 1400 Independence Avenue SW., Washington, DC 20250–0244, are designated as the referendum agents of the Department to conduct this referendum. The referendum procedures specified in sections 1210.600 through 1210.607 of the Plan, which were issued pursuant to the Act, shall be used to conduct the referendum.

List of Subjects in 7 CFR Part 1210

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Reporting and recordkeeping requirements, Watermelon promotion.

For the reasons set forth in the preamble, part 1210, chapter XI of title 7 is proposed to be amended as follows:

PART 1210—WATERMELON RESEARCH AND PROMOTION PLAN

■ 1. The authority citation for 7 CFR part 1210 continues to read as follows:

Authority: 7 U.S.C. 4901–4916 and 7 U.S.C. 7401.

■ 2. In § 1210.321, paragraph (d) is revised to read as follows:

§ 1210.321 Nomination and selection.

* * * * *

(d) Nominations for importer positions that become vacant may be made by mail ballot, nomination conventions, or by other means prescribed by the Secretary. The Board shall provide notice of such vacancies and the nomination process to all importers through press releases and any other available means as well as direct mailing to known importers. All importers may participate in the nomination process. A person who both imports and handles watermelons may participate in the nomination process and serve on the Board as either an importer or handler, but not both.

* * * * *

■ 3. In § 1210.363, paragraph (b) is revised to read as follows:

§ 1210.363 Suspension or termination.

* * * * *

(b) The Secretary may conduct a referendum at any time and shall hold a referendum on request of the Board or at least 10 percent of the combined total of the watermelon producers, handlers, and importers to determine if watermelon producers, handlers, and importers favor termination or suspension of this Plan. The Secretary shall suspend or terminate this Plan at the end of the marketing year whenever the Secretary determines that the suspension or termination is favored by a majority of the watermelon producers, handlers, and importers voting in such referendum who, during a representative period determined by the Secretary, have been engaged in the production, handling, or importing of watermelons and who produced, handled, or imported more than 50 percent of the combined total of the volume of watermelons produced, handled, or imported by those producers, handlers, and importers voting in the referendum. Any such referendum shall be conducted by mail ballot.

* * * * *

■ 4. In § 1210.404, paragraph (g) is revised to read as follows:

§ 1210.404 Importer member nomination and selection.

* * * * *

(g) A person who both imports and handles watermelons may participate in the nomination process and serve on the Board as either an importer or handler, but not both.

■ 5. In § 1210.602, paragraph (a) is revised to read as follows:

§ 1210.602 Voting.

(a) Each person who is an eligible producer, handler, or importer as defined in this subpart, at the time of the referendum and who also was a producer, handler, or importer during the representative period, shall be entitled to one vote in the referendum: *Provided,* That each producer in a landlord-tenant relationship or a divided ownership arrangement involving totally independent entities cooperating only to produce watermelons in which more than one of the parties is a producer, shall be entitled to one vote in the referendum covering only that producer's share of the ownership.

* * * * *

Dated: October 21, 2013.

Rex A. Barnes,

Associate Administrator.

[FR Doc. 2013–25155 Filed 10–28–13; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 51

[NRC–2012–0246]

RIN 3150–AJ20

Proposed Waste Confidence Rule and Draft Generic Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Rescheduling of public meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has rescheduled to November 12 the Waste Confidence public meeting it initially planned to hold in Oak Brook, Illinois, on October 24, 2013. The NRC postponed this meeting as a result of lapsed appropriations. The rescheduled meeting will allow the NRC to receive public comments on proposed amendments to the NRC's regulations pertaining to the environmental impacts of the continued storage of spent nuclear fuel beyond a reactor's licensed life for operation and prior to ultimate disposal (the proposed Waste Confidence rule) and the draft generic environmental impact statement (DGEIS), NUREG–2157, ''Waste Confidence Generic Environmental Impact Statement,'' that forms a regulatory basis for the proposed amendments. The meeting is open to the public, and anyone may attend. The NRC will publish notices for other postponed and rescheduled Waste Confidence public meetings as soon as practicable.

DATES: The NRC plans to hold its rescheduled Waste Confidence public meeting in Oak Brook, Illinois, on November 12, 2013. This document contains specific meeting information in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Please refer to Docket ID NRC–2012–0246 when contacting the NRC about the availability of information for the proposed Waste Confidence rule and DGEIS. You may access publicly available information related to these documents by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0246.
- *NRC's Waste Confidence Web site:* Go to *http://www.nrc.gov/waste/spent-fuel-storage/wcd.html.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The DGEIS is available in ADAMS under Accession No. ML13224A106.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–287–0675; email: *Sarah.Lopas@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC published the proposed Waste Confidence Rule in the **Federal Register** on September 13, 2013 (78 FR 56776). On the same day, the NRC and the U.S. Environmental Protection Agency issued notices of the availability for the DGEIS (78 FR 56621; 78 FR 56695).

Prior to the lapse in appropriations in October 2013, the NRC staff held two Waste Confidence public meetings (one in Rockville, Maryland, on October 1, and one in Denver, Colorado, on October 3). The NRC postponed five meetings (in San Luis Obispo and Carlsbad, California; Perrysburg, Ohio; Minnetonka, Minnesota; and Oak Brook, Illinois) as a result of lapsed appropriations. The NRC has rescheduled the meetings in Carlsbad and San Luis Obispo, California, on November 18 and November 20, respectively. The NRC will publish notices for rescheduled meetings in Perrysburg, Ohio, and Minnetonka, Minnesota, as soon as practicable. Five additional Waste Confidence public meetings remain scheduled as publicized in 78 FR 54789: Chelmsford, Massachusetts, on October 28; Tarrytown, New York, on October 30; Charlotte, North Carolina, on November 4; Orlando, Florida, on November 6; and Rockville, Maryland, on November 14.

The November 12 public meeting will take place in the Oak Brook Ballroom of the Chicago Marriott Oak Brook, 1401 West 22nd Street, Oak Brook, Illinois. The meeting will start at 7:00 p.m. Central Standard Time and will continue until 10:00 p.m. Central Standard Time. Additionally, the NRC staff will host informal discussions during an open house one hour prior to the start of the meeting. The open house will start at 6:00 p.m. Central Standard Time.

The NRC staff will receive comments from the public during the comment-period portion of the meeting. The public meeting will be transcribed and will include: (1) a presentation on the contents of the DGEIS and proposed Waste Confidence rule; and (2) the opportunity for government agencies, organizations, and individuals to provide comments on the DGEIS and proposed rule. No oral comments on the DGEIS or proposed Waste Confidence rule will be accepted during the pre-meeting, open-house session. To be considered, oral comments must be presented during the transcribed portion of the public meeting. The NRC staff will also accept written comments at any time during the public meeting.

Persons interested in presenting oral comments at the November 12 public meeting are encouraged to pre-register. Persons may pre-register to present oral comments by calling 301–287–9392 or by emailing *WCRegistration@nrc.gov* no later than 3 days prior to the meeting. Members of the public may also register in-person to provide oral comments at the meeting. Individual oral comments may be limited by the time available, depending on the number of people who register.

If special equipment or accommodations are needed to attend or present information at the public meeting, then the need should be brought to the NRC's attention no later than 10 days prior to the meeting to provide the NRC staff adequate notice to determine whether the request can be accommodated. The meeting agenda and participation details will be available on the NRC's Public Meeting Schedule Web site at *http://www.nrc.gov/public-involve/public-meetings/index.cfm* no later than 10 days prior to the meeting.

Dated at Rockville, Maryland, this 22nd day of October 2013.

For the Nuclear Regulatory Commission.

Keith I. McConnell,

Director, Waste Confidence Directorate, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2013–25614 Filed 10–28–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 51

[NRC–2012–0246]

RIN 3150–AJ20

Proposed Waste Confidence Rule and Draft Generic Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Rescheduling of public meetings.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has rescheduled the Waste Confidence public meetings it initially planned to hold in San Luis Obispo and Carlsbad, California, on October 7 and October 9, respectively. The NRC postponed these meetings as a result of lapsed appropriations. The Waste Confidence public meeting in Carlsbad will now be held on November 18, 2013. The Waste Confidence public meeting in San Luis Obispo will now be held on November 20, 2013. The rescheduled meetings will allow the NRC to receive public comments on proposed amendments to the NRC's regulations pertaining to the environmental impacts of the continued storage of spent nuclear fuel beyond a reactor's licensed life for operation and prior to ultimate disposal (the proposed Waste Confidence rule) and the draft generic environmental impact statement (DGEIS), NUREG–2157, ''Waste Confidence Generic Environmental Impact Statement,'' that forms a regulatory basis for the proposed rule. The meetings are open to the public, and anyone may attend. The NRC will publish notices for other postponed and rescheduled Waste Confidence public meetings as soon as practicable.

DATES: The NRC plans to hold a rescheduled Waste Confidence public meeting in Carlsbad, California, on November 18, 2013. The NRC plans to hold a rescheduled Waste Confidence public meeting in San Luis Obispo, California, on November 20, 2013. This document contains specific meeting information in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: Please refer to Docket ID NRC–2012–0246 when contacting the

NRC about the availability of information for the proposed Waste Confidence rule and DGEIS. You may access publicly available information related to these documents by any of the following methods:

- Federal Rulemaking Web Site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0246.
- NRC's Waste Confidence Web site: Go to *http://www.nrc.gov/waste/spent-fuel-storage/wcd.html.*
- NRC's Agencywide Documents Access and Management System (ADAMS): You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The DGEIS is available in ADAMS under Accession No. ML13224A106.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Sarah Lopas, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–287–0675; email: *Sarah.Lopas@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC published the proposed Waste Confidence Rule in the **Federal Register** on September 13, 2013 (78 FR 56776). On the same day, the NRC and the U.S. Environmental Protection Agency issued notices of availability for the DGEIS (78 FR 56621; 78 FR 56695).

Prior to the lapse in appropriations in October 2013, the NRC staff held two Waste Confidence public meetings (one in Rockville, Maryland, on October 1, and one in Denver, Colorado, on October 3). The NRC postponed five meetings (in San Luis Obispo and Carlsbad, California; Perrysburg, Ohio; Minnetonka, Minnesota; and Oak Brook, Illinois) as a result of lapsed appropriations. The NRC has rescheduled the meeting in Oak Brook, Illinois, on November 12. The NRC will publish notices for rescheduled meetings in Perrysburg, Ohio, and Minnetonka, Minnesota, as soon as practicable. Five additional Waste Confidence public meetings remain scheduled as publicized in 78 FR 54789: Chelmsford, Massachusetts, on October 28; Tarrytown, New York, on October 30; Charlotte, North Carolina, on November 4; Orlando, Florida, on November 6; and Rockville, Maryland, on November 14.

The November 18 public meeting will take place at the Sheraton Carlsbad Resort and Spa, 5480 Grand Pacific Drive, Carlsbad, California. The November 20 public meeting will take place at the Courtyard by Marriott San Luis Obispo, 1605 Calle Joaquin Road, San Luis Obispo, California. Each meeting will start at 7:00 p.m. Pacific Standard Time and will continue until 10:00 p.m. Pacific Standard Time. Additionally, the NRC staff will host informal discussions during an open house one hour prior to the start of each meeting. The open houses will start at 6:00 p.m. Pacific Standard Time.

The NRC staff will accept comments from the public during the comment-period portion of the meetings. The public meetings will be transcribed and will include: (1) A presentation on the contents of the DGEIS and proposed Waste Confidence rule; and (2) the opportunity for government agencies, organizations, and individuals to provide comments on the DGEIS and proposed rule. No oral comments on the DGEIS or proposed Waste Confidence rule will be accepted during the pre-meeting, open-house sessions. To be considered, oral comments must be presented during the transcribed portions of the public meetings. The NRC staff will also accept written comments at any time during the public meetings.

Persons interested in presenting oral comments at the November 18 or 20 public meetings are encouraged to pre-register. Persons may pre-register to present oral comments at either meeting by calling 301–287–9392 or by emailing *WCRegistration@nrc.gov* no later than 3 days prior to the meeting. Members of the public may also register in-person to provide oral comments at each meeting. Individual oral comments may be limited by the time available, depending on the number of persons who register.

If special equipment or accommodations are needed to attend or to present information at either public meeting, then the need should be brought to the NRC's attention no later than 10 days prior to the meeting to provide the NRC staff adequate notice to determine whether the request can be accommodated. The meeting agenda and participation details for each meeting will be available on the NRC's Public Meeting Schedule Web site at *http://www.nrc.gov/public-involve/public-meetings/index.cfm* no later than 10 days prior to each meeting.

Dated at Rockville, Maryland, this 22nd day of October 2013.

For the Nuclear Regulatory Commission.

Keith I. McConnell,

Director, Waste Confidence Directorate, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2013–25602 Filed 10–28–13; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 810

RIN 1994–AA02

Assistance to Foreign Atomic Energy Activities

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Notice of a second public meeting and extension of comment period.

SUMMARY: On September 7, 2011, DOE issued a notice of proposed rulemaking (NOPR) to propose the first comprehensive updating of regulations concerning Assistance to Foreign Atomic Energy Activities since 1986. The NOPR reflected a need to make the regulations consistent with current global civil nuclear trade practices and nonproliferation norms, and to update the activities and technologies subject to the Secretary of Energy's specific authorization and DOE reporting requirements. It also identified destinations with respect to which most assistance would be generally authorized. Remaining destinations would require a specific authorization by the Secretary of Energy. After careful consideration of all comments received, DOE published a supplemental notice of proposed rulemaking (SNOPR) on August 2, 2013, to respond to those comments, propose new or revised rule changes, and afford interested parties an opportunity to comment.

A public meeting on the SNOPR was held at DOE's headquarters on August 5, 2013. A second public meeting will be held on November 15, 2013 at the Washington Grand Hyatt, 1000 H St. NW., Washington, DC 20001.

In conjunction with the timing of this second public meeting, the Department is extending the comment period to November 29, 2013. The extension will facilitate conducting the second public meeting and afford additional time for the public to review and comment on the proposed regulation. The Department looks forward to hearing feedback from the public on the proposed regulations.

DATES: DOE will continue to accept written comments on the SNOPR published August 2, 2013 (78 FR 46829) submitted electronically or postmarked on or before November 29, 2013. The second public meeting will be held on November 15, 2013, from 9 a.m. to 12 p.m. at the Washington Grand Hyatt, 1000 H St. NW., Washington, DC 20001. Due to space limitations, DOE asks that interested persons send their requests to attend this meeting, by no later than 4:30 p.m. on November 13, 2013.

ADDRESSES: Interested persons should send their requests to attend the second public meeting via email to *Part810.SNOPR@nnsa.doe.gov.* DOE will confirm its receipt of requests. Comments may be submitted on the SNOPR, identified by RIN 1994–AA02, by any of the following methods:

1. *Federal Rulemaking Portal: http://www.regulations.gov/#!docketDetail;D=DOE-HQ-2011-0035.* Follow the instructions for submitting comments.

2. *Email: Part810.SNOPR@hq.doe.gov.* Include RIN 1994–AA02 in the subject line of the message.

3. *Mail:* Richard Goorevich, Senior Policy Advisor, Office of Nonproliferation and International Security, NA–24, National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585.

Due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, DOE encourages responders to submit comments electronically to ensure timely receipt.

All submissions must include the RIN for this rulemaking, RIN 1994–AA02. For additional information and instructions on submitting comments, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of the SNOPR.

FOR FURTHER INFORMATION CONTACT: Richard Goorevich, Senior Policy Advisor, Office of Nonproliferation and International Security, NA–24, National Nuclear Security Administration, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, telephone 202–586–0589; Janet Barsy, Office of the General Counsel, GC–53, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, telephone 202–586–3429; or Katie Strangis, National Nuclear Security Administration, 1000 Independence Avenue SW., Washington, DC 20585, telephone 202–586–8623.

SUPPLEMENTARY INFORMATION:

I. Background
II. Second Public Meeting
III. Extension of Comment Period

I. Background

On September 7, 2011, DOE issued a notice of proposed rulemaking (NOPR) to propose the first comprehensive updating of regulations concerning Assistance to Foreign Atomic Energy Activities since 1986. (76 FR 55278) The NOPR reflected a need to make the regulations consistent with current global civil nuclear trade practices and nonproliferation norms, and to update the activities and technologies subject to the Secretary of Energy's specific authorization and DOE reporting requirements. It also identified destinations with respect to which most assistance would be generally authorized and destinations that would require a specific authorization by the Secretary of Energy. After careful consideration of all comments received, DOE published a SNOPR on August 2, 2013, to respond to those comments, propose new or revised rule changes, and afford interested parties a second opportunity to comment. (78 FR 46829)

II. Second Public Meeting

A public meeting on the SNOPR was held at the DOE Forrestal Building located in Washington, DC, on August 5, 2013. A second public meeting on the SNOPR will be held on November 15, 2013, from 9 a.m. to 12 p.m. at the Washington Grand Hyatt, 1000 H St, NW Washington, DC, 20001. Interested persons should send their requests to attend the second public meeting via email to *Part810.SNOPR@nnsa.doe.gov.* DOE will confirm its receipt of requests.

Persons interested in giving an oral presentation at the second public meeting should provide a daytime phone number where the person can be reached in the email requesting attendance. Each oral presentation may be limited and may in no instance be longer than 20 minutes. Persons making an oral presentation are requested to provide 3 copies of their prepared statement to the public meeting and submit it at the registration desk. DOE reserves the right to select the persons who will speak. DOE also reserves the right to schedule speakers' presentations and to establish the procedures for conducting the meeting. A DOE official will be designated to preside at the meeting.

The meeting will not be a judicial or evidentiary-type hearing. Any further procedural rules for the conduct of the meeting will be announced by the presiding official. After the public meeting, interested persons may submit comments until the end of the comment period. A transcript of the meeting will be made, and the entire record of this rulemaking will be retained by DOE and posted at regulations.gov.

III. Extension of Comment Period

Due to the lapse in the fiscal year 2014 appropriation and associated impacts on government operations, the Department will extend the comment period to November 29, 2013. The extension will facilitate conducting the second public meeting and afford additional time for the public to review and comment on the SNOPR.

As provided in the SNOPR, if you submit information that you believe to be exempt by law from public disclosure, you should submit one complete copy, as well as one copy from which the information claimed to be exempt by law from public disclosure has been deleted. DOE is responsible for the final determination with regard to disclosure or nondisclosure of the information and for treating it accordingly under the DOE Freedom of Information regulations at 10 CFR 1004.11.

Issued in Washington, DC, on October 23, 2013.

Richard Goorevich,

Senior Policy Advisor.

[FR Doc. 2013–25551 Filed 10–28–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR part 25

[Docket No. FAA–2013–0890; Notice No. 25–13–10–SC]

Special Conditions: Airbus, Model A350–900 Series Airplane; Ground Pivoting Loads

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for Airbus Model A350–900 series airplanes. These airplanes will have a novel or unusual design feature(s) associated with a braking system that affects the airplane's pivoting behavior. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to

that established by the existing airworthiness standards.

DATES: Send your comments on or before December 13, 2013.

ADDRESSES: Send comments identified by docket number FAA–2013–0890 using any of the following methods:

- Federal eRegulations Portal: Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- Mail: Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- Hand Delivery or Courier: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.
- Fax: Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/*, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/*.

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Todd Martin, FAA, Airframe/Cabin Safety, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone (425) 227–1178; facsimile (425) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the proposed special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On August 25, 2008, Airbus applied for a type certificate for their new Model A350–900 series airplane. Later, Airbus requested and the FAA approved an extension to the application for FAA type certification to June 28, 2009. The Model A350–900 series airplane has a conventional layout with twin wing-mounted Rolls-Royce Trent engines. It features a twin aisle 9-abreast economy class layout, and accommodates side-by-side placement of LD–3 containers in the cargo compartment. The basic Model A350–900 series configuration will accommodate 315 passengers in a standard two-class arrangement. The design cruise speed is Mach 0.85 with a Maximum Take-Off Weight of 602,000 lbs. Airbus proposes the Model A350–900 series airplane to be certified for extended operations (ETOPS) beyond 180 minutes at entry into service for up to a 420-minute maximum diversion time.

The Airbus Model A350–900 series airplane is equipped with a braking system that affects the airplane's pivoting behavior. During pivoting the braking system inhibits braking on some wheels. Title 14 Code of Federal Regulations (14 CFR) 25.503 and European Aviation Safety Agency (EASA) Certification Specification (CS) section 25.503, each specify limit loads due to pivoting, however, system effects are not taken into account.

Type Certification Basis

Under Title 14, Code of Federal Regulations (14 CFR) 21.17, Airbus must show that the Model A350–900 series meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25–1 through 25–128.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model A350–900 series because of a novel or unusual design feature, special conditions are prescribed under § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the proposed special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and proposed special conditions, the Model A350–900 series must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36 and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in 14 CFR 11.19, under § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Airbus Model A350–900 series airplane will incorporate the following novel or unusual design features: a braking system that affects the airplane's pivoting behavior.

Discussion

Within the Aviation Rulemaking Advisory Committee, the Loads and Dynamics Harmonization Working Group developed criteria for determining pivoting loads. The group recommended, for airplanes with more than two main landing gear units, a rational pivoting maneuver that takes into account the effects of the braking system and tire characteristics, in lieu of the current requirement. Although the Airbus Model A350–900 series airplane has two main landing gear units, EASA and the FAA propose to apply the same criteria on this airplane.

Applicability

As discussed above, these proposed special conditions apply to Airbus Model A350–900 series airplanes. Should Airbus apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the proposed special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Airbus Model A350–900 series airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Airbus Model A350–900 series airplanes in lieu of § 25.503:

1. The main landing gear and supporting structure must be designed for the loads induced by pivoting during ground maneuvers.

(a) The following rational pivoting maneuvers must be considered:

(i) Towing at the nose gear at the critical towing angle with no brakes applied, including cases with torque links disconnected; and separately,

(ii) Application of symmetrical or unsymmetrical forward thrust to aid pivoting, with or without braking by pilot action on the pedals.

(b) The airplane is assumed to be in static equilibrium, with the loads being applied at the ground contact points.

(c) The limit vertical load factor must be 1.0, and:

(i) For wheels with brakes applied, the coefficient of friction must be 0.8,

(ii) For wheels with brakes not applied, the ground tire reactions must be based on reliable tire data.

Issued in Renton, Washington, on September 12, 2013.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–25398 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0393; Directorate Identifier 2012–CE–025–AD]

RIN 2120–AA64

Airworthiness Directives; Twin Commander Aircraft LLC Airplanes; Initial Regulatory Flexibility Analysis

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Availability of an initial regulatory flexibility analysis.

SUMMARY: This document announces the availability of and request for comments on the initial regulatory flexibility analysis for the previously published Airworthiness Directive (AD) 2013–09–05 that applies to certain Twin Commander Aircraft LLC Models 690, 690A, and 690B airplanes. AD 2013–09–05 requires inspection for cracking of the outer fuselage attachments, the lower wing main spar, the vertical channels, the upper picture window channels, aft cabin pressure web, external wing to fuselage fillets, and fasteners; repair or replacement of damaged parts as necessary; and modification of the structure with reinforced parts.

DATES: Comments must be received on or before December 13, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Aerospace Engineer, FAA, Seattle Aircraft Certification Office (ACO), Airframe Branch, ANM–120S, 1601 Lind Avenue SW., Renton, WA 98057; telephone: (425) 917–6426; fax: (425) 917–6590; email: *kathleen.arrigotti@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued AD 2013–09–05; Amendment 39–17446, which was published in the **Federal Register** on May 14, 2013 (78 FR 28125) (''AD 2013–09–05''), to amend 14 CFR part 39 to add an AD that would apply to the specified products. AD 2013–09–05 requires inspection for cracking of the outer fuselage attachments, the lower wing main spar, the vertical channels, the upper picture window channels, aft cabin pressure web, external wing to fuselage fillets, and fasteners; repair or replacement of damaged parts as necessary; and modification of the structure with reinforced parts.

Reason for This Action

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. In accordance with Section 608 of the Regulatory Flexibility Act, an agency head may waive or delay completion of some or all of the requirements of Section 603 by providing a written finding that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the provisions of Section 603 impracticable. The agency issued AD 2013–09–05 in response to an immediate safety of flight condition that made compliance with the provisions of Section 603 impracticable. After issuing AD 2013–09–05, the agency reviewed the AD actions and determined that the final rule did have a significant economic impact on a substantial number of small entities. The following presents the initial regulatory flexibility analysis prepared by the agency as described in the RFA.

1. Reason for Agency Action

We issued AD 2013–09–05 for certain Twin Commander Aircraft LLC Models 690, 690A, and 690B airplanes. The AD requires inspection for cracking of the outer fuselage attachments, the lower wing main spar, the vertical channels, the upper picture window channels, aft cabin pressure web, external wing to fuselage fillets, and fasteners; repair or replacement of damaged parts as necessary; and modification of the structure with reinforced parts. The AD was prompted by cracks found in the upper picture window frame channels, left- and right-hand wing main spar frame support channels, and aft pressure bulkhead web. This condition, if not corrected, could result in structural failure of the airplane. We issued the AD to correct the unsafe condition on these products.

2. Legal Basis and Objectives of the Final Rule

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs'' describes in more

detail the scope of the Agency's authority.

We issued the AD under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in the AD.

3. Recordkeeping and Other Compliance Requirements of the Final Rule

Compliance

Compliance with AD 2013–09–05 must occur within the times specified, unless already done.

Inspection

Inspect the airplane structural components, at the compliance times specified in paragraphs (g)(1)(i) through (g)(1)(iv) of the AD following Part I of Twin Commander Aircraft LLC Service Bulletin 241, September 26, 2012:

- For airplanes with 10,000 or more hours time-in-service (TIS), inspect within the next 30 days after May 29, 2013 (the effective date of the AD).
- For airplanes with 7,500 through 9,999 hours TIS, inspect within the next 60 days after May 29, 2013 (the effective date of the AD).
- For airplanes with 5,000 through 7,499 hours TIS, inspect within the next 6 months after May 29, 2013 (the effective date of the AD).
- For airplanes with less than 5,000 hours TIS, inspect when the airplane accumulates a total of 5,000 hours TIS or within the next 12 months after May 29, 2013 (the effective date of the AD), whichever occurs later.

Repair

If any damage, cracks, and/or cracks that exceed the allowable limits specified in the service bulletin are found during the inspection required in paragraph (g)(1) of the AD, before further flight, repair or replace parts as necessary following Twin Commander Aircraft LLC Service Bulletin 241, dated, September 26, 2012. If Twin Commander Aircraft LLC Service Bulletin 241, dated, September 26, 2012, does not give procedures for repair of the damaged area, before further flight, you must contact Twin Commander Aircraft LLC to obtain repair instructions approved by the Seattle ACO specifically for compliance with this AD and incorporate those instructions. You can find contact information for Twin Commander Aircraft LLC in paragraph (l)(2) of the AD.

Modification and Reassembly

- Before further flight after completing the actions in paragraphs (g) and (h) of the AD, modify and reassemble the airplane using the modification and reassembly procedures in Part II of Twin Commander Aircraft LLC Service Bulletin 241, dated, September 26, 2012.
- Although Twin Commander Aircraft LLC Service Bulletin 241, dated September 26, 2012, states that at least one person on the modification team must have completed the Twin Commander Aircraft LLC approved training, the FAA does not require that a mechanic complete this specialized training to do the modification work required in the AD. Regulations 14 CFR 65.81(a) and 14 CFR 65.81(b) provide criteria about qualifications of those performing maintenance; in this case, the requirements of the AD.

4. Federal Rules That May Duplicate, Overlap, or Conflict With the Final Rule

There are no rules that duplicate, overlap, or conflict with AD 2013–09–05.

5. Description and Estimation of the Number of Small Entities Affected by the Final Rule

Under the RFA, the FAA must determine whether a final rule significantly affects a substantial number of small entities. This determination is typically based on small entity size and revenue thresholds that vary depending on the affected industry. To determine the number of small entities affected by the airworthiness directive, we searched the FAA Aircraft Registry database. The database provides ownership information for 175 of the airplanes affected by AD 2013–09–05, and average airplane values for these airplanes are available in the *Aircraft Bluebook Price Digest*.

The FAA aircraft registry categorizes owners of affected airplanes as individuals, co-owners, corporations, and governments. A review of the corporations shows that an overwhelming majority are privately held. In most cases, the information about these corporations cannot be determined because financial and employment data for privately held entities is sparse. Nevertheless, the FAA believes the number of small business entities affected by the AD is substantial.

The serial numbers for the 175 affected airplanes that we have information on was used to look up average retail values in the *Aircraft Bluebook Price Digest*. The ''Digest'' provides average retail values by model, year, and serial number. It is only a guide since the actual condition and upgrades to individual airplanes are not known. The value range for the 175 affected airplanes is between $225,000 and $555,000 per airplane. The range is primarily due to age (i.e., the older an airplane the lower its retail value versus a newer model of the same airplane). The total retail value of the affected airplanes is equal to the sum of the retail value for each individual airplane. This summation equals $78.9 million (or an average of about $451,000 per airplane).

The economic impact on small entities due to the AD is significant. This determination is based on the percentage of the cost of compliance per airplane ($58,090) to the average retail value per airplane ($451,000), which is estimated to be 12.9 percent.

Based on the discussion above, complying with the AD is determined to be significant economic impact on a substantial number of small entities.

6. Alternatives Considered

The FAA considered possible alternative actions and determined the actions taken were necessary to address the unsafe condition. The FAA did not extend the compliance time because we needed to act immediately to address the immediate safety problem. The inspection and modification both involve a complex disassembly that comprises most of the labor cost associated with the AD. Performing the modification while the airplane is already disassembled for inspection saves owners the labor cost of disassembling twice. If discrepancies are not found in the inspection, no repair expense, beyond the mandated modification expense, will occur.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a

legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA assessed the potential effect of the AD and determined that because it addresses an immediate safety issue the AD is not considered an unnecessary obstacle to the foreign commerce of the United States.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $143.1 million in lieu of $100 million. The AD does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

Comments Invited

We invite you to send any written relevant data, views, or arguments about this IRFA. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0393; Directorate Identifier 2012–CE–025–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the IRFA as related to the AD action. The most helpful comments will reference a specific portion of the IRFA or related rulemaking document, explain the reason for any recommended change, and include supporting data.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about the AD.

Issued in Kansas City, Missouri, on October 22, 2013.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–25526 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0740; Directorate Identifier 2013–NE–24–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Pratt & Whitney (PW) PW2037, PW2037D, PW2037M, PW2040, PW2040D, PW2043, PW2146, PW2240, PW2337, PW2643, and F117–PW–100 turbofan engines. This proposed AD was prompted by a rupture of the diffuser-to-high-pressure turbine (HPT) case flange. This proposed AD would require a one-time eddy current inspection (ECI) of affected engines with certain diffuser and HPT cases installed. This AD also proposes to require a fluorescent-penetrant inspection (FPI) of the diffuser case rear flange and HPT case front flange. We are proposing this AD to prevent failure of the diffuser-to-HPT case flange, which could lead to uncontained engine failure and damage to the airplane.

DATES: We must receive comments on this proposed AD by December 30, 2013.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Pratt & Whitney, 400 Main St., East Hartford, CT 06108; phone: 860–565–8770; fax: 860–565–4503. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Robert Morlath, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7154; fax: 781–238–7199; email: *robert.c.morlath@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0740; Directorate Identifier 2013–NE–24–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We received a report of an engine event in October 2011 that resulted in a rupture of the engine diffuser-to-HPT case flange. The rupture caused the engine cowl doors to break open, which resulted in damage to the underside of the airplane's wing. Subsequent investigation revealed that the root cause of this rupture was a crack that originated in HPT case M-flange boltholes (the forward flange of the HPT case that mates with the rear outer flange of the diffuser case). This condition, if not corrected, could result in failure of the diffuser-to-HPT case flange, which may cause an uncontained engine failure and damage to the airplane.

Relevant Service Information

We reviewed PW Service Bulletin (SB) No. PW2000 72–763, Revision 1, dated August 30, 2013, and PW PW2000 Series Engine Manual part number 1A6231. The SB describes procedures for inspecting the flanges of the HPT case and the diffuser case.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require an on-wing ECI of the diffuser case and HPT case flanges. This proposed AD would also require an FPI of all engine diffuser cases and all HPT cases.

Differences Between the Proposed AD and the Service Information

PW SB No. PW2000 72–763, Revision 1, dated August 30, 2013, requires that operators complete an on-wing ECI by August 31, 2013. We are proposing that the ECI be performed within 100 flight cycles or 30 days after the effective date of this AD, whichever is earlier.

Costs of Compliance

We estimate that this proposed AD will affect 638 engines installed on airplanes of U.S. registry. Of the 638 engines, we estimate that about 58 engines will be subject to ECI and all engines will be subject to the FPI. We also estimate that it would take about 5 hours to perform the ECI and 3 hours to perform the FPI required by this proposed AD. Materials cost for the FPI will be about $20 per engine. The average labor rate is $85 per hour. Based on these figures, we estimate the total cost of this proposed AD to U.S. operators to be $200,100.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This proposed regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Pratt & Whitney: Docket No. FAA–2013–0740; Directorate Identifier 2013–NE–24–AD.

(a) Comments Due Date

We must receive comments by December 30, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Pratt & Whitney (PW) PW2037, PW2037D, PW2037M, PW2040, PW2040D, PW2043, PW2146, PW2240, PW2337, PW2643, and F117–PW–100 turbofan engines.

(d) Unsafe Condition

This AD was prompted by a rupture of the diffuser-to-high-pressure turbine (HPT) case flange. We are issuing this AD to prevent failure of the diffuser-to-HPT case flange, which could lead to uncontained engine failure and damage to the airplane.

(e) Compliance

Unless already done, comply with this AD within the compliance times specified.

(1) For diffuser and HPT cases identified by serial number (S/N) in Table 1 to paragraph (e) of this AD:

(i) Within 100 flight cycles or 30 days after the effective date of this AD, whichever is earlier, eddy current inspect the diffuser case and the HPT case M-flange.

(ii) For engines installed on the aircraft, use paragraphs 3.G. through 3.L. in the ''For Engines Installed on the Aircraft'' section of the Accomplishment Instructions of PW Service Bulletin (SB) No. PW2000 72–763, Revision 1, dated August 30, 2013, to perform the inspection.

(iii) For engines removed from the aircraft, use paragraphs 3.B. through 3.G. in the ''For Engines Removed From the Aircraft'' section of the Accomplishment Instructions of PW Service Bulletin (SB) No. PW2000 72–763, Revision 1, dated August 30, 2013, to perform the inspection.

TABLE 1 TO PARAGRAPH (e)—DIFFUSER AND HPT CASE P/NS AND SERIAL NUMBERS

Diffuser case part No. (P/N)	Diffuser case S/N	HPT case P/N	HPT case S/N
1B7407–001	DGUSAA0114	1A9030	RM6300
1B7407	WE2452	1B2440	DKLBB40125
1B7407	DGUSAA0097	1B2440	DKLBCH3429
1B7407	DGUSAA0670	1B2440	DKLBCS1032
1B7407–001	DGUSAA0622	1B2440	DKLBC00030
1B3055–001	DGUSAA0247	1B2440	DKLBC07691
1B7461	DGGUAK1308	1B2440	DKLBDB5108

TABLE 1 TO PARAGRAPH (e)—DIFFUSER AND HPT CASE P/NS AND SERIAL NUMBERS—Continued

Diffuser case part No. (P/N)	Diffuser case S/N	HPT case P/N	HPT case S/N
1B7461	DGGUAK1306	1B2440	DKLBDB5153
1B7461	DGGUAK1356	1B2440	DKLBDU3358
1B7477	DGGUAL1445	1A9030	RM6353
1B7477	DGGUAL1492	1A9030	PD3348
1B7477	DGGUAL1501	1A9030	PD3280
1B7477	DGGUAL1597	1A9030	ND5644
1B4091–001	RT6356	1B2440	DKLBBP0225
1B4091–002	ST2044	1A9030	DKLBBR3621
1B4091–005	PF3203	1A9030	PD3290
1B7461	DGGUAK1377	1B2440	WG6904
1B7477	DGGUAL1548	1B2440	WV1807
1B7407	DGGUAK0189	1B2440	WX2639
1B7407	DGUSAA0443	1B2440	WZ4057
1B7477	DGGUAL1441	1B2440	WX2664
1B7477	DGGUAL1560	1A9030	RM6359
1B7407–001	DGUSAA0329	1B2440	DKLBCM8956
1B7407	DGUSAA0334	1B2440	DKLBCM0214
		1B2440	DKLBDB5069
		1B2440	DKLBB02548
		1B2440	DKLBDC7336
		1B2440	DKLBDU3372
		1B2440	WM6913
		1B2440	DKLBBF6606
		1B2440	DKLBBB2861
		1B2440	DKLBCT1660
		1B2440	DKLBB94641
		1B2440	DKLBBX8092

(2) For all diffuser and HPT cases:

(i) At the next piece part exposure and every piece part exposure thereafter, perform a high sensitivity fluorescent-penetrant inspection (FPI) of the entire diffuser case rear flange (M-flange) and bolt holes.

(ii) At the next piece part exposure and every piece part exposure thereafter, perform a high sensitivity FPI of the entire HPT case forward flange (M-flange) and bolt holes.

(f) Prohibition Statement

After the effective date of this AD, do not install any engine with a diffuser or HPT case with serial number listed in Table 1 to paragraph (e) of this AD, onto any aircraft, that was not inspected per paragraph (e) of this AD.

(g) Credit for Previous Actions

If you performed an eddy current inspection of the diffuser case and HPT case M-flange using paragraphs 3.G. through 3.L. in the ''For Engines Installed on the Aircraft'' section or paragraphs 3.B. through 3.G. in the ''For Engines Removed from the Aircraft'' section of the Accomplishment Instructions of PW SB PW2000 72–763, dated March 22, 2013, you met the requirements of paragraph (e)(1) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(i) Related Information

(1) For more information about this AD, contact Robert Morlath, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7154; fax: 781–238–7199; email: *robert.c.morlath@faa.gov*.

(2) Pratt & Whitney Engine Manual, part number 1A6231, Chapter 72–41–00, Inspection/Check-02, (Task 72–41–00–230–002) and Chapter 72–52–00, Inspection/Check-02 (Task 72–52–00–230–000), which are not incorporated by reference in this AD, can be obtained from Pratt & Whitney, using the contact information in paragraph (i)(3) of this AD.

(3) For service information identified in this AD, contact Pratt & Whitney, United Technologies Corporation, 400 Main St., East Hartford, CT 06108; phone: 860–565–8770; fax: 860–565–4503.

(4) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on October 7, 2013.

Colleen M. D'Alessandro,

Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–25459 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada Corp. Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Pratt & Whitney Canada Corp. (P&WC) PT6A–114 and PT6A–114A turboprop engines. This proposed AD was prompted by several incidents of compressor turbine (CT) blade failure, including two fatalities, resulting in power loss and in-flight shutdown (IFSD) of the engine. This proposed AD would require initial and repetitive borescope inspections (BSIs) of CT blades, and the removal from service of blades that fail inspection. We are proposing this AD to prevent failure of CT blades, which could lead to damage to the engine or to the airplane.

DATES: We must receive comments on this proposed AD by December 30, 2013.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this proposed AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; Internet: *www.pwc.ca*. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (phone: 800–647–5527) is the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7176; fax: 781–238–7199; email: *james.lawrence@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Discussion

Transport Canada Civil Aviation, which is the aviation authority for Canada, has issued Canada AD CF–2013–21, dated August 1, 2013, (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> There have been a number of reported incidents where compressor turbine (CT) blade failures have caused power loss on PT6A–114 & PT6A–114A engines, resulting in in-flight shutdown (IFSD). Investigation by engine manufacturer Pratt & Whitney Canada (P&WC) has determined that when operated at high power and high temperature settings, the subject CT blades are prone to crack/fracture as result of creep and/or sulfidation.

You may obtain further information by examining the MCAI in the AD docket. We are proposing this AD to prevent failure of CT blades, which could lead to damage to the engine or to the airplane.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of Canada and is approved for operation in the United States. Pursuant to our bilateral agreement with Canada, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information provided by Transport Canada Civil Aviation and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require initial and repetitive BSI of CT blades and the removal from service of blades that fail the inspection.

Costs of Compliance

We estimate that this proposed AD affects 300 engines installed on aircraft of U.S. registry. We also estimate that it would take about 4 hours per engine to comply with this proposed AD. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $102,000.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This proposed regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Pratt & Whitney Canada Corp.: Docket No. FAA–2013–0766; Directorate Identifier 2013–NE–26–AD.

(a) Comments Due Date

We must receive comments by December 30, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Pratt & Whitney Canada Corp. (P&WC) PT6A–114 and PT6A–114A turboprop engines.

(d) Reason

This AD was prompted by several incidents of compressor turbine (CT) blade failure, including two fatalities, resulting in power loss and in-flight shutdown (IFSD) of the engine. We are issuing this AD to prevent failure of CT blades, which could lead to damage to the engine or to the airplane.

(e) Actions and Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Within 150 operating hours after the effective date of this AD, perform a borescope inspection (BSI) of CT blades for engines with 500 or more hours time since new (TSN) that have not been previously inspected, or more than 500 flight hours time since last inspection (TSLI).

(2) Thereafter, repeat the inspection in paragraph (e)(1) of this AD within every additional 500 flight hours TSLI.

(3) During the next hot section inspection (HSI) after the effective date of this AD, replace the complete set of CT blades with blades eligible for installation.

(4) If CT blades listed in paragraphs (g)(1) or (g)(2) of this AD, are installed to comply with paragraph (e)(3) of this AD, you must still comply with the 500-hour TSLI repetitive inspection requirement of paragraph (e)(2) of this AD.

(f) Optional Terminating Action

Replacing all CT blades with new CT blades, P/N 3072791–01, and Disk Balance Assembly, P/N 3072801–01; or with new CT blades, P/N 3072791–02, and Disk Balance Assembly, P/N 3072801–02; is terminating action for this AD.

(g) Definition

CT blades eligible for installation are:

(1) New CT blades, other than those listed in paragraphs (g)(3) and (g)(4) of this AD;

(2) CT blades, other than those listed in paragraphs (g)(3) and (g)(4) of this AD, that have met the inspection requirements of paragraphs (e)(1) and (e)(2) of this AD;

(3) CT blade, P/N 3072791–01, and Disk Balance Assembly, P/N 3072801–01; and

(4) CT blade, P/N 3072791–02, and Disk Balance Assembly, P/N 3072801–02.

(h) Credit for Previous Actions

If you performed P&WC Service Bulletin (SB) No. PT6A–72–1669, Revision 9, dated June 28, 2013, or earlier versions, you have met the initial inspection requirements of this AD. However, you must still comply with the 500-hour TSLI repetitive inspection requirement of paragraph (e)(2) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(j) Related Information

(1) For more information about this AD, contact James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7176; fax: 781–238–7199; email: *james.lawrence@faa.gov.*

(2) Refer to Transport Canada Civil Aviation AD CF–2013–21, dated August 1, 2013, for more information. You may examine the AD on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2013–0766.

(3) For guidance on the initial and repetitive BSIs mandated by this AD, refer to P&WC SB No. PT6A–72–1669 and P&WC SB No. PT6A–72–1727, which are not incorporated by reference in this AD. The SBs can be obtained from Pratt & Whitney Canada Corp. using the contact information in paragraph (j)(4) of this AD.

(4) For service information identified in this AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; Internet: *www.pwc.ca.*

(5) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on October 7, 2013.

Colleen M. D'Alessandro,

Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–25460 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 312

RIN 3084–AB20

Children's Online Privacy Protection Rule Applications for Approval of Proposed Parental Consent Methods by AssertID, Inc., Imperium LLC, and iVeriFly, Inc.; Application for Approval of Safe Harbor Program by kidSAFE Seal Program

AGENCY: Federal Trade Commission (FTC or Commission).

ACTION: Notice of extension of Commission determination and public comment deadlines.

SUMMARY: The FTC is extending the deadlines for Commission determination of applications for approval of proposed parental consent methods by AssertID, Inc. (''AssertID''), Imperium LLC (''Imperium''), and iVeriFly, Inc. (''iVeriFly'') pursuant to the Children's Online Privacy Protection Rule. In addition, the FTC is extending the deadline for filing public comments concerning Imperium's application for approval of a parental consent method and the proposed self-regulatory guidelines submitted by the kidSAFE Seal Program (''kidSAFE''), owned and operated by Samet Privacy, LLC, under the safe harbor provision of the Children's Online Privacy Protection Rule.

DATES: Written comments must be received by November 4, 2013.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. For comments concerning Imperium, write ''Imperium Application for Parental Consent Method, Project No. P–135419'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/pmcoppaimperiumapp*, by following the instructions on the web-based form. For comments concerning kidSAFE, write ''kidSAFE Application for Safe Harbor, Project No. P–135418'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/coppakidsafeapp*, by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex E), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Kandi Parsons, Attorney, (202) 326–2369, Peder Magee, Attorney, (202) 326–3538, or Kristin Cohen, (202) 326–2276, Division of Privacy and Identity Protection, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Section A. Background

On October 20, 1999, the Commission issued its final Rule [1] pursuant to the Children's Online Privacy Protection Act, 15 U.S.C. 6501 *et seq.,* which became effective on April 21, 2000.[2] On December 19, 2012, the Commission amended the Rule, and these amendments became effective on July 1, 2013.[3] The Rule requires certain Web site operators to post privacy policies and provide notice, and to obtain verifiable parental consent, prior to collecting, using, or disclosing personal information from children under the age of 13. The Rule enumerates methods for obtaining verifiable parental consent, while also allowing an interested party to file a written request for Commission approval of parental consent methods not currently enumerated.[4] To be considered, the party must submit a detailed description of the proposed parental consent method, together with an analysis of how the method meets the requirements for parental consent described in 16 CFR 312.5(b)(1). AssertID, Imperium, and iVeriFly have submitted proposed parental consent methods to the Commission for approval. The Rule also contains a ''safe harbor'' provision enabling industry groups or others to submit to the Commission for approval self-regulatory guidelines that would implement the Rule's protections.[5] Pursuant to that provision, kidSAFE has submitted proposed self-regulatory guidelines to the Commission for approval. The full text of the verifiable parental consent method applications and kidSAFE's proposed guidelines are available on the Commission's Web site at www.ftc.gov.

The Children's Online Privacy Protection Rule provides that the Commission shall issue a written determination within 120 days of the filing of an application for approval of a verifiable parental consent method.[6] Because of the federal government shutdown, which began on October 1, 2013, the Commission was unable to review comments and prepare determinations on the applications. The federal government re-opened on October 17, 2013. In order to ensure that it can give full consideration to the applications submitted by AssertID, Imperium, and iVeriFly, the Commission has determined to extend the timetable laid out in 16 CFR 312.12(a) by sixteen days in order to account for the time period in which the government was shut down. Accordingly, the Commission will issue its determination for AssertID by November 13, 2013; for Imperium by December 26, 2013; and for iVeriFly by February 4, 2014.

In addition, during the time when the government was shut down, interested parties were unable to submit comments on Imperium's application for approval of a parental consent method or on kidSAFE's proposed self-regulatory guidelines. The Commission has decided to extend the comment period for both matters until November 4, 2013.

Section B. Invitation To Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before November 4, 2013. For comments concerning Imperium, write ''Imperium Application for Parental Consent Method, Project No. P–135419'' on your comment. For comments concerning kidSAFE, write ''kidSAFE Application for Safe Harbor, Project No. P–135418'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment doesn't include any sensitive personal information, such as Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment doesn't include any sensitive health information, including medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential,'' as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[5] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file your comment concerning Imperium at *https://ftcpublic.commentworks.com/ftc/pmcoppaimperiumapp*, and your comment concerning kidSAFE at *https://ftcpublic.commentworks.com/ftc/coppakidsafeapp*, by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment concerning Imperium on paper, write ''Imperium Application for Parental Consent Method, Project No. P–135419'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex E), 600 Pennsylvania Avenue NW., Washington, DC 20580. If you file your comment concerning kidSAFE on paper, write ''kidSAFE Application for Safe Harbor, Project No. P–135418'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex E), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the

[1] 64 FR 59888 (1999).

[2] 16 CFR part 312.

[3] 78 FR 3972 (2013).

[4] 16 CFR 312.12(a); 78 FR at 3991–3992, 4013.

[5] *See* 16 CFR 312.11; 78 FR at 3995–96, 4012–13.

[6] 16 CFR 312.12(a).

[5] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before November 4, 2013. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2013–25452 Filed 10–28–13; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 225, 500, 507, and 579

[Docket No. FDA–2011–N–0922]

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Public Meeting on Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing three public meetings to discuss the proposed rule to establish requirements for current good manufacturing practice and hazard analysis and risk-based preventive controls for animal food. This proposed rule is one of several proposed rules that will establish the foundation of, and central framework for, the modern food safety system envisioned by Congress in the FDA Food Safety Modernization Act (FSMA). The purpose of the public meetings is to inform the public of the provisions of the proposed rule and the rulemaking process (including how to submit comments, data, and other information to the rulemaking docket) as well as solicit oral stakeholder and public comments on the proposed rule and to respond to questions about the proposed rule.

DATES: See section II, ''How to Participate in the Public Meetings,'' in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: See section II, ''How to Participate in the Public Meetings,'' in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *For general questions about the meeting, for assistance to register for the meeting, to request an opportunity to make an oral presentation, or to request special accommodations due to a disability, contact:* Aleta Sindelar, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rm. 133, Rockville, MD 20855, 240–276–9230, FAX: 240–276–9241, email: *aleta.sindelar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Pub. L. 111–353) was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations requiring preventive controls for human food and animal food, set standards for produce safety, and require importers to have a program to verify that the food products they bring into the United States are produced in a manner consistent with applicable FDA food safety requirements.

FSMA was the first major legislative reform of FDA's food safety authorities in more than 70 years, even though FDA has increased the focus of its food safety efforts on prevention over the past several years. The proposed rule for preventive controls for food for animals can be found elsewhere in this issue of the **Federal Register**, and it establishes a docket so that the public can review the proposed rule and submit comments to FDA. This proposed rulemaking is one of several key proposals in furtherance of FSMA's food safety mandate.

The proposed rule would establish regulations regarding the manufacturing, processing, packing, or holding of animal food in two ways. First, it would create new current good manufacturing practice (CGMP) regulations that specifically address the manufacturing, processing, packing, and holding of animal food. Second, it would include new preventive control provisions intended to implement section 103 of FSMA for animal food. In general, with some exceptions the new preventive control provisions would apply to animal food facilities that are required to register with FDA under the FD&C Act. These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take appropriate corrective actions, and maintain records documenting these actions.

For information on the proposed rule for preventive controls for food for animals and related fact sheets, see FDA's FSMA Web page located at *www.fda.gov/FSMA.*

II. How To Participate in the Public Meetings

FDA is holding the public meetings on the proposed rule for preventive controls for food for animals to inform the public about the proposed rule and the rulemaking process, including how to submit comments, data, and other information to the rulemaking docket; to respond to questions about the proposed rule; and to provide an opportunity for interested persons to make oral presentations. Due to limited space and time, FDA encourages all persons who wish to attend the meetings to register in advance. There is no fee to register for the public meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request and to provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment and limited time available, FDA is allocating 3 minutes to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (i.e., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administration record (the docket) for the rulemaking. All relevant data and documentation should be submitted with the comments to Docket No. FDA–2011–N–0922. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number FDA–2011–N–0922. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Table 1 of this document provides information on participation in the public meetings:

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETINGS AND ON SUBMITTING COMMENTS TO THE RULEMAKING DOCKETS

	Date	Electronic address	Address	Other information
College Park, MD, Public meeting.	November 21, 2013, from 8:30 a.m. to 2:30 p.m.	This meeting will be available for public viewing via Adobe Connect at *https://collaboration.fda.gov/r4g7zwj0vea/* at the time of the meeting.	Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740.	Onsite registration from 8 a.m. to 8:30 a.m.
College Park, MD, Advance registration.	By November 19, 2013.	Individuals who wish to participate in person are asked to preregister at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm.*	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
College Park, MD, Request to make an oral presentation.	By November 14, 2013.	*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm* [2].	.....	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to *http://www.regulations.gov,* including any personal information provided.
College Park, MD, Request special accommodations due to a disability.	By November 14, 2013.	Aleta Sindelar, email: *aleta.sindelar@fda.hhs.gov.*	See **FOR FURTHER INFORMATION CONTACT**.	
College Park, MD, Submit electronic or written comments.	By February 26, 2014	Docket No. FDA 2011–N–0922.		
Chicago, IL, Public meeting.	November 25, 2013, from 8:30 a.m. to 2:30 p.m.	.....	Ralph Metcalfe Federal Building, 77 West Jackson Blvd., Chicago, IL 60604.	Onsite registration from 8 a.m. to 8:30 a.m.
Chicago, IL, Advance registration.	By November 21, 2013.	Individuals who wish to participate in person are asked to preregister at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm.*	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Chicago, IL, Request to make an oral presentation.	By November 18, 2013.	*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm* [2].	.....	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to *http://www.regulations.gov,* including any personal information provided.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETINGS AND ON SUBMITTING COMMENTS TO THE RULEMAKING DOCKETS—Continued

	Date	Electronic address	Address	Other information
Chicago, IL, Request special accommodations due to a disability.	By November 18, 2013.	Aleta Sindelar, email: *aleta.sindelar@fda.hhs.gov*.	See **FOR FURTHER INFORMATION CONTACT**.	
Chicago, IL, Submit electronic or written comments.	By February 26, 2014	Docket No. FDA 2011–N–0922.		
Sacramento, CA, Public meeting.	December 6, 2013, from 8:30 a.m. to 2:30 p.m.	This meeting will be available for public viewing via Adobe Connect *https://collaboration.fda.gov/dec_6_fda_fsma_public_meeting/*.	Stanford Room, 650 Capitol Mall, Sacramento, CA 95814.	Onsite registration from 8 a.m. to 8:30 a.m.
Sacramento, CA, Advance registration.	By December 4, 2013	Individuals who wish to participate in person are asked to preregister at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm*.	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Sacramento, CA, Request to make an oral presentation.	By November 29, 2013.	*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm* [2].	.....	Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to *http://www.regulations.gov,* including any personal information provided.
Sacramento, CA, Request special accommodations due to a disability.	By November 29, 2013.	Aleta Sindelar, email: *aleta.sindelar@fda.hhs.gov*.	See **FOR FURTHER INFORMATION CONTACT**.	
Sacramento, CA, Submit electronic or written comments.	By February 26, 2014	Docket No. FDA 2011–N–0922.		

[1] You may also register via email, mail, or FAX. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to: Aleta Sindelar, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rm. 133, Rockville, MD 20855, 240–276–9230, FAX: 240–276–9241, email: *aleta.sindelar@fda.hhs.gov*. Onsite registration will also be available.

[2] You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Aleta Sindelar, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rm. 133, Rockville, MD 20855, 240–276–9230, FAX: 240–276–9241, email: *aleta.sindelar@fda.hhs.gov.*

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the rulemaking and will be accessible to the public at *http://www.regulations.gov.* The transcript of the proceedings from the public meeting will become part of the administrative record for the rulemaking. Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov,* Docket No. FDA–2011–N–0922, and at FDA's FSMA Web site at: *http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be recording the meeting via adobe connect on November 21, 2013. Once the recording has been made 508 compliant, it will be accessible at FDA's FSMA Web site at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.*

Dated: October 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25125 Filed 10–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 507

[Docket No. FDA–2013–N–1043]

Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and requesting comment on, a document entitled ''Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft RA). The purpose of the draft RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk. FDA conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

DATES: Submit either electronic or written comments on the draft RA by February 26, 2014.

ADDRESSES: Submit electronic comments on the draft RA to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary J. Bartholomew, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8172.

SUPPLEMENTARY INFORMATION:

I. Background

On January 4, 2011, FSMA (Pub. L. 111–353) was signed into law. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to create a new section 418 with the same name. Section 418 of the FD&C Act (21 U.S.C. 350g) contains requirements applicable to food facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) and mandates Agency rulemaking. Section 418(a) of the FD&C Act is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food (including animal food) manufactured, processed, packed, or held by the facility; identify and implement preventive controls; monitor the performance of those controls; and maintain records of the monitoring. Section 418(a) of the FD&C Act specifies that the purpose of the preventive controls is to prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 (21 U.S.C. 342). Section 418(b) of the FD&C Act requires that the hazard analysis identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility. Sections 418(c) to (i) of the FD&C Act contain additional requirements applicable to facilities, including requirements for preventive controls (section 418(c)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule (the proposed preventive controls rule for food for animals) to implement section 418 of the FD&C Act. FDA is using the results of the draft RA to propose to exempt animal food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/animal food combinations from the requirements of the FD&C Act for hazard analysis and risk-based preventive controls.

Section 103(c) of FSMA requires rulemaking in two areas: (1) Clarification of the activities that are included as part of the definition of the term ''facility'' under section 415 of the FD&C Act (Registration of Food Facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 (21 U.S.C. 350j) (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report) of the FD&C Act for certain facilities as FDA deems appropriate. Section 415 of the FD&C Act directs FDA to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for human or animal consumption in the United States be registered with FDA. The registration requirement in section 415 of the FD&C Act does not apply to farms. Our regulations that implement section 415 and require food facilities to register with FDA are established in 21 CFR part 1, subpart H (Registration of Food Facilities).

Section 103(c)(1)(C) of FSMA directs the Secretary of Health and Human Services (the Secretary) to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover: (1) Specific types of on-farm packing or holding of animal food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific animal foods and (2) specific on-farm manufacturing and processing activities as such activities relate to specific animal foods that are not consumed on that farm or on another farm under common ownership.

Section 103(c)(1)(D)(i) of FSMA requires that the Secretary consider the results of the science-based risk analysis and exempt certain facilities from the requirements in section 418 of the FD&C Act (including requirements for hazard analysis and preventive controls) and the mandatory inspection frequency in section 421 of the FD&C Act, or modify the requirements in sections 418 or 421 of the FD&C Act, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific animal foods the Secretary determines to be low risk. Section 103(c)(1)(D)(ii) of FSMA provides, in relevant part, that the exemptions or modifications described in section 103(c)(1)(D)(i) shall apply only to small businesses and very small businesses, as defined in the regulation issued under section 418(n) of the FD&C Act.

II. Qualitative Risk Assessment

As explained in the draft RA, we conducted the qualitative risk assessment to identify activity/animal food combinations that would be considered low risk (Ref. 1). We focused on activity/animal food combinations that we identified as being conducted on farms, but we did not consider activity/animal food combinations that would be solely within the farm definition (such as growing grains) and, thus, are not relevant to the requirements of section 103 of FSMA. We considered the risk of activity/animal food combinations rather than separately considering the risk of

specific animal food categories because doing so better enabled us to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on animal food on a farm warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act. In the remainder of this document, we use the term ''farm mixed-type facility'' to refer to an establishment that grows and harvests crops or raises animals and may conduct other activities applicable to farms and to animal food facilities co-located on farms.

In the draft RA, we describe the approach applied to define a low-risk activity and low-risk activity/animal food combinations to determine activities on animal food that are out of scope of the draft RA, and to evaluate hazards associated with activity/animal food combinations within the scope of the draft RA (Ref. 1). We followed the risk assessment framework of the Codex Alimentarius Commission (Ref. 2), which involves hazard identification, hazard characterization, exposure assessment, and risk characterization.

The draft RA addresses nine specific questions:

Question 1: What are the animal foods that would be manufactured, processed, packed, or held by a farm mixed-type facility?

Question 2: What are the activities that might be conducted by farm mixed-type facilities on those animal foods?

Question 3: What are the hazards reasonably likely to occur in those animal foods?

Question 4: For the purpose of determining whether an activity/animal food combination is low risk, which hazards should be considered to have a reasonable probability of causing serious adverse health consequences or death to humans or animals?

Question 5: For the purpose of determining whether an activity/animal food combination is low risk, what animal foods have inherent controls that significantly minimize or prevent a biological hazard that is reasonably likely to occur in these animal foods and that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

Question 6: What interventions significantly minimize or prevent a hazard that is reasonably likely to occur in these animal foods and that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

Question 7: Which of these activities are reasonably likely to introduce, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals and what are these hazards?

Question 8: Which of these activities are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals from consumption of these animal foods?

Question 9: Which activity/animal food combinations are low risk, i.e., what on-farm activity/animal food combinations are not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals or serve as preventive controls (interventions) to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

As discussed in the draft RA, a specific activity may have a different classification within the classes of manufacturing, processing, packing, and holding (with consequences for what regulations apply to the activity) based on whether the animal food being operated upon is a raw agricultural commodity (RAC) or a processed animal food and whether a RAC was grown or raised on the farm performing the activity or a farm under the same ownership (Ref. 1). In the draft RA, we first characterize the risk of activity/animal food combinations without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/animal food combinations themselves. We then add that regulatory overlay and characterize the risk of activity/animal food combinations in three regulatory groups shaped by the applicable regulatory factors and the resulting activity classifications:

- Regulatory Group Type 1: Low-risk packing and holding activities that might be conducted on a farm on animal food not grown, raised, or consumed on that farm or another farm under the same ownership;
- Regulatory Group Type 2: Low-risk manufacturing and processing activities that might be conducted on a farm on the farm's own RACs for distribution into commerce; and
- Regulatory Group Type 3: Low-risk manufacturing and processing activities that might be conducted on a farm on animal food other than the farm's own RACs for distribution into commerce.

We are seeking comments that can be used to improve:

- The approach used;
- The assumptions made;
- The data used; and
- The transparency of the draft RA.

Specifically we request comment on:

- The definitions of ''low-risk activity'' and ''low-risk activity/animal food combination'';
- The animal food types and activity/animal food combinations that we are considering outside the scope of the draft RA and those we are considering within the scope of the draft RA;
- The approach to characterizing the risk of an activity/animal food combination;
- The questions addressed by the draft RA; and
- The answers to those questions.

We submitted a draft RA to a group of scientific experts external to FDA for peer review and revised the draft RA, as appropriate, considering the experts' comments. A report concerning the external peer review is available for public review, and can be accessed from our Web site (Ref. 3). We will consider public comments regarding the draft RA in preparing a final version of the RA.

III. Comments

Interested persons may submit either electronic comments regarding the draft RA to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

The draft RA is available electronically at *http://www.regulations.gov* and *http://www.fda.gov/downloads/Animal Veterinary/Products/AnimalFoodFeeds/UCM366906.pdf.*

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested person between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this references section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, ''Draft Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the

Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2012. Available at *http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf.*

2. Codex Alimentarius Commission, ''Codex Alimentarius Commission Procedural Manual, Twentieth Edition,'' 2011.

3. FDA, ''Peer Review Report. External Peer Review of the FDA/CVM Draft Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2013. Available at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*

Dated: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25124 Filed 10–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–112815–12]

RIN 1545–BK99

Mixed Straddles; Straddle-by-Straddle Identification Under Section 1092(b)(2)(A)(i)(I); Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing; correction.

SUMMARY: This document contains amendments to proposed regulations relating to guidance for taxpayers electing to establish a mixed straddle using straddle-by-straddle identification. These amendments include a change to the applicability date of the proposed regulations pursuant to which the proposed regulations would apply to transactions established after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. The amendments to the proposed regulations will affect taxpayers who elect to establish a mixed straddle using straddle-by-straddle identification.

DATES: Comments must be received by October 31, 2013. Request to speak and outlines of topics to be discussed at the public hearing scheduled for December 4, 2013, at 10 a.m. must be received by October 31, 2013.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–112815–12), room 5205, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–112815–12), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–112815–12).

FOR FURTHER INFORMATION CONTACT: Pamela Lew or Robert B. Williams at (202) 622–3950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The proposed regulations that are the subject of these amendments are under section 1092 of the Internal Revenue Code (Code). The text of temporary regulations (TD 9627), published in the **Federal Register** on Friday, August 2, 2013 (78 FR 46807), serves as the text of the proposed regulations. The proposed regulations (REG–112815–12) were published in the **Federal Register** on Friday, August 2, 2013 (78 FR 46854). The proposed regulations were proposed to apply to all identified mixed straddles established after the date of filing, August 1, 2013.

Need for amendments

The Treasury Department and the IRS received comments raising concerns about the immediate applicability date of the temporary regulations. In response to those comments, the Treasury Department and the IRS are amending the temporary regulations to limit the application of the identified mixed straddle transaction rules in § 1.1092(b)-6T to section 1092(b)(2) identified mixed straddles established after the date of publication of the Treasury decision adopting the rules as final regulations in the **Federal Register**. The text of the temporary regulations, as amended, continues to serve as the text of these proposed regulations, and this document amends the proposed regulations to conform to the changes to the temporary regulations. The Treasury Department and the IRS anticipate finalizing the regulations no later than the end of the current Priority Guidance Plan year on June 30, 2014, and will as part of that process consider all comments received.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *.

Section 1.1092(b)–6 also issued under 26 U.S.C. 1092(b)(1).

Section 1.1092(b)–6 also issued under 26 U.S.C. 1092(b)(2).* * *

■ **Par. 2.** Section 1.1092(b)–6 is amended by revising the heading to read as follows:

§ 1.1092(b)–6 Mixed straddles; accrued gain and loss associated with a position that becomes part of a section 1092(b)(2) identified mixed straddle.

* * * * *

Martin Franks,

Branch Chief, Publications & Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure & Administration).

[FR Doc. 2013–25360 Filed 10–25–13; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR part 52

[EPA–R09–OAR–2013–0663; FRL–9902–10–Region9]

Partial Approval and Disapproval of Air Quality State Implementation Plans; Nevada; Infrastructure Requirements for Lead (Pb)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to partially approve and partially disapprove State Implementation Plan (SIP) revisions submitted by the State of Nevada on October 12, 2011, July 23, 2012, and August 30, 2012, pursuant to the requirements of the Clean Air Act (CAA or the Act) for the implementation, maintenance, and enforcement of the 2008 Lead (Pb) national ambient air quality standards (NAAQS). We refer to such SIP revisions as ''infrastructure'' SIPs because they are intended to address basic structural SIP requirements for new or revised NAAQS including, but not limited to, legal authority, regulatory structure, resources, permit programs, monitoring, and modeling necessary to assure attainment and maintenance of the standards. We are taking comments on

this proposal and plan to follow with a final action.

DATES: Written comments must be received on or before November 29, 2013.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R09–OAR–2013–0663, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: mays.rory@epa.gov.*
3. *Fax:* 415–947–3579.
4. *Mail or deliver:* Rory Mays (AIR–2), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901. Deliveries are only accepted during the Regional Office's normal hours of operation.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or email. *http://www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Rory Mays, Air Planning Office (AIR–2), U.S. Environmental Protection Agency, Region IX, (415) 972–3227, *mays.rory@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' and ''our'' refer to EPA.

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I. Background

A. Statutory Framework and Scope of Infrastructure SIPs

Section 110(a)(1) of the CAA requires each state to submit to EPA, within three years after the promulgation of a primary or secondary NAAQS or any revision thereof, a SIP that provides for the ''implementation, maintenance, and enforcement'' of such NAAQS. Many of the section 110(a)(2) SIP elements relate to the general information and authorities that constitute the ''infrastructure'' of a state's air quality management program and SIP submittals that address these requirements are referred to as ''infrastructure SIPs.'' These infrastructure SIP elements are as follows:

- Section 110(a)(2)(A): Emission limits and other control measures.
- Section 110(a)(2)(B): Ambient air quality monitoring/data system.
- Section 110(a)(2)(C): Program for enforcement of control measures and regulation of new and modified stationary sources.
- Section 110(a)(2)(D)(i): Interstate pollution transport.
- Section 110(a)(2)(D)(ii): Interstate and international pollution abatement.
- Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local and regional government agencies.
- Section 110(a)(2)(F): Stationary source monitoring and reporting.
- Section 110(a)(2)(G): Emergency episodes.
- Section 110(a)(2)(H): SIP revisions.
- Section 110(a)(2)(J): Consultation with government officials, public notification, and prevention of significant deterioration (PSD) and visibility protection.
- Section 110(a)(2)(K): Air quality modeling and submission of modeling data.
- Section 110(a)(2)(L): Permitting fees.
- Section 110(a)(2)(M): Consultation/participation by affected local entities.

Two elements identified in section 110(a)(2) are not governed by the three-year submission deadline of section 110(a)(1) and are therefore not addressed in this action. These elements relate to part D of title I of the CAA, and submissions to satisfy them are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the same time nonattainment area plan requirements are due under section 172. The two elements are: (i) section 110(a)(2)(C) to the extent it refers to permit programs required under part D [nonattainment new source review (NSR)], and (ii) section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure elements related to the nonattainment NSR portion of section 110(a)(2)(C) or related to 110(a)(2)(I).

In addition, this rulemaking does not address three substantive issues that are not integral to acting on a state's infrastructure SIP submission: (i) Existing provisions related to excess emissions during periods of start-up, shutdown, or malfunction (SSM) at sources, that may be contrary to the CAA and EPA's policies addressing such excess emissions; (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that purport to permit revisions to SIP approved emissions limits with limited public process or without requiring further approval by EPA, that may be contrary to the CAA (''director's discretion''); and, (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule.'' [1]

Instead, EPA has indicated that it has other authority to address any such existing SIP defects in other rulemakings, as appropriate. A detailed rationale for why these issues are not part of the scope of infrastructure SIP rulemakings can be found in EPA's August 3, 2012 proposed rule entitled ''Partial Approval and Disapproval of Air Quality Implementation Plans; Nevada; Infrastructure Requirements for Ozone and Fine Particulate Matter'' in section I.C. (''Scope of the Infrastructure SIP Evaluation'').[2]

B. Regulatory Background

On October 15, 2008, EPA issued a revised NAAQS for Pb.[3] This action

[1] 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) (NSR Reform).

[2] 77 FR 46361 at 46362 thru 46365.

[3] 73 FR 66964. The final rule was signed on October 15, 2008 and published in the **Federal Register** on November 12, 2008. The 1978 Pb

Continued

triggered a requirement for states to submit an infrastructure SIP to address the applicable requirements of section 110(a)(2) by October 15, 2011. EPA issued guidance in 2011 for such infrastructure SIPs entitled ''Guidance on Section 110 Infrastructure SIPs for the 2008 Pb NAAQS'' (''EPA's 2011 Pb Guidance'').[4]

II. The State's Submittals

The Nevada Division of Environmental Protection (NDEP) submitted ''Nevada's Clean Air Act § 110(a)(1) and (2) State Implementation Plan for the 2008 Pb NAAQS'' on October 12, 2011,[5] which included the NDEP and Washoe County Air Quality Management Division (AQMD) portions of the state's Pb infrastructure SIP submittal; and submitted the ''Clark County Lead Infrastructure State Implementation Plan'' on July 23, 2012,[6] which is the Clark County Department of Air Quality (DAQ) portion of the state's Pb infrastructure SIP submittal. On August 30, 2012, NDEP submitted the ''Revisions to Nevada's Clean Air Act § 110(a)(2) State Implementation Plan Submittals,''[7] which amended several of the state's infrastructure SIP submittals, including the October 12, 2011 submittal for the 2008 Pb NAAQS.

These submittals included cover letters from the NDEP Administrator to the Region IX Regional Administrator and tables for each air quality management jurisdiction in Nevada (i.e., NDEP, Clark County, and Washoe County Health District) that list and discuss how state and local provisions address the elements of CAA section 110(a)(2). Each submittal also includes attachments that, among other things, compile the State and local rules and statutes that are currently approved into the Nevada SIP or that apply locally and are supportive of Nevada meeting the infrastructure SIP requirements, and provide evidence of public notice and an opportunity for public comment or hearing prior to adoption and submittal of the SIP revisions. We find that these submittals meet the procedural requirements for public participation under CAA section 110(a)(2) and 40 CFR 51.102.

We are proposing to act on all three submittals since they collectively address the infrastructure SIP requirements for the 2008 Pb NAAQS. We refer to them collectively herein as ''Nevada's Pb Infrastructure Submittal.''

III. EPA's Evaluation and Proposed Action

EPA has evaluated Nevada's Pb Infrastructure Submittal and the existing provisions of the Nevada SIP for compliance with the CAA section 110(a) requirements for the 2008 Pb NAAQS. Our Pb Infrastructure SIP Technical Support Document (''Pb TSD'') contains more detailed evaluations and is available in the public docket for this rulemaking, which may be accessed online at *http://www.regulations.gov*, docket number EPA–R09–OAR–2013–0663. We also rely on our technical support document (TSD) for the conflict of interest requirements of CAA sections 110(a)(2)(E)(ii) and 128 (''Section 128 TSD''), which was prepared for our 2012 rulemaking on Nevada's infrastructure SIPs for the 1997 ozone, 1997 fine particulate ($PM_{2.5}$), and 2006 $PM_{2.5}$ NAAQS.[8] That Section 128 TSD is also included in the public docket for today's rulemaking.

A. Proposed Approvals

Based upon our evaluation as presented in the TSDs, EPA proposes to approve Nevada's Pb Infrastructure Submittal with respect to the following infrastructure SIP requirements:

- Section 110(a)(2)(A): Emission limits and other control measures.
- Section 110(a)(2)(B): Ambient air quality monitoring/data system.
- Section 110(a)(2)(C) (in part): Program for enforcement of control measures and regulation of new and modified stationary sources.
- Section 110(a)(2)(D)(i) (in part): Interstate pollution transport.
- Section 110(a)(2)(D)(ii) (in part): Interstate pollution abatement and international air pollution.
- Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local and regional government agencies.
- Section 110(a)(2)(F) (in part): Stationary source monitoring and reporting.
- Section 110(a)(2)(G): Emergency episodes.
- Section 110(a)(2)(H): SIP revisions.
- Section 110(a)(2)(J) (in part): Consultation with government officials, public notification, and prevention of significant deterioration (PSD) and visibility protection.
- Section 110(a)(2)(K): Air quality modeling and submission of modeling data.
- Section 110(a)(2)(L): Permitting fees.
- Section 110(a)(2)(M): Consultation/participation by affected local entities.

B. Proposed Disapprovals

EPA proposes to disapprove Nevada's Pb Infrastructure Submittal with respect to the following infrastructure SIP requirements (details of the partial disapprovals are presented after this list):

- Section 110(a)(2)(C) (in part): Program for enforcement of control measures and regulation of new and modified stationary sources.
- Section 110(a)(2)(D)(i) (in part): Interstate pollution transport.
- Section 110(a)(2)(D)(ii) (in part): Interstate pollution abatement and international air pollution.
- Section 110(a)(2)(F) (in part): Stationary source monitoring and reporting.
- Section 110(a)(2)(J) (in part): Consultation with government officials, public notification, and prevention of significant deterioration (PSD) and visibility protection.

As explained more fully in our Pb TSD, we are proposing to disapprove the NDEP and Washoe County portions of Nevada's Pb Infrastructure Submittal with respect to the PSD-related requirements of sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(D)(ii), and 110(a)(2)(J) because the Nevada SIP does not fully satisfy the statutory and regulatory requirements for PSD permit programs under part C, title I of the Act. Both NDEP and Washoe County AQMD currently implement the Federal PSD program in 40 CFR 52.21 for all regulated new source review (NSR) pollutants, pursuant to delegation agreements with EPA. See 40 CFR 52.1485.[9] Accordingly, although the Nevada SIP remains deficient with respect to PSD requirements in both the NDEP and Washoe County portions of the SIP, these deficiencies are

standard (1.5 μg/m3 as a quarterly average) was modified to a rolling 3-month average not to exceed 0.15 μg/m3. EPA also revised the secondary NAAQS to 0.15 μg/m3 and made it identical to the revised primary standard.

[4] *See* Memorandum from Stephen D. Page, Director, Office of Air Quality Planning and Standards, to Regional Air Division Directors, Regions 1–10 (October 14, 2011).

[5] *See* letter dated October 12, 2011 from Colleen Cripps, Administrator, NDEP, to Jared Blumenfeld, Regional Administrator, EPA Region 9.

[6] *See* letter dated July 23, 2012 from Colleen Cripps, Administrator, NDEP, to Jared Blumenfeld, Regional Administrator, EPA Region 9.

[7] *See* letter dated August 30, 2012 from Colleen Cripps, Administrator, NDEP, to Jared Blumenfeld, Regional Administrator, EPA Region 9.

[8] 77 FR 64737, October 23, 2012.

[9] EPA fully delegated the implementation of the federal PSD programs to NDEP on October 19, 2004 (''Agreement for Delegation of the Federal Prevention of Significant Deterioration (PSD) Program by the United States Environmental Protection Agency, Region 9 to the Nevada Division of Environmental Protection''), as updated on September 15, 2011 and November 7, 2012, and to Washoe County on March 13, 2008 (''Agreement for Delegation of the Federal Prevention of Significant Deterioration (PSD) Program by the United States Environmental Protection Agency, Region 9 to the Washoe County District Health Department'').

adequately addressed in both areas by the federal PSD program.

We are proposing to disapprove the Clark County portion of Nevada's Pb Infrastructure Submittal with respect to the PSD-related requirements of CAA sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), and 110(a)(2)(J) because Clark County's SIP-approved PSD permit program does not contain provisions that satisfy the statutory and regulatory requirements concerning condensable particulate matter (PM) and $PM_{2.5}$ increments under part C, title I of the Act and in 40 CFR 51.166.[10] We address these PSD requirements as part of this proposal on Nevada's Pb Infrastructure Submittal for the 2008 Pb NAAQS because section 110(a)(2) of the Act requires that each SIP contain a comprehensive PSD permitting program that addresses all regulated NSR pollutants, including greenhouse gases (GHG).[11] As explained in more detail below and in our Pb TSD, our proposed disapproval of the Clark County portion of Nevada's Pb Infrastructure Submittal based on these PSD program deficiencies would, if finalized, trigger a FIP obligation with respect to the requirements concerning $PM_{2.5}$ increments in Clark County but would not trigger a FIP obligation with respect to the requirements concerning condensable PM, as a FIP clock to address this requirement has already been triggered by EPA's 2012 action on the NSR rules submitted for sources under Clark County's jurisdiction.[12]

Our proposed disapprovals of the NDEP and Clark County portions of the Nevada Pb Infrastructure Submittal with respect to section 110(a)(2)(C) also stem from unique circumstances regarding NDEP and Clark County's permit programs for the regulation of new and modified minor sources and minor modifications of major sources, herein referred to as ''minor NSR.'' Within this infrastructure SIP proposal, we are not proposing to approve or disapprove existing minor NSR regulations. However, in 2012, EPA finalized rulemakings on Nevada's submittals addressing minor NSR for sources under NDEP and Clark County DAQ jurisdiction, which included limited disapprovals.[13] Upon review of those actions, we found that the NDEP and Clark County minor NSR programs lack provisions to address the 2008 Pb NAAQS. Accordingly, we cannot rely on NDEP and Clark County's existing minor NSR programs to ensure that new and modified sources not captured by the major NSR permitting programs do not interfere with attainment and maintenance of the 2008 Pb NAAQS. Therefore, with respect to section 110(a)(2)(C), we propose to find that the Nevada SIP does not meet the minor NSR program requirements for sources under NDEP and Clark County jurisdiction for the 2008 Pb NAAQS.

As described in our Pb TSD, the resulting FIP obligations for these minor NSR program deficiencies have already been triggered by EPA's 2012 actions on the NSR rules submitted for sources under NDEP[14] and Clark County jurisdiction.[15] As such, our proposed disapproval of Nevada's Pb Infrastructure Submittal with respect to the minor NSR requirement in CAA section 110(a)(2)(C) for the NDEP and Clark County portions of the Nevada SIP would not trigger a new FIP obligation because a FIP obligation already exists for the same identified SIP deficiencies.

For the requirement of section 110(a)(2)(D)(i)(II) (regarding interference with other states' required measures to prevent significant deterioration of air quality), we propose to disapprove Nevada's Pb Infrastructure SIP for the reasons discussed above and in our Pb TSD in connection with the PSD-related requirements of CAA section 110(a)(2)(C).

With respect to the requirement in CAA section 110(a)(2)(D)(ii) concerning compliance with section 126 requirements regarding interstate pollution abatement, EPA proposes to disapprove the NDEP and Washoe County portions of Nevada's Pb Infrastructure Submittal, for the reasons discussed above and in our Pb TSD in connection with the PSD-related requirements of CAA section 110(a)(2)(C).

For Section 110(a)(2)(F), we propose to disapprove the Clark County portion of Nevada's Pb Infrastructure Submittal with respect to subsection 110(a)(2)(F)(iii) because Clark County has repealed its regulation, Section 24, which formerly addressed the correlation requirement of this subsection, without submitting a SIP revision to replace it.

As discussed in our Pb TSD, the resulting FIP obligation for this stationary source correlation requirement for the Clark County portion of the Nevada SIP has already been triggered by EPA's 2012 action on Nevada's infrastructure SIP submittals for the 1997 ozone, 1997 $PM_{2.5}$, and 2006 $PM_{2.5}$ NAAQS.[16] As such, we propose that this disapproval for section 110(a)(2)(F)(iii) for the Clark County portion of the Nevada SIP for the 2008 Pb NAAQS does not trigger a new FIP obligation because a FIP obligation already exists for the same identified SIP deficiency.

For the PSD related requirements of Section 110(a)(2)(J) we propose to disapprove Nevada's Pb Infrastructure Submittal for the reasons discussed above and in our Pb TSD in connection with the PSD-related requirements of section 110(a)(2)(C).

EPA takes very seriously a proposal to disapprove a state plan, as we believe that it is preferable, and preferred in the provisions of the Clean Air Act, that these requirements be implemented through state plans. A state plan need not contain exactly the same provisions that EPA might require, but EPA must be able to find that the state plan is consistent with the requirements of the Act. Further, EPA's oversight role requires that it assure consistent implementation of Clean Air Act requirements by states across the country, even while acknowledging that individual decisions from source to source or state to state may not have identical outcomes. EPA believes these proposed disapprovals are the only path that is consistent with the Act at this time.

C. Consequences of Proposed Disapprovals

Under section 179(a) of the CAA, final disapproval of a submittal that addresses a requirement of part D, title I of the CAA (CAA sections 171–193) or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP Call) starts a sanctions clock. Nevada's Pb Infrastructure Submittal was not submitted to meet either of these

[10] Requirements for condensable PM were promulgated in EPA's NSR/PSD implementation rule for the 1997 $PM_{2.5}$ NAAQS. *See* 73 FR 28321, May 16, 2008; codified at 40 CFR 51.166(b)(49). Requirements for PSD increments for $PM_{2.5}$ were promulgated in EPA's PSD implementation rule for the 1997 $PM_{2.5}$ and 2006 $PM_{2.5}$ NAAQS. *See* 75 FR 64864, October 10, 2010; codified at 40 CFR 51.166(c).

[11] The concept of a ''comprehensive'' PSD program (i.e., covering the PSD requirements for all regulated NSR pollutants, including GHGs) has been discussed in numerous infrastructure SIP rulemakings. *See,* e.g., EPA's final rule on Nevada's infrastructure SIP submittals for the 1997 ozone, 1997 $PM_{2.5}$, and 2006 $PM_{2.5}$ NAAQS. 77 FR 64737 at 64738–64739, October 23, 2012. This concept is also discussed in EPA's 2011 Pb Guidance, page 6.

[12] 77 FR 64039, October 18, 2012.

[13] Regarding NDEP's minor NSR permit program, *see* our proposal (77 FR 38557 at 38564, June 28, 2012) and final rules (77 FR 59321 at 59325–59326, September 27, 2012). Regarding Clark County's permit program, *see* our proposed (77 FR 43206, July 24, 2012) and final rules (77 FR 64309, October 18, 2012). These final rules and their context specific to the 2008 Pb NAAQS are discussed further in our Pb TSD.

[14] 77 FR 59321, September 27, 2012.

[15] 77 FR 64039, October 18, 2012.

[16] 77 FR 64737, October 23, 2012.

requirements. Therefore, any action we take to finalize the described partial disapprovals will not trigger mandatory sanctions under CAA section 179.

In addition, CAA section 110(c)(1) provides that EPA must promulgate a FIP within two years after finding that a State has failed to make a required submission or disapproving a State implementation plan submission in whole or in part, unless EPA approves a SIP revision correcting the deficiencies within that two-year period. As discussed in section III.B of this proposed rule and in our Pb TSD, we are proposing several partial disapprovals. With one exception, however, these disapprovals would not result in new FIP obligations, either because EPA has already promulgated a FIP to address the identified deficiency or because a FIP clock has been triggered by EPA's disapproval of a prior SIP submission based on the same identified deficiency. The provisions for which our proposed disapproval, if finalized, would not result in a new FIP obligation include:

- PSD-related requirements in sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(D)(ii), and 110(a)(2)(J): For NDEP and Washoe County, EPA has already promulgated the federal PSD program (see 40 CFR 52.1485);
- PSD-related requirements in sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), and 110(a)(2)(J): For Clark County, EPA's October 18, 2012 final action on Clark County's PSD regulations triggered a November 19, 2014 deadline for EPA to promulgate a FIP addressing this requirement (77 FR 64039);
- Minor NSR requirement in section 110(a)(2)(C): EPA's September 27, 2012 final action on NDEP's minor NSR regulations (77 FR 59321) and October 18, 2012 final action on Clark County's minor NSR regulations (77 FR 64039) triggered deadlines of October 29, 2014 and November 19, 2014, respectively, for EPA to promulgate FIPs addressing the identified deficiencies;
- Section 110(a)(2)(F)(iii): For Clark County, EPA's October 23, 2012 final action on Nevada's Infrastructure SIP submittals for the 1997 ozone, 1997 $PM_{2.5}$, and 2006 $PM_{2.5}$ NAAQS (77 FR 64737) triggered a November 23, 2014 deadline for EPA to promulgate a FIP addressing the requirement for correlation of stationary source emissions with emission limits.

The one disapproval that would trigger a new FIP clock concerns the requirement under sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) and 110(a)(2)(J) regarding PSD increments for $PM_{2.5}$ in Clark County. EPA has not previously promulgated a FIP or triggered a FIP clock through disapproval of a prior SIP submission based on this deficiency. Thus, under CAA section 110(c)(1), our partial disapproval of the Clark County portion of Nevada's Pb Infrastructure Submittal based on this deficiency would, if finalized, require EPA to promulgate a FIP establishing $PM_{2.5}$ increments for Clark County within two years after the effective date of our final rule, unless the State submits and EPA approves a SIP revision that corrects this deficiency prior to the expiration of this two-year period.

We anticipate that NDEP will submit SIP revisions that adequately address the deficiencies identified in EPA's 2012 actions on NDEP's minor NSR program, Clark County's permit program (i.e., both PSD and minor NSR), Nevada's infrastructure SIPs for the 1997 ozone, 1997 $PM_{2.5}$, and 2006 $PM_{2.5}$ NAAQS, and today's proposed action on Nevada's Pb Infrastructure Submittal prior to expiration of the 2-year FIP deadline triggered by each of these actions. We further anticipate that EPA approval of such revisions would also serve to adequately address the partial disapprovals of the Nevada Pb Infrastructure SIP where no FIP is currently in place (i.e., the disapprovals proposed herein, except for those tied to the federal PSD programs for sources under NDEP and Washoe County Health District's jurisdiction). We stand ready to work with the State of Nevada to develop such SIP revisions.

IV. Statutory and Executive Order Reviews

Executive Order 12866, Regulatory Planning and Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq, because this proposed partial approval and partial disapproval of SIP revisions under CAA section 110 will not in-and-of itself create any new information collection burdens but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP. Burden is defined at 5 CFR 1320.3(b).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule, we certify that this proposed action will not have a significant impact on a substantial number of small entities. This proposed rule does not impose any requirements or create impacts on small entities. This proposed partial SIP approval and partial SIP disapproval under CAA section 110 will not in-and-of itself create any new requirements but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP. Accordingly, it affords no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. Therefore, this action will not have a significant economic impact on a substantial number of small entities.

We continue to be interested in the potential impacts of this proposed rule on small entities and welcome comments on issues related to such impacts.

Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. EPA has determined that the proposed partial approval and partial disapproval action does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This action proposes to approve certain pre-existing requirements, and to disapprove certain other pre-existing requirements, under State or local law,

and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this proposed action.

Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

Executive Order 13175, Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP on which EPA is proposing action would not apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this proposed action.

Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This proposed action is not subject to Executive Order 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed partial approval and partial disapproval under CAA section 110 will not in-and-of itself create any new regulations but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP.

Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The EPA believes that this proposed action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the Clean Air Act.

Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this proposed rulemaking.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Particulate matter, Pb, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 et seq.

Dated: September 30, 2013.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2013–25586 Filed 10–28–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, 127, 403, 501, and 503

[EPA–HQ–OECA–2009–0274; FRL–9902–11–OECA]

Extension of Comment Period for the NPDES Electronic Reporting Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The U.S. Environmental Protection Agency is extending the comment period for the NPDES Electronic Reporting Rule, published on July 30, 2013. EPA is soliciting public comment on a new regulation that would require electronic reporting for current paper-based NPDES reports. This action will save time and resources for permittees, states, tribes, territories, and EPA while improving compliance and providing better protection of the Nation's waters. The proposed Clean Water Act regulation would require permittees and regulators to use existing, available information technology to electronically report information and data related to the NPDES permit program in lieu of filing written reports. In response to requests from stakeholders, this action extends the comment period for 45 days.

DATES: Comments on the preliminary plan published on July 30, 2013 (78 FR 46006), will be accepted through December 12, 2013. Comments provided electronically will be considered timely if they are submitted by 11:59 p.m. Eastern Time on December 12, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OECA–2009–0274 by one of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

• *Email: docket.oeca@epa.gov,* Attention Docket ID No. EPA–HQ–OECA–2009–0274.

• *Mail:* Send the original and three copies of your comments to: U.S. Environmental Protection Agency, EPA Docket Center, Enforcement and Compliance Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–OECA–2009–0274. In addition, if applicable, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.

• *Hand Deliver:* Deliver your comments to: EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC, 20004, Attention Docket ID No. EPA–HQ–OECA–2009–0274. Such deliveries are only accepted during the EPA Docket Center's normal hours of operation and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OECA–2009–0274. EPA's policy is that all comments received by the deadline will be included in the public docket without charge, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it within the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment, and, if applicable, with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, please visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard-copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard-copy at the Enforcement and Compliance Docket in the EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC, 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Docket for the Office of Enforcement and Compliance Assurance (OECA) is (202) 566–1752. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and are subject to search. Visitors will be provided an EPA visitor's badge that must be visible at all times in the building and returned upon departure. The ''User Guide to the Docket for the NPDES Electronic Reporting Rule [DCN 0010]'' is document that provides easy to follow instructions on how to access documents through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information, please contact John Dombrowski, Director, Enforcement Targeting and Data Division, Office of Compliance (mail code 2222A), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC, 20460; telephone number: (202) 566–0742; email address: *dombrowski.john@epa.gov.*

SUPPLEMENTARY INFORMATION: On July 30, 2013 (78 FR 46006), EPA published the proposed NPDES Electronic Reporting Rule. This proposed rule describes EPA's approach to substitute electronic reporting for paper-based reports, which will over the long term save time and resources for permittees, states, tribes, territories, and EPA while improving compliance and better protecting the Nation's waters. The proposed rule would require permittees and regulators to use existing, available information technology to electronically report information and data related to the NPDES permit program in lieu of filing written reports.

The original comment deadline was October 28, 2013. Numerous stakeholders have requested an extension to the comment period in order to adequately understand and comment on the preliminary plan. This action extends the comment period for 45 days.

Dated: September 30, 2013.

Lisa Lund,

Director, Office of Compliance.

[FR Doc. 2013–25577 Filed 10–28–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 10

[NPS–WASO–NAGPRA–7724; PPWOCRADN0–PCU00RP14.R50000]

RIN 1024–AE00

Disposition of Unclaimed Human Remains and Other Cultural Items Discovered on Federal Lands After November 16, 1990

AGENCY: Office of the Secretary, Interior.

ACTION: Proposed rule.

SUMMARY: This rule proposes procedures for the disposition of unclaimed human remains, funerary objects, sacred objects, or objects of cultural patrimony discovered on Federal lands after November 16, 1990. It would implement section 3 (b) of the Native American Graves Protection and Repatriation Act of 1990.

DATES: Comments must be received by December 30, 2013.

ADDRESSES: You may submit comments, identified by the Regulation Identifier Number (RIN) 1024–AE00, by any of the following methods:

• Federal rulemaking portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

• Mail or hand delivery to: Dr. Sherry Hutt, Manager, National NAGPRA Program, National Park Service, 1201 Eye Street NW., (2253), Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Dr. Sherry Hutt, Manager, National NAGPRA Program, National Park Service, 1201 Eye Street NW., 8th floor, Washington, DC 20005; telephone (202) 354–1479; facsimile (202) 371–5197.

SUPPLEMENTARY INFORMATION:

Authority

The Native American Graves Protection and Repatriation Act of 1990 (NAGPRA, or the Act) requires the Secretary of the Interior to:

(1) Promulgate regulations for disposition of human remains, funerary objects, sacred objects, or objects of cultural patrimony (''cultural items'' under NAGPRA) not claimed under section 3(a) of the Act.

(2) Develop these regulations in consultation with the Review Committee established under the Act, Native American groups, representatives of museums and the scientific community pursuant to Section 3(b) of the Act.

To the extent that Federal agencies have possession of and responsibility to care for human remains, funerary objects, sacred objects, or objects of cultural patrimony, the authority in 36 CFR Part 79 under section 101(a)(7)(A) of the National Historic Preservation Act (16 U.S.C. 470a) applies. When we published the NAGPRA regulations on December 4, 1995 (60 FR 62134), we reserved section 10.7, where we are now proposing to locate this new rule.

Background

Consultation History

Consultation regarding 43 CFR 10.7 began in 2005. On three separate occasions, we (the National Native American Graves Protection and Repatriation Program) consulted with representatives of Indian tribes, Native Hawaiian organizations, museums, and scientific organizations. We also consulted with the Review Committee during its scheduled meetings in Albuquerque, NM (November 2005); Washington, DC (April 2007); Phoenix, AZ (October 2007); and again in Washington, DC (November 2010). Before the first three meetings with tribal representatives, museums, and scientific organizations, we published a Notice of Consultation in the **Federal Register** that provided meeting details, as well as a list of proposed questions for consideration by consultation participants. In addition, each notice outlined a process and deadline for submission of written comments.

Albuquerque, NM, November 2005

We published the proposed questions for the consultation at Albuquerque, NM on November 15–17, 2005 as part of the Notice of Consultation on October 7, 2005 (70 FR 58741). They were as follows:

(1) How should the regulations deal with the distinction between cultural items for which ownership or control has been ascertained under 43 CFR 10.6(a) but the identified lineal descendant, Indian tribe, or Native Hawaiian organization has not claimed the cultural items and cultural items for which ownership or control cannot be ascertained under 43 CFR 10.6(a)?

(2) How long may a cultural item removed from Federal land after November 16, 1990 remain in Federal agency possession before it is considered unclaimed?

(3) What are the appropriate dispositions for unclaimed cultural items?

(4) How should the regulations deal with the management, preservation, and use of unclaimed cultural items?

Over 100 people attended the consultation meetings. Oral and written comments and recommendations were provided from representatives of 18 Indian tribes and 7 museums and scientific organizations. The oral comments were transcribed and all comments retained.

Results of the comments and recommendations according to the four published questions were as follows:

(1) How should the regulations deal with the distinction between cultural items for which ownership or control has been ascertained under 43 CFR 10.6(a) but the identified lineal descendant, Indian tribe, or Native Hawaiian organization has not claimed the cultural items and cultural items for which ownership or control cannot be ascertained under 43 CFR 10.6(a)? This question elicited the greatest diversity of opinion.

- Some commenters acknowledged the distinction as posed. Cultural items in the first category would be subject to special conditions, such as restrictions on research, exhibition, conservation without the written permission of the appropriate lineal descendant or tribal official.
- Some commenters rejected the distinction, recommending that all cultural items must be treated with respect while in Federal control.
- Some commenters proposed alternative distinctions among cultural items for which ownership or control is ''inherent'' under 25 U.S.C. 3002(a)(1) and (a)(2)(B); cultural items that are claimable under 25 U.S.C. 3002(a)(2)(B) or (a)(2)(C); and cultural items that are not claimable under 25 U.S.C. 2002(a)(2)(B) or (a)(2)(C). Only cultural items in the second category would be subject to regulations regarding the disposition of unclaimed cultural items.
- Some commenters proposed another alternative distinction between human remains and funerary objects and sacred objects and objects of cultural patrimony.

As a general matter, participants emphasized that human remains and funerary objects would be subject to a common understanding of respect for the dead and the right to a proper burial.

(2) How long may a cultural item removed from Federal land after November 16, 1990, remain in Federal agency possession before it is considered unclaimed?

Most commenters recommended that Federal agencies should maintain cultural items removed from Federal land until a claim is made, although some proposed that unclaimed human remains and funerary objects should be reburied in a timely manner.

(3) What are the appropriate dispositions for unclaimed cultural items?

Most commenters recommended that unclaimed cultural items should be held indefinitely until claimed by a lineal descendant, Indian tribe, or Native Hawaiian organization, although some proposed that unclaimed human remains and funerary objects should be reburied in a timely manner.

(4) How should the regulations deal with the management, preservation, and use of unclaimed cultural items?

Commenters generally agreed that unclaimed cultural items should be managed, preserved, and used in accordance with provisions of the regulations at 36 CFR Part 79 governing federally owned and administered archeological collections.

Washington, DC, April 2007

We published the proposed questions for comment at the consultation meeting scheduled for Washington, DC, as part of the Notice of Consultation on April 11, 2007 (69 FR 18192). They were as follows:

(1) How should the regulations address distinctions between human remains, funerary objects, sacred objects, or objects of cultural patrimony that remain in Federal care and for which ownership or control is with a lineal descendant or an Indian tribe or Native Hawaiian organization on whose lands the cultural items were discovered; an Indian tribe or Native Hawaiian organization has stated a claim based on cultural affiliation, aboriginal land, or cultural relationship; a non-federally recognized Indian group has stated a claim based on relationship of shared group identity; and no claim has been made?

(2) Do current regulations regarding the curation of federally owned and administered archaeological collections at 36 CFR 79 adequately address

management, preservation, and use of human remains, funerary objects, sacred objects, or objects of cultural patrimony remaining in Federal care?

Oral and written comments and recommendations were provided from representatives of 16 Indian tribes and 5 museums and scientific organizations. The comments were as follows:

• Tribal representatives spoke to the general importance of treating all human remains and cultural objects with respect. Information about unclaimed remains or objects should be widely accessible by Native peoples and not limited to distribution only to recognized tribes.

• For many tribal people, ''unclaimed'' is a concept in law but without cultural meaning. Others may be willing to undertake repatriation on behalf of those tribes. Reinterment is paramount. If there are cases of unclaimed remains and items, the first critical question that should be answered is ''why?''

• The ability to respond with claims may be limited by scarce tribal resources. This does not diminish the importance of cultural beliefs about remains and objects. Often, the difficulty of assessing the significance of scientific knowledge relative to traditional knowledge derives from misunderstandings when either is not well understood.

• Tribal representatives stated there should be no time limits for consultation on disposition. This is especially important when healing is a critical aspect of repatriation. There should be early consultation among tribes and Federal agencies regarding appropriate treatments, repatriation procedures, and the potential for formal agreements. This should include archival care for records about Native Americans and considerations to ensure confidentiality and security for those records.

• Museum and scientific organization representatives spoke to the general importance of treating all human remains and cultural objects with dignity and respect. There was support for all of the procedures and types of information needed to establish the priorities of claimants. The paramount role of federally recognized tribes was supported.

• The regulations should include a definition of ''unclaimed.'' This is particularly important because sound curation methods should ensure that care is sensitive and effective until a substantiated claim and decision about disposition can be made. The Federal curation regulations at 36 CFR Part 79 are sufficient. They also are sufficiently flexible to allow consideration of a variety of sensitive treatments in consultation with tribes and Native Hawaiian organizations.

• Information about collections should be shared. One of the most important aspects of this is that claimants have the opportunity to have a broader understanding about curatorial procedures, the potential for cooperative relationships, and the availability of the widest range of disposition alternatives.

Phoenix, AZ, October 2007

We published the proposed questions for comment at the consultation meeting scheduled for Phoenix, AZ, as part of the Notice of Consultation on August 13, 2007 (72 FR 45213); they were the same questions as those in the prior notice.

The consultation meetings were attended by representatives of more than 13 Indian tribes and 5 museums and scientific organizations. Oral and written comments and recommendations were provided from representatives of 12 Indian tribes and 11 museum and scientific organizations.

Participants made general comments and recommendations as follows:

• For remains with lineal descendents on or off of tribal land it was stressed by tribal representatives that the care of these remains should be addressed in full consultation with the tribes. Further analysis should be addressed only with tribal consent. Tribes should have access to all burial records regardless of where they originate. One tribe recommended that when control is determined to be vested with a tribe, that tribe must determine proper and respectful disposition of remains, funerary objects, sacred objects or objects of cultural patrimony.

• For remains where there has been a claim based on cultural affiliation or aboriginal land consultation with the tribes must take place and analysis must take place only with tribal consent. Tribes should have access to all burial records regardless where they originate. Tribal representatives stressed that when cultural affiliation has been established, tribal representatives may designate a lead tribe to address consultation. It was stressed that it can be hard to understand ownership from a tribal perspective. While the concept of ownership can be hard for traditional tribal people to comprehend, museums and universities embrace the concept of ownership, making mutual understanding more difficult. Tribal representatives emphasized another major perspective about the difficulty of conducting research to determine cultural affiliation without economic and human resources.

• From the perspective of the tribal representatives, the treatment of unclaimed human remains must be done with the utmost respect. One scientific organization stated that there should be no statute of limitations on NAGPRA claims. Curation should continue in accordance with applicable law until a lineal descendent or group authorized by NAGPRA directs otherwise. All parties should be encouraged to communicate with applicable institutions regarding their rights and interests, especially to reduce the risk of other claimants with lesser rights obtaining repatriation due to lack of knowledge about the existence of higher priority claimants' rights.

• Tribal leaders noted that if the culturally affiliated tribe does not wish to repatriate the remains, funerary objects, objects of cultural patrimony, or sacred objects, they must be consulted on proper and respectful housing for the remains or objects.

• If a non-federally recognized Indian group states a claim based on a cultural connection, a determination about the extent of that connection with that group should be made. The remains must be housed in accordance to specifications determined through consultation with the culturally connected group, regardless of the Federal status of the tribe, until a decision regarding permanent disposition can be reached. Tribal representatives concurred that remains or objects should be repatriated to the lineal descendent or an Indian tribe or Native Hawaiian organization most closely connected for appropriate care and handling regardless of the Federal status of the tribe or group. If the culturally connected group does not wish to accept repatriation, they still should be consulted about proper and respectful housing.

• Tribes recognized that claims might not be made because potential claimant tribes do not have information or do not have resources necessary to receive remains or other collections. These facts do not diminish the cultural or spiritual beliefs associated with remains or objects, especially with regard to basic conditions of respect and dignity that should be accorded to human remains. There was discussion about the government-to-government relationship that must be maintained between Federal agencies and Indian tribes. Tribes noted that tribal sovereignty also was an issue that should be considered by institutions, universities, and states. They considered that the importance of traditional knowledge should be part of

effective consultation. Respect and dignity were described as including avoidance of:

○ Separation of human remains from associated funerary objects.

○ Public displays of human remains and funerary objects.

○ Unnecessary disturbance, handling or transport of human remains.

○ Archeological processing of human remains and funerary objects.

○ Physical modifications of human remains and associated funerary objects.

○ Housing together sacred objects and objects of cultural patrimony.

• Tribes were concerned about the extent to which the regulations for curation of federally owned and administered archeological collections at 36 CFR Part 79 adequately address the management, preservation, and use of human remains, funerary objects, sacred objects, or objects of cultural patrimony. One tribe recommended amendment of the curation regulations to reflect the fact that human remains cannot be ''owned.'' Others noted that the care aspects listed above should be incorporated into the curation regulations. Tribes discussed amendments on the section on ''uses of collections'' to include limitations on scientific or educational purposes, limitations on loans and access by tribes for religious or cultural purposes.

• Tribal representatives noted that, regardless of the provisions in the Federal statutes, working closely with the states to address state burial laws was important.

Summary of Consultation With the NAGPRA Review Committee

The meeting agendas were made public 30 days or more before each meeting, and notice of the date and place of each meeting was published in the **Federal Register** 30–180 days before the meetings in Albuquerque, NM, November 2005; Washington, DC, April 2007; Phoenix, AZ, October 2007; De Pere, WI, May 2008; Sarasota, FL, October 2009; and Washington, DC, November 2010. Review Committee suggestions were as follows:

• There should be ways to provide technical assistance through the National NAGPRA Program for making determinations involving aboriginal lands, for accessing reference materials, and for using databases.

• Potential claimants should be fully informed, and should be consulted when no claims are made and alternative dispositions are considered. Until determinations are made, collections should remain with Federal agencies.

• Sensitivity toward traditional cultural practices, respect, and dignity regarding treatment of human remains and associated funerary objects was important.

• Reinterment was acknowledged as an important option.

• New categories for unclaimed remains should be avoided, especially given the potential for new information that may be developed which would help in any determinations about disposition.

• There is a need for a database of unclaimed remains and objects.

• Human remains and funerary objects should remain separate from other cultural objects and should be subject to special care and handling in consultation with priority claimants.

• Study or documentation of the unclaimed human remains and cultural items should proceed only with consent of the priority claimants or after consultation with the culturally affiliated or culturally related tribes. Baseline documentation, however, such as number of individuals, age, sex, should be recorded.

• No time limit should be imposed for responding to potential claimants, and human remains and cultural items should remain in Federal care until such time as a claimant comes forward and disposition is determined.

• To facilitate claims, Federal agencies should hold consultations with lineal descendants, tribes or Native Hawaiian organizations on whose tribal lands such objects or remains were discovered, and other tribal entities that may have a cultural affiliation or relationship with the human remains or cultural objects.

• Federal agencies considering treatments should be guided by the regulations at 36 CFR Part 79.

• There is a need for a definition of ''unclaimed.'' It is important to shield unclaimed cultural items from educational uses.

• It is important to allow access for traditional cultural practices.

Section-by-Section Analysis

§ 10.2 Definitions

A definition of ''unclaimed cultural items'' (that is, human remains, funerary objects, sacred objects, or objects of cultural patrimony) clarifies that this is a category subject to the provisions of the NAGPRA and of regulations to determine priority of ownership and control. Those procedures are the subject of 43 CFR 10.3 through 10.6. Once priority of ownership has been determined, some priority claimants may choose not to exercise their right. Alternatively, no potential claimants may have been identified. These two conditions constitute the category of unclaimed cultural items. The procedures defined in the new § 10.7 provide guidance on how to proceed.

§ 10.7 Disposition of Unclaimed Cultural Items

A general statement in paragraph 10.7(a) about the purposes of the new section clarifies the applicable statutory authority, how the new section is to be applied, and what procedures in the regulations must be completed. The results of work done previously, particularly with regard to consultation and appropriate determination of disposition, have continued applicability, and the new section imposes no new requirements for consultation and documentation.

The rule is limited to Federal lands, as NAGPRA's provision on new discoveries on tribal lands puts the tribal land owner in control of cultural items above all claimants except lineal descendants.

The provisions in paragraph 10.7(b) provide guidance about disposition. They:

• Clarify which regulatory procedures must be completed before any potential implementation of § 10.7;

• Provide options for disposition, according to the new definition of ''unclaimed cultural items'' in paragraph 10.2(h), including considerations for reinterment;

• Require public notification before disposition;

• Establish Federal curation regulations at 36 CFR Part 79 as standards for care and management;

• Encourage consideration of care with specific sensitivity to tribal and Native Hawaiian traditions;

• Provide flexibility to house human remains and associated funerary objects separately;

• Require appropriate information about remains and objects to be made publicly accessible via a nationwide database to be maintained by the National NAGPRA Program;

• Require Federal agencies to submit their lists of unclaimed cultural items, with descriptive information, within two years of the excavation; and

• Acknowledge that, while human remains and funerary objects are intrinsically protected under NAGPRA, no items are intrinsically sacred objects or objects of cultural patrimony, but instead they rely on tribal or group context to qualify as protected items under NAGPRA.

Compliance With Other Laws and Executive Orders

Regulatory Planning and Review (Executive Order 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is significant because it could interfere with an action taken or planned by another agency.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will affect the disposition of only those Native American human remains and cultural items for which potential claimants have chosen not to take ownership or control, or when no potential claimants have been identified.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the SBREFA. This rule:

a. Does not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (UMRA)

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments, or the private sector. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12603. A takings implication assessment is not required. This rule concerns the discretionary disposition of only those Native American cultural items for which identified potential claimants, upon notice, have not exercised their right to claim or no potential claimants can reasonably be identified.

Federalism (E.O. 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. A Federalism summary impact statement is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175)

In accordance with the President's memorandum of April 29, 1994, ''Government to Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 218), and Department of Interior Manual 512 DM 2, ''Departmental Responsibilities for Indian Trust Resources,'' this rule has a potential effect on federally recognized Indian tribes. The proposed rule was developed in consultation with the NAGPRA Review Committee, which includes members nominated by Indian tribes. Formal consultation with the NAGPRA Review Committee was held on November 16–17, 2005, in Albuquerque, NM; on April 19–20, 2007, in Washington, DC; on October 15–16, 2007, in Phoenix, AZ; on May 15–16, 2008, in De Pere, WI; on October 30–31, 2009, in Sarasota, FL; and on November 18–19, 2010, in Washington, DC.

Formal consultation with Indian tribes began on November 15, 2005, in Albuquerque, NM, and continued on April 18, 2007, in Washington, DC, and October 14, 2007, in Phoenix, AZ. Testimony or comments were received from representatives of 18 Indian tribes and three Indian organizations. We will fully consider tribal and Review Committee views in the final rule.

Paperwork Reduction Act (PRA)

This rule does not contain any new collection of information that requires approval by the Office of Management and Budget under the PRA of 1995 (44 U.S.C. 3501 *et seq.*). OMB has approved the information collection requirements associated with regulations implementing NAGPRA and has assigned OMB control number 1024–0144 (expires 11/30/15). An agency may not conduct or sponsor and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.

National Environmental Policy Act of 1969 (NEPA)

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required because the rule is covered by a categorical exclusion under 516 DM 2, Appendix 1.10, Policies, directives, regulations, and guidelines that are of an administrative, financial, legal, technical, or procedural nature and whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively or case-by-case. We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under the NEPA.

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A statement of Energy Effects is not required.

Clarity of This rule

We are required by Executive Orders 12866 (section 1(b)(12)), 12988 (section

3(b)(1)(B)), and 13563 (section 1(a)), and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Drafting Information

This proposed rule was prepared by staff of the National NAGPRA Program and counsel of the Division of Parks and Wildlife and the Division of Indian Affairs in the Office of the Solicitor.

Public Participation

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding this proposed rule identified by the RIN 1024–AE00 to *http://www.regulations.gov* (by following the Web site's instructions for submitting comments), or by mail to: Dr. Sherry Hutt, Manager, National NAGPRA Program, National Park Service, 1201 Eye Street NW (2253), Washington, DC 20005. We specifically request comments from Indian tribes, Native Hawaiian organizations, museums, Federal agencies, and other interested persons regarding:

1. The applicability of Federal curation regulations at 36 CFR Part 79 or other standards, guidelines, and protocols being used by state, local, or tribal governments that address the preservation or management of Native American cultural items.

2. The appropriateness of using a priority structure in determining the disposition of unclaimed human remains, funerary objects, sacred objects, or objects of cultural patrimony.

3. The alternative of reinterment.

4. Using newspaper notice for potential claimants of unclaimed items, and any other approaches of notifying the public that are equally or more effective. Is there a role in other technological means to provide effective notice to tribes? Is it necessary for notices under this section be published in the **Federal Register** as are notices in the collections provisions?

This proposed rule may also be viewed at *http://www.nps.gov/nagpra.* A hardcopy of this proposed rule may be obtained by submitting a request to the Manager, National NAGPRA Program, National Park Service, 1201 Eye Street NW (2253) Washington, DC 20005. Commenters wishing the National Park Service to acknowledge receipt of their comments must submit those comments with a self-addressed, stamped postcard on which the following statement is made: ''Comments to RIN 1024–AE00.'' The postcard will be date stamped and returned to the commenter.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment- including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

List of Subjects in 43 CFR Part 10

Administrative practice and procedure, Hawaiian Natives, Historic preservation, Indians-claims, Indians-lands, Museums, Reporting and record keeping requirements.

In consideration of the foregoing, the NPS proposes to amend 43 CFR Part 10 as follows:

PART 10—NATIVE AMERICAN GRAVES PROTECTION AND REPATRIATION REGULATIONS

■ 1. The authority for Part 10 continues to read as follows:

Authority: 16 U.S.C. 470dd, 25 U.S.C. 9 and 3001 *et seq.*

■ 2. In § 10.2 add paragraph (h) to read as follows:

§ 10.2 Definitions.

* * * * *

(h) *Unclaimed cultural items* means Native American human remains, funerary objects, sacred objects, or objects of cultural patrimony:

(1) That have been excavated or removed from Federal lands after November 16, 1990; and

(2) Whose disposition of ownership or control under 25 U.S.C. 3002(a) and § 10.6 of this part has not occurred because either:

(i) No identified potential claimant, upon notice, has exercised its right to claim ownership or control of the cultural items; or

(ii) No potential claimant can reasonably be identified.

* * * * *

■ 3. Add § 10.7 to read as follows:

§ 10.7 Disposition of unclaimed cultural items.

(a) A Federal agency that has unclaimed cultural items (human remains, funerary objects, sacred objects, or objects of cultural patrimony) must:

(1) Submit a list of the items to the Manager, National NAGPRA Program that describes the place of discovery and the nature of the unclaimed cultural items. This list must be received by [DATE 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], or within 2 years after excavating or removing the items, whichever is later.

(2) Care for and manage unclaimed cultural items consistent with the regulations at 36 CFR Part 79.

(3) To the maximum extent feasible, consider and respect the traditions of any potential claimants concerning the unclaimed cultural items, including, but not limited to, traditions regarding housing, maintenance, and preservation.

(b) Subject to paragraph (d) of this section, a Federal agency that has unclaimed cultural items may transfer them to another Indian tribe or Native Hawaiian organization.

(c) Subject to paragraph (d) of this section, a Federal agency that has unclaimed human remains and funerary objects may reinter them or offer them for disposition according to applicable State or other law.

(d) Before a Federal agency makes a transfer or reinterment under paragraphs (b) or (c) of this section, it must:

(1) Submit the list required under paragraph (a)(1) of this section to the Manager, National NAGPRA Program.

(2) Publish a notice of the proposed transfer or reinterment in a newspaper of general circulation in the area in which the unclaimed cultural items were excavated or removed and in a newspaper of general circulation in the area in which each potential claimant now resides. The notice must explain the nature and affiliation, if any, of the unclaimed cultural items, and solicit claims under the priority of ownership or control in section 3(a) of the Act and

§ 10.6 of this part. The notice must be published at least two times at least a week apart. The transfer or reinterment may not take place until at least 30 days after publication of the second notice to allow time for any claimants under the priority of ownership or control in section 3(a) of the Act and § 10.6 of this part to come forward.

(3) Send to the Manager, National NAGPRA Program a copy of the notice published under paragraph (d)(2) of this section and information on when and in what newspaper(s) the notice was published.

(e) This section implements section 3(b) of the Native American Graves Protection and Repatriation Act at 25 U.S.C. 3002(b).

Dated: October 21, 2013.

Rachel Jacobson,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2013–25511 Filed 10–28–13; 8:45 am]

BILLING CODE 4312–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, 25, 27, and 101

[WT Docket Nos. 12–70, 04–356; ET Docket No. 10–142; Report No. 2992]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: In this document, a Petition for Reconsideration (Petition) has been filed in the Commission's Rulemaking proceeding by Donald J. Evans on behalf of NTCH, Inc.

DATES: Oppositions to the Petition must be filed on or before November 13, 2013. Replies to an opposition must be filed on or before November 25, 2013.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Matthew Pearl, Wireless Telecommunications Bureau, phone: (202) 418–2607 or TTY (202) 418–7233.

SUPPLEMENTARY INFORMATION: This is a summary of Commission's document, Report No. 2992, released September 24, 2013. The full text of Report No. 2992 is available for viewing and copying in Room CY–B402, 445 12th Street SW., Washington, DC or may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI) (1–800–378–3160). The Commission will not send a copy of this *Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *Notice* does not have an impact on any rules of particular applicability.

Subject: Service Rules for Advanced Wireless Services in the 2000–2020 MHz and 2180–2200 MHz Bands, published at 78 FR 8229 February 5, 2013, in WT Docket Nos. 12–70, 04–356 and ET Docket No. 10–142; and published pursuant to 47 CFR 1.429(e). *See also* § 1.4(b)(1) of the Commission's rules.

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2013–25435 Filed 10–28–13; 8:45 am]

BILLING CODE 6712–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1815 and 1852

RIN 2700–AE13

NASA FAR Supplement: Proposal Adequacy Checklist

AGENCY: National Aeronautics and Space Administration.

ACTION: Proposed rule.

SUMMARY: NASA is proposing to amend the NASA FAR Supplement (NFS) to incorporate a proposal adequacy checklist for proposals in response to solicitations that require the submission of certified cost or pricing data.

DATES: Interested parties should submit comments to NASA at the address below on or before December 30, 2013 to be considered in formulation of the final rule.

ADDRESSES: Interested parties may submit comments, identified by RIN number 2700–AE13 via the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments may also be submitted to William Roets via email at *william.roets-1@NASA.gov.*

FOR FURTHER INFORMATION CONTACT: William Roets, NASA, Office of Procurement, email: *william.roets-1@NASA.gov*, or phone: 202–358–4483.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed rule supports the NASA Assistant Administrator for Procurement's ''Reducing Transaction Costs in NASA Procurements'' initiative by incorporating the requirement for a proposal adequacy checklist into the NFS at 1815.408–70(c), and associated solicitation provision at NFS 1852.215–85, to ensure offerors take responsibility for submitting thorough, accurate, and complete proposals. The provision will be included in solicitations that require the submission of certified cost or pricing data.

B. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866. This proposed rule is not a major rule under 5 U.S.C. 804.

C. Regulatory Flexibility Act

NASA does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. However, an Initial Regulatory Flexibility Analysis has been performed and is summarized as follows:

This proposed rule amends the NFS to add a checklist for NASA contractors to complete under solicitations that require the submission of certified cost or pricing data. This rule supports the NASA Assistant Administrator for Procurement's ''Reducing Transaction Costs in NASA Procurements'' initiative by increasing uniformity across NASA and minimizing local variations in this area which will decrease proposal preparation costs.

The objective of this proposed rule is to ensure that offerors submit thorough, accurate, and complete proposals. By completing the checklist, offerors will be able to self-validate the adequacy of their proposals which will improve the quality of their initial proposal submissions. This will reduce the need for contractors to rework their initial proposal submissions which will save the Government time and resources in performing the evaluation of the proposal.

The rule will apply to actions where certified cost or pricing data is required. Based on data collected in FPDS–NG for FY2010–2012, there are on average 1162

actions per year that met the criteria where the proposal adequacy checklist is to be utilized. On average, 462 of those actions were with small business concerns.

This proposed rule imposes no new reporting requirements. The rule does not duplicate, overlap, or conflict with any other Federal rules. No alternatives were identified that would meet the objectives of the rule. Excluding the small number of small business concerns that may be subject to the rule would not be in the best interest of the small business concerns or the Government because the proposal adequacy checklist was created directly from requirements already in the Federal Acquisition Regulation. While the checklist does not add burden, it provides a useful tool for ensuring proposal adequacy.

NASA invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities. NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 and RIN number 2700–AE13 in correspondence.

D. Paperwork Reduction Act

This proposed rule contains information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. Chapter 35). However, these changes to the NFS do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 9000–0013, entitled ''Cost or Pricing Data Exemption Information.''

List of Subjects in 48 CFR 1815 and 1852

Government procurement.

William P. McNally,

Assistant Administrator for Procurement.

Accordingly, 48 CFR parts 1815 and 1852 are proposed to be amended as follows:

PART 1815—CONTRACTING BY NEGOTIATION ACQUISITION

■ 1. The authority citation for part 1815 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

■ 2. In section 1815.408–70, paragraph (c) is added to read as follows:

1815.408–70 NASA solicitation provisions and contract clauses.

* * * * *

(c) When the solicitation requires the submission of certified cost or pricing data, the contracting officer shall include 1815.215–85, Proposal Adequacy Checklist, in the solicitation to facilitate submission of a thorough, accurate, and complete proposal.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. The authority citation for part 1852 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

■ 4. Clause 1852.215–85 is added to read as follows:

1852.215–85 Proposal Adequacy Checklist.

As prescribed in 1815.408–70(c), use the following provision:

PROPOSAL ADEQUACY CHECKLIST (XX/XX)

The offeror shall complete and submit as part of their proposal the following checklist, providing location of requested information, or an explanation of why the requested information is not provided. In preparation of the offeror's checklist, offerors may elect to have their prospective subcontractors use the same or similar checklist as appropriate.

PROPOSAL ADEQUACY CHECKLIST

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
	General Instructions		
1. FAR 15.408, Table 15–2, Section I Paragraph A.	Is there a properly completed first page of the proposal per FAR 15.408 Table 15–2 I.A or as specified in the solicitation?		
2. FAR 15.408, Table 15–2, Section I Paragraph A(7).	Does the proposal identify the need for Government-furnished material/tooling/test equipment? Include the accountable contract number and contracting officer contact information if known.		
3. FAR 15.408, Table 15–2, Section I Paragraph A(8).	If your organization is subject to Cost Accounting Standards (CAS), does the proposal identify the current status of your CAS Disclosure Statement? Does the proposal identify and explain notifications of noncompliance with Cost Accounting Standards Board or Cost Accounting Standards (CAS); any proposal inconsistencies with your disclosed practices or applicable CAS; and inconsistencies with your established estimating and accounting principles and procedures?		
4. FAR 15.408, Table 15–2, Section I, Paragraph C(1), FAR 2.101, ''Cost or pricing data''.	Does the proposal disclose any other known activity that could materially impact the costs? This may include, but is not limited to, such factors as— (1) Vendor quotations; (2) Nonrecurring costs; (3) Information on changes in production methods and in production or purchasing volume; (4) Data supporting projections of business prospects and objectives and related operations costs; (5) Unit-cost trends such as those associated with labor efficiency; (6) Make-or-buy decisions; (7) Estimated resources to attain business goals; and		

PROPOSAL ADEQUACY CHECKLIST—Continued

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
	(8) Information on management decisions that could have a significant bearing on costs.		
5. FAR 15.408, Table 15–2, Section I Paragraph B.	Is an Index of all certified cost or pricing data and information accompanying or identified in the proposal provided and appropriately referenced?		
6. FAR 15.403–1(b)	Are there any exceptions to submission of certified cost or pricing data pursuant to FAR 15.403–1(b)? If so, is supporting documentation included in the proposal? (Note questions 18–20.)		
7. FAR 15.408, Table 15–2, Section I Paragraph C(2)(i).	Does the proposal disclose the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data?		
8. FAR 15.408, Table 15–2, Section I Paragraph C(2)(ii).	Does the proposal disclose the nature and amount of any contingencies included in the proposed price?		
9. FAR 15.408 Table 15–2, Section II, Paragraph A or B.	Does the proposal explain the basis of all cost estimating relationships (labor hours or material) proposed on other than a discrete basis?		
10. FAR 15.408, Table 15–2, Section I Paragraphs D and E.	Is there a summary of total cost by element of cost and are the elements of cost cross-referenced to the supporting cost or pricing data? (Breakdowns for each cost element must be consistent with your cost accounting system, including breakdown by year.)		
11. FAR 15.408, Table 15–2, Section I Paragraphs D and E.	If more than one Contract Line Item Number (CLIN) or sub Contract Line Item Number (sub-CLIN) is proposed as required by the RFP, are there summary total amounts covering all line items for each element of cost and is it cross-referenced to the supporting cost or pricing data?		
12. FAR 15.408, Table 15–2, Section I Paragraph F.	Does the proposal identify any incurred costs for work performed before the submission of the proposal?		
13. FAR 15.408, Table 15–2, Section I Paragraph G.	Is there a Government forward pricing rate agreement (FPRA)? If so, the offeror shall identify the official submittal of such rate and factor data. If not, does the proposal include all rates and factors by year that are utilized in the development of the proposal and the basis for those rates and factors?		
Cost Elements			
Materials and Services			
14. FAR 15.408, Table 15–2, Section II Paragraph A.	Does the proposal include a consolidated summary of individual material and services, frequently referred to as a Consolidated Bill of Material (CBOM), to include the basis for pricing? The offeror's consolidated summary shall include raw materials, parts, components, assemblies, subcontracts and services to be produced or performed by others, identifying as a minimum the item, source, quantity, and price.		
Subcontracts (Purchased materials or services)			
15. FAR 15.404–3(c), FAR 52.244–2.	Per the thresholds of FAR 15.404–3(c), Subcontract Pricing Considerations, does the proposal include a copy of the applicable subcontractor's certified cost or pricing data?		
16. FAR 15.408, Table 15–2, Note 1; Section II Paragraph A.	Is there a price/cost analysis establishing the reasonableness of each of the proposed subcontracts included with the proposal? If the offeror's price/cost analyses are not provided with the proposal, does the proposal include a matrix identifying dates for receipt of subcontractor proposal, completion of fact finding for purposes of price/cost analysis, and submission of the price/cost analysis?		
Exceptions to Certified Cost or Pricing Data			
17. FAR 52.215–20, FAR 2.101, "commercial item".	Has the offeror submitted an exception to the submission of certified cost or pricing data for commercial items proposed either at the prime or subcontractor level, in accordance with provision 52.215–20? a. Has the offeror specifically identified the type of commercial item claim (FAR 2.101 commercial item definition, paragraphs (1) through (8)), and the basis on which the item meets the definition?		

PROPOSAL ADEQUACY CHECKLIST—Continued

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
	b. For modified commercial items (FAR 2.101 commercial item definition paragraph (3)); did the offeror classify the modification(s) as either— i. A modification of a type customarily available in the commercial marketplace (paragraph (3)(i)); or ii. A minor modification (paragraph (3)(ii)) of a type not customarily available in the commercial marketplace made to meet Federal Government requirements not exceeding the thresholds in FAR 15.403–1(c)(3)(iii)(B)? c. For proposed commercial items ''of a type'', or ''evolved'' or modified (FAR 2.101 commercial item definition paragraphs (1) through (3)), did the contractor provide a technical description of the differences between the proposed item and the comparison item(s)?		
18. FAR 15.408, Table 15–2, Section II Paragraph A(1).	Does the proposal support the degree of competition and the basis for establishing the source and reasonableness of price for each subcontract or purchase order priced on a competitive basis exceeding the threshold for certified cost or pricing data?		
Interorganizational Transfers			
19. FAR 15.408, Table 15–2, Section II Paragraph A.(2).	For inter-organizational transfers proposed at cost, does the proposal include a complete cost proposal in compliance with Table 15–2?		
20. FAR 15.408, Table 15–2, Section II Paragraph A(1).	For inter-organizational transfers proposed at price in accordance with FAR 31.205–26(e), does the proposal provide an analysis by the prime that supports the exception from certified cost or pricing data in accordance with FAR 15.403–1?		
Direct Labor			
21. FAR 15.408, Table 15–2, Section II Paragraph B.	Does the proposal include a time phased (i.e.; monthly, quarterly) breakdown of labor hours, rates and costs by category or skill level? If labor is the allocation base for indirect costs, the labor cost must be summarized in order that the applicable overhead rate can be applied.		
22. FAR 15.408, Table 15–2, Section II Paragraph B.	For labor Basis of Estimates (BOEs), does the proposal include labor categories, labor hours, and task descriptions, (e.g.; Statement of Work reference, applicable CLIN, Work Breakdown Structure, rationale for estimate, applicable history, and time-phasing)?		
23. FAR subpart 22.10	If covered by the Service Contract Labor Standards statute (41 U.S.C. chapter 67), are the rates in the proposal in compliance with the minimum rates specified in the statute?		
Indirect Costs			
24. FAR 15.408, Table 15–2, Section II Paragraph C.	Does the proposal indicate the basis of estimate for proposed indirect costs and how they are applied? (Support for the indirect rates could consist of cost breakdowns, trends, and budgetary data.)		
Other Costs			
25. FAR 15.408, Table 15–2, Section II Paragraph D.	Does the proposal include other direct costs and the basis for pricing? If travel is included does the proposal include number of trips, number of people, number of days per trip, locations, and rates (e.g. airfare, per diem, hotel, car rental, etc.)?		
26. FAR 15.408, Table 15–2, Section II Paragraph E.	If royalties exceed $1,500 does the proposal provide the information/data identified by Table 15–2?		
27. FAR 15.408, Table 15–2, Section II Paragraph F.	When facilities capital cost of money is proposed, does the proposal include submission of Form CASB–CMF or reference to an FPRA/FPRP and show the calculation of the proposed amount?		
Formats for Submission of Line Item Summaries			
28. FAR 15.408, Table 15–2, Section III.	Are all cost element breakdowns provided using the applicable format prescribed in FAR 15.408, Table 15–2 III? (or alternative format if specified in the request for proposal)		

PROPOSAL ADEQUACY CHECKLIST—Continued

References	Submission item	Proposal page No.	If not provided explain (may use continuation pages traceable to this checklist)
29. FAR 15.408, Table 15–2, Section III Paragraph B.	If the proposal is for a modification or change order, have cost of work deleted (credits) and cost of work added (debits) been provided in the format described in FAR 15.408, Table 15–2.III.B?		
30. FAR 15.408, Table 15–2, Section III Paragraph C.	For price revisions/redeterminations, does the proposal follow the format in FAR 15.408, Table 15–2.III.C?		
Other			
31. FAR 16.4	If an incentive contract type, does the proposal include offeror proposed target cost, target profit or fee, share ratio, and, when applicable, minimum/maximum fee, ceiling price?		
32. FAR 16.203–4 and FAR 15.408 Table 15–2, Section II, Paragraphs A, B, C, and D.	If Economic Price Adjustments are being proposed, does the proposal show the rationale and application for the economic price adjustment?		
33. FAR 52.232–28	If the offeror is proposing Performance-Based Payments did the offeror comply with FAR 52.232–28?		
34. FAR 15.408(n), FAR 52.215–22, FAR 52.215–23.	Excessive Pass-through Charges-Identification of Subcontract Effort: If the offeror intends to subcontract more than 70% of the total cost of work to be performed, does the proposal identify: (i) the amount of the offeror's indirect costs and profit applicable to the work to be performed by the proposed subcontractor(s); and (ii) a description of the added value provided by the offeror as related to the work to be performed by the proposed subcontractor(s)?		

(End of provision)

[FR Doc. 2013–25287 Filed 10–28–13; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R8–ES–2013–0049; 4500030113]

50 CFR Part 17

RIN 1018–AZ33

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for Diplacus vandenbergensis (Vandenberg Monkeyflower)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to designate critical habitat for *Diplacus vandenbergensis* (Vandenberg monkeyflower) under the Endangered Species Act. If we finalize this rule as proposed, it would extend the Act's protections to this species' critical habitat. The effect of this regulation is to conserve Vandenberg monkeyflower's habitat under the Endangered Species Act.

DATES: We will accept comments received or postmarked on or before December 30, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by December 13, 2013.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter Docket No. FWS–R8–ES–2013–0049, which is the docket number for this rulemaking. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2013–0049; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Information Requested section below for more information).

FOR FURTHER INFORMATION CONTACT: Stephen P. Henry, Acting Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA, 93003; telephone 805–644–1766; facsimile 805–644–3958. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Designations and revisions of critical habitat can only be completed by issuing a rule. Elsewhere in today's **Federal Register**, we propose to list the *Diplacus vandenbergensis* (hereafter referred to as Vandenberg monkeyflower) as an endangered species under the Act. This document consists of a proposed rule for designation of critical habitat for Vandenberg monkeyflower.

The basis for our action. Under the Act, when a species is proposed for listing, to the maximum extent prudent and determinable, we must designate critical habitat for the species. The species has been proposed for listing as endangered, and therefore, we also propose to designate approximately 5,785 acres (ac) (2,341 hectares (ha)) of habitat as critical habitat in Santa Barbara County, California.

We will seek peer review. We are seeking comments from knowledgeable individuals with scientific expertise to review our analysis of the best available science and application of that science and to provide any additional scientific information to improve this proposed rule. Because we will consider all comments and information received during the comment period, our final determination may differ from this proposal.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific data available and be as accurate and as effective as possible. Therefore, we request comments or information from the public, other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threats outweighs the benefit of designation such that the designation of critical habitat is not prudent.

(2) Specific information on:

(a) The amount and distribution of Vandenberg monkeyflower and its habitat;

(b) What may constitute ''physical or biological features essential to the conservation of the species,'' within the geographical range currently occupied by the species;

(c) Where these features are currently found;

(d) Whether any of these features may require special management considerations or protection;

(e) What areas that are currently occupied by the species contain features essential to the conservation of the species that should be included in the designation and why; and

(f) What areas not occupied at the time of listing are essential for the conservation of the species and why.

(3) Land use designations and current or planned activities in the areas occupied by the species or proposed to be designated as critical habitat, and possible impacts of these activities on this species and proposed critical habitat.

(4) Comments or information that may assist us in identifying or clarifying the primary constituent elements (PCEs).

(5) Information on the projected and reasonably likely impacts of climate change on Vandenberg monkeyflower and proposed critical habitat.

(6) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation. We are particularly interested in any impacts on small entities, and the benefits of including or excluding areas from the proposed designation that are subject to these impacts.

(7) Any foreseeable impacts on energy supplies, distribution, and use resulting from the proposed designation and, in particular, any impacts on electricity production, and the benefits of including or excluding any particular areas that exhibit these impacts.

(8) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act. We specifically seek comments on whether the existing management plans for Burton Mesa Ecological Reserve and La Purisima Mission State Historic Park (SHP), respectively, provide a conservation benefit to Vandenberg monkeyflower and its habitat. We also seek comments on whether there is a reasonable expectation that the conservation management strategies and actions in these management plans will be implemented into the future.

(9) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

(10) The likelihood of adverse social reactions to the designation of critical habitat and how the consequences of such reactions, if likely to occur, would relate to the conservation and regulatory benefits of the proposed critical habitat designation.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in the **ADDRESSES** section.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* You may request at the top of your document that we withhold personal information such as your street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service (Service), Ventura Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Previous Federal Actions

All previous Federal actions are described in the proposal to list Vandenberg monkeyflower as an endangered species under the Act published elsewhere in today's **Federal Register**.

Background

In this proposed rule, we intend to discuss only those topics directly relevant to the designation of critical habitat. Additional information pertaining to Vandenberg monkeyflower description, taxonomy, life history, geographic setting, climate, and habitat can be found in the proposed listing rule published elsewhere in today's **Federal Register**.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features:

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance,

propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographic area occupied by the species at the time it is listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical and biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements (PCEs) such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that are essential to the conservation of the species. We consider PCEs to be those specific elements of the physical or biological features that provide for a species' life history processes and, under the appropriate conditions, are essential to the conservation of the species.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographic area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. We designate critical habitat in areas outside the geographic area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria and guidance and establish procedures to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. Therefore, we recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) the prohibitions of section 9 of the Act if actions occurring in these areas may affect the species. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species; or (2) the designation of critical habitat would not be beneficial to the species.

As discussed in the Factor B discussion of our proposed listing rule (published elsewhere in today's **Federal Register**), there is currently no indication that collection or vandalism is a threat to Vandenberg monkeyflower, and identification and mapping of critical habitat is not expected to initiate such threat. Most of the areas proposed for critical habitat either have restricted public access (Burton Mesa Ecological Reserve) or are already open to the public (hiking trails in the Reserve and La Purisima Mission SHP). The degree of threat from casual human access, or any other identified threat (see the listing rule published elsewhere in today's **Federal Register**), is not expected to increase as a result of critical habitat designation.

In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, then a prudent finding is

warranted. Here, the potential benefits of designating critical habitat for Vandenberg monkeyflower include, but are not limited, to: (1) Focusing conservation activities on the most essential features and areas; (2) providing educational benefits to State or county governments, private entities, and the public; and (3) reducing the potential for the public to cause inadvertent harm to the species. Therefore, because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and may provide some measure of benefit, we find that designation of critical habitat is prudent for Vandenberg monkeyflower.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the Vandenberg monkeyflower is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species, habitat characteristics where this species is located, and potential impacts of designation. This and other information represent the best scientific data available and led us to conclude that the designation of critical habitat is determinable for Vandenberg monkeyflower.

Climate Change and Critical Habitat

Climate change will be a particular challenge for biodiversity because the interaction of additional stressors associated with climate change and current stressors may push species beyond their ability to survive (Lovejoy 2005, pp. 325–326). The synergistic implications of climate change and habitat fragmentation are the most threatening facet of climate change for biodiversity (Hannah and Lovejoy 2005, p. 4). Current climate change predictions for terrestrial areas in the Northern Hemisphere indicate warmer air temperatures, more intense precipitation events, and increased summer continental drying (Field *et al.* 1999, pp. 1–3; Hayhoe *et al.* 2004, p. 12422; Cayan *et al.* 2005, p. 6; Seager *et al.* 2007, p. 1181). Climate change may lead to increased frequency and duration of severe storms and droughts (McLaughlin *et al.* 2002, p. 6074; Golladay *et al.* 2004, p. 504; Cook *et al.* 2004, p. 1015).

Documentation of climate-related changes that have already occurred in California (Bell *et al.* 2004; Snyder *et al.* 2004; PRBO Conservation Science 2011; Lenihan *et al.* 2008), and predictions of changes in temperature and precipitation for the Santa Barbara County area (such as an increase in temperature of approximately 2.5 °F (1.4 °C) and a decrease in precipitation of approximately 10 percent (ClimateWizard 2012)) and North America (IPCC 2007, p. 9) indicate climate-related changes will continue in the future. We anticipate these changes could affect Vandenberg monkeyflower by reducing suitable habitat; however, because of the influence of the ocean temperatures, the effect of climate change on Burton Mesa may be moderated (see also ''Factor A—Climate Change'' section of the proposed listing rule published elsewhere in today's **Federal Register**).

Physical or Biological Features

In accordance with section 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographic area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographic, and ecological distributions of a species.

We derive the specific physical or biological features required for Vandenberg monkeyflower from studies of this species' habitat, ecology, and life history as described below. Additional information can be found in the proposed listing rule published elsewhere in today's **Federal Register**. We have determined that the following physical or biological features are essential for Vandenberg monkeyflower:

Space for Reproduction, Dispersal, and Individual and Population Growth

Canopy Openings

Vandenberg monkeyflower only occurs in sandy openings (canopy gaps) within dominant vegetation consisting of Burton Mesa chaparral (see the ''Background'' section in the proposed listing rule published elsewhere in today's **Federal Register**). The sunny openings provide the space needed for individual and population growth, including sites for germination, reproduction, seed dispersal, seed banks, and pollination.

Canopy gaps are important for seed germination and seedling establishment, and for maintaining the seed banks of many chaparral species (Davis *et al.* 1989, pp. 60–64; Zammit and Zedler 1994, pp. 11–13). As the canopy closes and grows in height, the understory is generally bare, with most herbs restricted to remaining canopy gaps (Van Dyke *et al.* 2001, p. 9). Because gaps receive more light, soil temperatures may be as much as 23 °C (73 °F) higher than under the surrounding shrub canopy (Christensen and Muller 1975b, p. 50). Such temperatures are high enough to stimulate seed germination in many species (for example, *Helianthemum scoparium* (rush-rose)) (Christensen and Muller 1975a, p. 77). Additionally, herbivory is less pronounced in openings than under or near the canopy (Halligan 1973, pp. 430–432; Christensen and Muller 1975b, p. 53; Davis and Mooney 1985, p. 528). Furthermore, allelopathic (biochemical) effects of the shrub canopy are probably reduced in openings (Muller *et al.* 1968, pp. 227–230).

Numerous studies have recognized canopy gaps in mature chaparral as important microhabitats where some subshrubs and herbs [such as Vandenberg monkeyflower] persist between fires (Horton and Kraebel 1955, pp. 258–261; Vogl and Schorr 1972, pp. 1182–1187; Keeley *et al.* 1981, pp. 1615–1617; Davis *et al.* 1989, p. 64). Additionally, many chaparral plants have characteristics that promote reestablishment after fires. Thus, fire plays a significant role in maintaining chaparral community heterogeneity and in nutrient cycling, and its role has been extensively documented (see Christensen and Muller 1975a, b; Keeley 1987) (See ''Factor A—Anthropogenic Fire'' section in the proposed listing

rule published elsewhere in today's **Federal Register**).

When fire occurs, it clears out aboveground living vegetation and dead wood, deposits nutrient-rich ash, and makes space and sunlight available for seedling establishment. High numbers of herbaceous annuals and perennials appear shortly after fire has cleared away the tall, dense shrubs (Gevirtz *et al.* 2007, p. 58). Many of these fire-followers decline over time after a fire, although some persist in small numbers for decades after their peak post-fire densities (Gevirtz *et al.* 2007, p. 103). In the first few years, habitat may appear as coastal scrub rather than chaparral, both in structure and in the species present (e.g., (*Salvia mellifera*) black sage, (*Artemisia californica*) California sagebrush, (*Frangula californica*) coffee berry, (*Baccharis pilularis*) coyote brush, *Toxicodendron pubescens* (poison oak)). Gradually, however, (*Arctostaphylos* spp.) manzanita, (*Ceanothus* spp.) ceanothus, (*Adenostoma fasciculatum*) chamise, and other species overtop the early species and come to dominate the landscape. The response of Vandenberg monkeyflower to fire is not currently known; however, because this species occurs within maritime chaparral, it is likely adapted to a naturally occurring fire regime of the Burton Mesa. Because Vandenberg monkeyflower occurs within the canopy gaps of Burton Mesa chaparral, these gaps are important for the plants' persistence between fire events. As the canopy closes with dominant vegetation, the gaps provide the space for annuals small in stature, such as Vandenberg monkeyflower, to grow and reproduce. Therefore, we identify canopy gaps to be a physical or biological feature for Vandenberg monkeyflower.

Loose Sandy Soils

The gaps in the canopy where this species occurs consist of loose, sandy soils. The Burton Mesa dune sheet is the largest exposure of mid-Pleistocene sands in the Santa Maria Basin (Hunt 1993, p. 14). These dunes are old enough to have developed a soil profile, classified as Tangair and Narlon soils (Soil Conservation Service 1972). Subsurface soils are typically hardened by iron oxides; however, surface exposures are commonly composed of loose sand (Hunt 1993, p. 15). The oldest dune deposits lie beneath dunes that were wind-deposited approximately 10,000 to 25,000 to as much as 125,000 years ago (Orme and Tchakerian 1986, pp. 155–156; Johnson 1983, in Hunt 1993, p. 15). Contributing to the formation of these vast dune systems was a rapid fall in sea level approximately 18,000 years ago, perhaps as much as 300 ft (91 m) below the present shoreline, which exposed vast quantities of sediment that were later transported miles inland by onshore winds (Hunt 1993, p. 16).

The more recent dune deposits (i.e., 10,000 to 125,000 years ago) comprise the bulk of the dunes found on Burton Mesa. These newer dunes on Burton Mesa are composed of poorly consolidated to unconsolidated red to yellow sands with a clay-enriched B-horizon profile; the substratum is generally a dense, cemented sand layer (Hunt 1993, p. 16). This cemented layer may contribute to the water-holding capacity of the soil, which in turn affects the types of plants and vegetation communities observed. Additionally, both the older and newer dune deposits have substrates with significantly higher proportions of fine sands relative to even more recent sand deposits, thus forming a dense soil (Hunt 1993, p. 16). Topsoil in Burton Mesa is uniformly medium sand, but the depth of soil to bedrock varies throughout the mesa, and several soil types are present (Davis *et al.* 1988, pp. 170–171). The most widespread soils are Marina, Tangair, and Narlon sands; however, other soil types, such as Arnold Sand, Botella Loam, Terrace Escarpments, and Gullied Land, are present on Burton Mesa where Vandenberg monkeyflower grows (Soil Conservation Service 1972).

This species appears more closely tied to loose, sandy soil than to a specific soil type. Therefore, because Vandenberg monkeyflower occurs on all soil types listed above, but appears to be more closely associated with loose, sandy soils regardless of the soil type, we identify loose, sandy soils on Burton Mesa as a physical or biological feature for Vandenberg monkeyflower.

Contiguous Chaparral Habitat

The structure of the chaparral habitat on Burton Mesa is a mosaic of maritime chaparral vegetation (which includes maritime chaparral and maritime chaparral mixed with coastal scrub, oak woodland, and small patches of native grasslands (Wilken and Wardlaw 2010, p. 2)) and sandy openings (canopy gaps) that varies from place to place (see *Background—Habitat* in the proposed Listing rule, published elsewhere in today's **Federal Register**). The invasion of nonnative plants can directly alter the structure of this habitat by displacing native vegetation, including individuals of Vandenberg monkeyflower (see ''Factor A—Invasive, Nonnative Species'' section in the listing rule published elsewhere in today's **Federal Register**). Fragmentation of the habitat (due to invasive, nonnative plants) has negative effects on rare plant populations (Aguilar *et al.* 2008, pp. 5177–5186). Therefore, the presence of contiguous chaparral habitat on Burton Mesa is important for population growth of Vandenberg monkeyflower because it provides available habitat for seed dispersal and establishment. Gene flow occurs through movement of seeds and pollen within and between occurrences of Vandenberg monkeyflower. Seeds of this species are small and light in weight and are dispersed primarily by gravity but also by wind and water over relatively short distances (Fraga *in litt.* 2012; Thompson 2005, p. 130). A small fraction of wind-dispersed seeds, however, may be caught in updrafts and would be expected to travel longer distances (Greene and Johnson 1995, p. 1036). The principal wind direction in all seasons is north-northwest (Bowen and Inman 1966, p. 3; Cooper 1967, pp. 73–74; Hunt 1993, p. 27), which would aid local dispersal of seeds after falling from the parent plant. Long-distance dispersal occurs in numerous ways, including vertebrate dispersal (by adhesion or ingestion), wind dispersal of seeds (in updrafts and storms, or by secondary dispersal over the substrate), wind dispersal of plants (tumble-plant dispersal), and water dispersal (Cain *et al.* 2000, p. 1218). Landscape fragmentation over time may reduce the ability of seeds to move longer distances (Cain *et al.* 2000, p. 1223).

Contiguous chaparral habitat on Burton Mesa is important for population growth of Vandenberg monkeyflower because it also provides habitat for insect pollinators. Pollinators move pollen from one flower to another predominantly within the same plant population, but they can move pollen to another plant population if it is close enough and the pollinator is capable of carrying the pollen across that distance. Annual *Diplacus* species have a variety of visitors, including insects, bees, and butterflies. Although no research has been done to determine the effectiveness of various pollinators for Vandenberg monkeyflower (Fraga *in litt.* 2012), based on observations of other small annual *Diplacus* species, small solitary bees are likely an important class of pollinator. Therefore, because contiguous chaparral habitat on Burton Mesa provides habitat connectivity that ensures space for seed dispersal and establishment and movement of pollinators, we identify contiguous chaparral habitat as a physical or biological feature for Vandenberg monkeyflower.

Primary Constituent Elements (PCEs) for Vandenberg Monkeyflower

Under the Act and its implementing regulations, we are required to identify the physical or biological features essential to the conservation of Vandenberg monkeyflower in areas occupied at the time of listing, focusing on the features' PCEs. We consider PCEs to be the elements of physical or biological features that provide for a species' life history processes and, under the appropriate conditions, are essential to the conservation of the species.

Based on our current knowledge of the physical or biological features and habitat characteristics required to sustain the species' life-history processes, we determine that the PCEs specific to Vandenberg monkeyflower are:

(1) Native maritime chaparral communities of Burton Mesa comprising maritime chaparral and maritime chaparral mixed with coastal scrub, oak woodland, and small patches of native grasslands. The mosaic structure of the native plant communities (arranged in a mosaic of dominant vegetation and sandy openings (canopy gaps)), may change spatially as a result of succession, and physical processes such as windblown sand and wildfire.

(2) Loose sandy soils on Burton Mesa. As mapped by the Natural Resources Conservation Service (NRCS), these could include the following soil series: Arnold Sand, Marina Sand, Narlon Sand, Tangair Sand, Botella Loam, Terrace Escarpments, and Gullied Land.

With this proposed designation of critical habitat, we intend to identify the physical or biological features essential to the conservation of the species, through the identification of the features' PCEs sufficient to support the life-history processes of the species. All units and subunits proposed to be designated as critical habitat are currently occupied by Vandenberg monkeyflower and contain the PCEs.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographic area occupied by the species at the time of listing contain physical and biological features that are essential to the conservation of the species and that may require special management considerations or protection. All areas proposed as critical habitat will require some level of management to address the current and future threats to the physical and biological features essential to the conservation of Vandenberg monkeyflower. In all areas, special management is needed to ensure that the habitat is able to provide for the growth and reproduction of the species.

The habitat where Vandenberg monkeyflower occurs faces threats from urban development, maintenance of existing utility pipelines, anthropogenic fire, unauthorized recreational activities, and most substantially the expansion of invasive, nonnative plants (see *Factors A and E* in the proposed listing rule). Management activities that may reduce these threats include, but are not limited to: (1) Protecting from development lands that provide suitable habitat; (2) minimizing habitat fragmentation; (3) minimizing the spread of invasive, nonnative plants; (4) limiting authorized casual recreational use to existing paths and trails (as opposed to off-trail use that can spread invasive species to unaffected areas); (5) controlled burning; and (6) encouraging habitat restoration. These management activities would limit the impact to the physical or biological features for Vandenberg monkeyflower by decreasing the direct loss of habitat, maintaining the appropriate vegetation structure that provides the sandy openings that are necessary components of Vandenberg monkeyflower habitat, and minimizing invasive, nonnative plants spreading to areas where they currently do not exist. Preserving large areas of contiguous suitable habitat throughout the range of the species should maintain the mosaic structure of the Burton Mesa chaparral that may be present at any given time, and maintain the genetic and demographic diversity of Vandenberg monkeyflower.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. We review available information pertaining to the habitat requirements of the species. In accordance with the Act and its implementing regulation at 50 CFR 424.12(e), we consider whether designating additional areas—outside those occupied at the time of listing—are necessary to ensure the conservation of the species. We are proposing to designate critical habitat in areas within the geographic area occupied by Vandenberg monkeyflower at the time of listing and that contain sufficient elements of the physical or biological features essential to the conservation of the species. We are not currently proposing to designate any areas outside the geographic area occupied by the species at the time of listing because the area within Burton Mesa that encompasses the extant occurrences would be sufficient for the conservation of the species.

We used data from research published in peer-reviewed articles; reports and survey forms prepared for Federal, State, and local agencies and private corporations; site visits; regional Geographic Information Systems (GIS) layers, including soil and land use coverage; and data submitted to the California Natural Diversity Database (CNDDB). We also reviewed available information that pertains to the ecology, life history, and habitat requirements of this species. This material included information and data in peer-reviewed articles, reports of monitoring and habitat characterizations, reports submitted during section 7 consultations, and information received from local experts regarding Burton Mesa or Vandenberg monkeyflower.

Determining specific areas that Vandenberg monkeyflower occupies is challenging because areas may be occupied by the species even if no plants appear above ground (i.e., resident seed banks may be present with little or no visible aboveground expression of the species) (see ''Background—Life History'' section of the listing rule published elsewhere in today's **Federal Register**). Additionally, depending upon the climate and other annual variations in habitat conditions, the observed distribution of the species may shrink, temporarily disappear, or enlarge to encompass more locations on Burton Mesa. Because Vandenberg monkeyflower occurs in sandy soils within canopy gaps, and plant communities may undergo changes in which the gaps may shift spatially over time, the degree of cover that is provided by a vegetation type may favor the presence of Vandenberg monkeyflower or not. Furthermore, the way the current distribution of Vandenberg monkeyflower is mapped by the various agencies, organizations, or surveyors has varied depending on the scale at which occurrences of individuals were recorded (such as many small occurrences versus one large occurrence). Therefore, we considered areas as occupied where suitable habitat is present and contiguous with an extant occurrence of Vandenberg monkeyflower, but which may not currently contain aboveground individuals.

We used a multistep process to delineate critical habitat boundaries.

(1) Using Burton Mesa as a palette, we placed a minimum convex polygon around all nine extant occurrences and

one potentially extirpated occurrence (Lower Santa Lucia Canyon) of Vandenberg monkeyflower based on CNDDB and herbarium records, as well as survey information not yet formalized in a database. This resulted in a data layer of Vandenberg monkeyflower's current and historical range on Burton Mesa (see ''Distribution of Vandenberg Monkeyflower'' section of the proposed listing rule published elsewhere in today's **Federal Register**). We eliminated the 1931 occurrence that was identified approximately 5 mi (8 km) downwind and to the east in the Santa Rita Valley because there is no suitable habitat remaining at this site; thus, we consider this occurrence to be extirpated (see ''Historical Locations'' section in the proposed listing rule published elsewhere in today's **Federal Register**).

(2) We used GIS to overlay soil data (NRCS) across Burton Mesa, not excluding any soil types at this time because Vandenberg monkeyflower appears to be tied more closely to loose sandy soil than to a specific soil type. Therefore, to define suitable sandy soil where Vandenberg monkeyflower may occur, we included all soil types where the species is currently extant. These soil types include Arnold Sand, Marina Sand, Narlon Sand, Tangair Sand, Botella Loam, Terrace Escarpments, and Gullied Land. Additionally, we did not remove areas that comprise a small percentage of a different soil type if it was within a larger polygon of a suitable soil type because these areas were below the mapping resolution of the NRCS soil data we utilized.

(3) We expanded the distance from each extant occurrence and one potentially extirpated occurrence up to 1 mi (1.6 km) beyond the known outer edge of each occurrence of Vandenberg monkeyflower for the following reasons:

(a) We sought to maintain connectivity between occurrences of Vandenberg monkeyflower because seeds are primarily dispersed by gravity, along with wind, water, and small mammals. Habitat connectivity, especially canopy gaps where the species occurs, provides the necessary space needed for reproduction, dispersal, and individual and population growth (see ''Physical and Biological Features'' section above).

(b) A 1-mi (1.6-km) distance from each extant occurrence provides space for pollinator habitat. Vandenberg monkeyflower has a mixed mating system, and is dependent on pollinators to achieve seed production (see ''Life History'' section of the proposed listing rule published elsewhere in today's **Federal Register**). We used general pollinator travel distances described in the literature to help determine a distance that would capture pollinator habitat most representative of invertebrate species that visit annual *Diplacus* flowers. Typically, pollinators fly distances that are in proportion to their body sizes, with larger pollinators flying longer distances (Greenleaf *et al.* 2007, pp. 593–596). Therefore, if a pollinator can fly long distances, pollen transfer is also possible across these distances. Pollinators often focus on small, nearby areas where floral resources are abundant; however, occasional longer distance pollination may occur. Studies by Steffan-Dewenter and Tscharntke (2000, pp. 288–296) demonstrated that it is possible for bees to fly as far as 3,280 ft (1,000 m) to pollinate flowers. Walther-Hellwig and Frankl (2000, p. 303) showed *Bombus terrestris* (bumblebee) foraging distances from 0.93 to 1.1 mi (1.5 to 1.8 km). Heinrich (1979, pp. 109–122) assumed that *Bombus* species forage flights of 3.1 mi (5 km) could be effective, if the foraging habitats visited are more rewarding than others close by. Bumblebees, however, are not a likely pollinator of Vandenberg monkeyflower. Based on observations of other small annual *Diplacus* species, small solitary bees, which have shorter foraging distances than wild social bees such as bumblebees, are likely an important class of pollinator; therefore, we are using shorter foraging distances of the smaller solitary bees. See additional discussion in this section under (d) below for a rationale of why other distance values are inappropriate.

(c) Providing a critical habitat boundary that is 1 mi (1.6 km) from the nine extant occurrences and one potentially extirpated occurrence of Vandenberg monkeyflower captures most of the remaining native vegetation on Burton Mesa, from east of the developed area on Vandenberg AFB through La Purisima Mission SHP (see ''Distribution of Vandenberg Monkeyflower'' section of proposed listing rule). In some instances, we expanded critical habitat farther than 1 mi (1.6 km) if the PCEs were contiguously present up-canyon. Expanding the boundary to 1 mi (1.6 km) created larger and contiguous blocks of suitable habitat, which have the highest likelihood of persisting through the environmental extremes that characterize California's climate, and of retaining the genetic variability to withstand future stressors (such as invasive, nonnative species or climate change). Additionally, contiguous blocks of habitat maintain connectivity, which is important because habitat fragmentation can result in loss of genetic variation (Young *et al.* 1996, pp. 413–417), have negative effects on biological populations (especially rare plants), and affect survival and recovery (Aguilar *et al.* 2008, pp. 5177–5186). Furthermore, fragmentation has been shown to disrupt plant-pollinator interactions and predator-prey interactions (Steffan-Dewenter and Tscharntke 1999, p. 437), alter seed germination percentages (Menges 1991, pp. 158–164), and result in low fruit set (Jennerston 1988, pp. 359–366; Cunningham 2000, pp. 1149–1152). Fragments are often not of sufficient size to support the natural diversity prevalent in an area and thus exhibit a decline in biodiversity (Noss and Cooperrider 1994, pp. 50–54).

(d) We considered a critical habitat boundary at a distance of 0.5 mi (0.8 km) from the nine extant locations and one potentially extirpated location. This shorter distance, however, did not maintain connectivity of occurrences, did not encompass the remaining native vegetation of Burton Mesa, and did not represent a sufficient distance to encompass long-distance seed dispersal or the distance that pollinators may travel. Except as described above in (c), we did not consider any distance larger than 1 mi (1.6 km) because the 1-mile distance captures the remaining native vegetation and the distribution of Vandenberg monkeyflower, and any distance greater than 1 mi (1.6 km) also captured habitat that is not suitable for this species. Therefore, the areas within our critical habitat boundaries include the range of plant communities and soil types in which Vandenberg monkeyflower is found, maintain connectivity of occurrences, and provide for the sandy openings mixed within the dominant vegetation. The delineated critical habitat contains the elements of physical and biological features that are essential to the conservation of the species.

We did not include agricultural areas because, while the underlying dune sheet may be present depending on the land use practices, the topsoil would most likely not consist of loose sandy soil and the associated vegetation community would not exist. A few smaller agriculture and grazing plots exist within the Burton Mesa Ecological Reserve, but agricultural lands mostly occur to the south and east of the Reserve and La Purisima Mission SHP.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other

structures because such lands lack physical or biological features necessary for Vandenberg monkeyflower. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We are proposing to designate critical habitat on lands that we have determined are within the geographical area occupied by the species at the time of listing (occupied at the time of listing) and contain the physical or biological features essential to the conservation of the species and which may require special management considerations or protection.

One unit (including four subunits) is proposed for designation based on sufficient elements of physical or biological features being present to support Vandenberg monkeyflower life-history processes. All of the subunits contain all of the identified elements of physical or biological features and support multiple life-history processes.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document in the rule portion. We include more detailed information on the boundaries of the critical habitat designation in the unit descriptions section of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R8–ES–2013–0049, on our Internet site *http://www.fws.gov/ventura/,* and at the field office responsible for the designation (see **FOR FURTHER INFORMATION CONTACT** above).

Proposed Critical Habitat Designation

We are proposing one unit consisting of four subunits as critical habitat for Vandenberg monkeyflower. The critical habitat areas we describe below constitute our best assessment of areas that meet the definition of critical habitat for Vandenberg monkeyflower. The unit we propose as critical habitat is Burton Mesa, which contains four subunits: (1) Vandenberg, (2) Santa Lucia, (3) Encina, and (4) La Purisima (see Table 1 below). The critical habitat areas described below are within the geographical area occupied by the species at the time of listing, contain the physical and biological features essential to the conservation of the species, and may require special management considerations or protections. We are not proposing to designate any critical habitat in areas outside the geographical area occupied by the species at the time of listing. Table 1 includes the approximate area included within each proposed critical habitat subunit.

TABLE 1—PROPOSED CRITICAL HABITAT SUBUNITS FOR VANDENBERG MONKEYFLOWER

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Land ownership by type	Area proposed for critical habitat in acres (hectares)	Total size of unit in acres (hectares)
Burton Mesa Unit:			
1. Vandenberg Subunit	Federal	277 (112)	277 (112)
2. Santa Lucia Subunit	State	1,422 (576)	1,484 (601)
	Local Agency	10 (4)	
	Private	52 (21)	
3. Encina Subunit	State	1,460 (591)	2,000 (810)
	Local Agency	24 (10)	
	Private	516 (209)	
4. La Purisima Subunit	State	1,792 (725)	2,024 (819)
	Local Agency	4 (2)	
	Private	228 (92)	
Subtotals	Federal	277 (112)	
	State	4,674 (1,892)	
	Local Agency	38 (16)	
	Private	796 (322)	
Total [1]		5,785 (2,341)	5,785 (2,341)

Note: Area sizes may not sum due to rounding.

[1] This total does not include 4,159 ac (1,683 ha) of lands within Vandenberg AFB that were identified as areas that meet the definition of critical habitat but are exempt from critical habitat designation under section 4(a)(3)(B) of the Act (see Exemptions section below).

We present brief descriptions of the Burton Mesa Unit and the four subunits, and reasons why they meet the definition of critical habitat for Vandenberg monkeyflower below.

Burton Mesa Unit

The Burton Mesa Unit contains most of the remaining native maritime chaparral vegetation on Burton Mesa, roughly from the eastern boundary of Vandenberg AFB; to the eastern boundary of La Purisima Mission SHP; to the Purisima Hills in the north; and to the agricultural fields south of the Burton Mesa Ecological Reserve and north of the Santa Ynez River. The vegetation is structured in a mosaic that contains canopy gaps mixed with dominant woody and herbaceous vegetation (PCE 1), and the unit contains the loose, sandy soils on which Vandenberg monkeyflower occurs (PCE 2). Therefore, the Burton Mesa Unit provides all of the basic requirements for Vandenberg monkeyflower individual and population growth and

contains the physical and biological features essential to the conservation of the species. The Burton Mesa Unit is within the geographical area occupied at the time of listing and is comprised of the four subunits described below.

Subunit 1: Vandenberg Subunit

Subunit 1 is within the geographical area occupied by Vandenberg monkeyflower at the time of listing and consists of 277 ac (112 ha). Subunit 1 is located adjacent to and between two extant occurrences (Oak Canyon and Pine Canyon, which are located on Vandenberg AFB) and is known to support suitable habitat for Vandenberg monkeyflower. Although Vandenberg monkeyflower plants have not yet been documented within this subunit, the area harbors the PCEs, and is contiguous with and between Vandenberg AFB lands that are known to be occupied; thus, this area within the proposed subunit (and the adjacent, contiguous land on Vandenberg AFB) is considered to be within the geographical area occupied by the species at the time of listing. The adjacent land on Vandenberg AFB is essential to the conservation of the species; however, we are not proposing to designate Vandenberg AFB as critical habitat within this subunit because we have exempted Vandenberg AFB from critical habitat designation under section 4(a)(3)(B) of the Act (see Exemptions section below). Therefore, subunit 1 is composed entirely of Federal land (100 percent) exclusively owned and managed by the Department of Justice (DOJ) and which contains the U.S. Bureau of Prisons Federal Penitentiary Complex at Lompoc (Lompoc Penitentiary). The subunit consists of the westernmost portion of DOJ lands, from the Vandenberg AFB boundary line to roughly the bottom slope of Santa Lucia Canyon. Subunit 1 contains the appropriate vegetation structure of contiguous chaparral habitat with canopy gaps (PCE 1) and loose, sandy soils (PCE 2) that support Vandenberg monkeyflower. Subunit 1 provides connectivity of habitat between occurrences, habitat for pollinators, and space for establishment of new plants from seeds that are dispersed from adjacent extant occurrences of Vandenberg monkeyflower.

The features essential to the conservation of the species may require special management considerations or protection due to threats from invasion of nonnative plants. Ground disturbance within this subunit could remove suitable habitat and create additional openings for nonnative plants to invade and degrade the quality of the habitat.

Subunit 2: Santa Lucia Subunit

Subunit 2 is within the geographical area occupied by Vandenberg monkeyflower at the time of listing, is currently occupied by the species, and consists of 1,484 ac (601 ha). This subunit includes State lands (96 percent) within Burton Mesa Ecological Reserve, relatively small portions of local agency lands (for example, school districts, water districts, community services districts) (less than 1 percent) and private lands (3 percent). Subunit 2 contains the appropriate vegetation structure of contiguous chaparral habitat with canopy gaps (PCE 1) and loose, sandy soils (PCE 2) that support Vandenberg monkeyflower. The eastern boundary of Vandenberg AFB delineates the western boundary of this subunit. Subunit 2 includes most of the Vandenberg and Santa Lucia Management Units of the Reserve. Subunit 2 extends from Purisima Hills at the northern extent through the width of Burton Mesa to the agricultural lands south of the Reserve, and to the eastern boundary of the Vandenberg and Santa Lucia Management Units where these units abut Vandenberg Village.

Subunit 2 supports one extant occurrence (Volans Avenue) and one potentially extirpated occurrence (Lower Santa Lucia Canyon) of Vandenberg monkeyflower. Between 2006 and 2011, the Volans Avenue occurrence has consisted of no more than 25 individuals; the potentially extirpated occurrence was last observed in 1985 (see the ''Distribution of Vandenberg Monkeyflower—Historical Locations'' section of the proposed listing rule published elsewhere in today's **Federal Register**). Subunit 2 provides connectivity of habitat between occurrences within this subunit, habitat for pollinators, space for establishment of seeds blown from upwind seed sources, and space for establishment of new plants from seeds that are dispersed from existing Vandenberg monkeyflower plants within the subunit.

The features essential to the conservation of the species may require special management considerations or protection due to threats from invasion of nonnative plants, and activities such as utility maintenance, and ORV and casual recreational uses. These activities could remove suitable habitat and Vandenberg monkeyflower individuals, and create additional openings for nonnative plants to invade and degrade the quality of the habitat. We are considering to exclude from the Santa Lucia Subunit approximately 1,422 ac (576 ha) of lands within the Burton Mesa Ecological Reserve pursuant to section 4(b)(2) of the Act (see Exclusions section below).

Subunit 3: Encina Subunit

Subunit 3 is within the geographical area occupied by Vandenberg monkeyflower at the time of listing and consists of 2,000 ac (809 ha). This subunit contains State-owned lands (73 percent), including most of the Encina Management Unit of the Burton Mesa Ecological Reserve, local agency lands (1.2 percent), and privately owned lands such as areas adjacent to the Clubhouse Estates residential development (26 percent) (see Table 1 above). Subunit 3 contains the appropriate vegetation structure of contiguous chaparral habitat with canopy gaps (PCE 1) and loose, sandy soils (PCE 2) that support Vandenberg monkeyflower. Subunit 3 extends from approximately the Purisima Hills to the north, through the Reserve and to the agricultural lands just south of the Reserve boundary, and is between Vandenberg Village and State Route 1 to the east and the residential communities of Mesa Oaks and Mission Hills to the west. Subunit 3 supports two extant occurrences of Vandenberg monkeyflower (Clubhouse Estates and Davis Creek). Between 2006 and 2011, hundreds of individuals have been observed on more than one occasion at each of these occurrences (see ''Current Status of Vandenberg Monkeyflower'' section of the proposed listing rule published elsewhere in today's **Federal Register**). Subunit 3 provides connectivity of habitat between occurrences within this subunit, habitat for pollinators, space for establishment of seeds blown from upwind seed sources, and space for establishment of new plants from seeds that are dispersed from existing Vandenberg monkeyflower plants within the subunit.

The features essential to the conservation of the species may require special management considerations or protection due to threats from invasion of nonnative plants, development, utility maintenance, and OHV and casual recreational uses. These activities could remove suitable habitat and Vandenberg monkeyflower individuals, result in trampling of individual plants, and create additional openings for nonnatives to invade and degrade the quality of the habitat. We are considering to exclude from the Encina Subunit approximately 1,460 ac (591 ha) of lands within the Burton Mesa Ecological Reserve (see Exclusions section below) pursuant to section 4(b)(2) of the Act.

Subunit 4: La Purisima Subunit

Subunit 4 is within the geographical area occupied by Vandenberg monkeyflower at the time of listing and consists of 2,024 ac (819 ha). Subunit 4 contains mostly State-owned lands (89 percent) consisting of most of La Purisima Mission SHP and a small portion of the La Purisima Management Unit of the Burton Mesa Ecological Reserve that is north of La Purisima Mission SHP. This subunit also contains private land to the east of La Purisima Mission SHP (11 percent), and a small portion of local agency lands (less than 1 percent) (see Table 1 above). Subunit 4 contains the appropriate vegetation structure of contiguous chaparral habitat with canopy gaps (PCE 1) and loose, sandy soils (PCE 2) that support Vandenberg monkeyflower. This subunit extends approximately from the Purisima Hills in the north to the southern boundary of La Purisima Mission SHP, and between the residential communities of Mesa Oaks and Mission Hills to the west and to just east of, and outside, the State Park's eastern boundary. Subunit 4 supports two extant occurrences of Vandenberg monkeyflower in La Purisima Mission SHP (La Purisima East and La Purisima West). Between 2006 and 2011, more than 2,000 individuals of Vandenberg monkeyflower have been observed among the sites on both the east and west side of Purisima Canyon (see ''Current Status of Vandenberg Monkeyflower'' section of the proposed listing rule published elsewhere in today's **Federal Register**). This subunit provides connectivity of habitat between occurrences within this subunit, habitat for pollinators, space for establishment of seeds blown from upwind seed sources, and space for establishment of new plants from seeds that are dispersed from existing Vandenberg monkeyflower plants within the subunit.

The features essential to the conservation of the species may require special management considerations or protection due to threats from invasion of nonnative plants that could reduce the amount and quality of suitable habitat. We are considering to exclude from the La Purisima Subunit approximately 1,792 ac (725 ha) of State lands—250 ac (101 ha) of Reserve lands managed by California Department of Fish and Wildlife (CDFW) and 1,542 ac (624 ha) of La Purisima Mission SHP lands managed by California State Parks (see Exclusions section below) pursuant to section 4(b)(2) of the Act.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Decisions by the 5th and 9th Circuit Courts of Appeals have invalidated our regulatory definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.,* 245 F.3d 434, 442 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the statutory provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, or are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical

habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical or biological features to an extent that appreciably reduces the conservation value of critical habitat for Vandenberg monkeyflower. As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for Vandenberg monkeyflower. These activities include, but are not limited to:

(1) Actions that would lead to the destruction or alteration of Vandenberg monkeyflower habitat. Such activities could include, but are not limited to, development, road and utility repairs and maintenance, anthropogenic fires, and some casual recreational uses. These activities could lead to loss of habitat; removal of the seed bank; introduction and proliferation of invasive, nonnative plants; reduction of pollinators; and habitat fragmentation.

(2) Actions that create ground disturbance and would lead to significant invasive, nonnative plant competition. Such activities could include, but are not limited to, any activity that results in ground disturbance and creates additional open areas for invasive, nonnative plants to invade Vandenberg monkeyflower habitat. Invasive, nonnative plants quickly establish in disturbed areas and outcompete native vegetation, including Vandenberg monkeyflower in the sandy openings (see *Factor A—Invasive, Nonnative Species* in the proposed listing rule).

Exemptions

Application of Section 4(a)(3)(B) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resource management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographic areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

We consult with the military on the development and implementation of INRMPs for installations with listed species. We analyzed INRMPs developed by military installations located within the range of the proposed critical habitat designation for Vandenberg monkeyflower to determine if they are exempt under section 4(a)(3) of the Act. Vandenberg AFB is the only Department of Defense land with a completed, Service-approved INRMP within the proposed critical habitat designation.

Approved INRMPs—Vandenberg Air Force Base (Vandenberg AFB)

Vandenberg AFB has a Service-approved INRMP. The U.S. Air Force (on Vandenberg AFB) committed to working closely with us and CDFW to continually refine the existing INRMP as part of the Sikes Act's INRMP review process. Based on our review of the INRMP for this military installation, and in accordance with section 4(a)(3)(B)(i) of the Act, we have determined that certain lands within this installation meet the definition of critical habitat, and that conservation efforts identified in this INRMP, as modified by the 2012 Addendum, will provide a benefit to Vandenberg monkeyflower (see the following sections that detail this determination for the installation). Therefore, lands within this installation are exempt from critical habitat designation under section 4(a)(3)(B) of the Act. In summary, we are not including as proposed critical habitat approximately 4,159 ac (1,683 ha) on Vandenberg AFB that meet the definition of critical habitat but are exempt from designation under section 4(a)(3)(B) of the Act.

Vandenberg Air Force Base

Vandenberg AFB is headquarters for the 30th Space Wing, the Air Force's Space Command unit that operates Vandenberg AFB and the Western Test Range and Pacific Missile Range. Vandenberg AFB operates as an aerospace center supporting west coast launch activities for the Air Force, Department of Defense, National Aeronautics and Space Administration, and commercial contractors. The three primary operational missions of Vandenberg AFB are to launch, place, and track satellites in near-polar orbit; to test and evaluate the Intercontinental ballistic missile systems; and to support aircraft operations in the western range. Vandenberg AFB lies on the south-central California coast, approximately 275 mi (442 km) south of San Francisco, 140 mi (225 km) northwest of Los Angeles, and 55 mi (88 km) northwest of Santa Barbara. The 99,100-ac (40,104-ha) base extends along approximately 42 mi (67 km) of Santa Barbara County coast, and varies in width from 5 to 15 mi (8 to 24 km).

The Vandenberg AFB INRMP was prepared to provide strategic direction to ecosystem and natural resources management on the Base. The long-term goal of the INRMP is to integrate all management activities in a manner that sustains, promotes, and restores the health and integrity of ecosystems using an adaptive management approach. The INRMP was designed to: (1) Summarize existing management plans and natural resources literature pertaining to Vandenberg AFB, (2) identify and analyze management goals in existing plans, (3) integrate the management goals and objectives of individual plans, (4) support Base compliance with applicable regulatory requirements, (5) support the integration of natural resource stewardship with the Air Force mission, and (6) provide direction for monitoring strategies.

Vandenberg AFB completed an INRMP in May 2011 (Air Force 2011c). The INRMP includes chapters that identify invasive, nonnative plants on the Base as well as step-down goals for the management of threatened and endangered species on the Base. However, since Vandenberg monkeyflower was not a listed species at that time, specific goals for this plant were not included. In 2012, the Air Force approved an addendum to the May 2011 INRMP that addresses specific goals for Vandenberg monkeyfower (Air Force 2012). Management considerations that provide a conservation benefit to Vandenberg monkeyflower in the addendum are:

(1) Avoiding Vandenberg monkeyflower and its habitat to the maximum extent practicable by relocating and redesigning proposed projects, and using biological monitors during project activities.

(2) Conducting nonnative species control efforts that target veldt grass across Vandenberg AFB. The Air Force has programmed more than $500,000 to treat veldt grass, with funding that started in 2009 and would continue through 2019.

(3) Training Base personnel in the identification of sensitive species and their habitats, including Vandenberg monkeyflower, prior to implementing nonnative species control actions.

(4) Implementing a fire response program, such as a Burned Area Emergency Response project, which includes post-fire monitoring, habitat restoration, erosion control, and nonnative species management.

(5) Developing a controlled burning program that would include portions of Vandenberg monkeyflower habitat.

(6) Conducting habitat and threat assessments to help decide the best approach for restoration actions.

(7) Periodic surveys of Vandenberg monkeyflower populations on the Base.

Vandenberg AFB supports four extant occurrences of Vandenberg monkeyflower located in Oak, Pine, Lakes, and Santa Lucia Canyons. Between 2006 and 2011, these four locations contained multiple occurrences; in 2010 specifically, more than 5,000 individuals were observed amongst all occurrences (see ''Occurrences Located on Vandenberg AFB'' section of the proposed listing rule published elsewhere in today's **Federal Register**). Vandenberg AFB provides approximately half of the available suitable habitat (Burton Mesa chaparral) for Vandenberg monkeyflower and has four out of nine extant occurrences. However, based on the considerations above, and in accordance with section 4(a)(3)(B)(i) of the Act, we have determined that the identified lands are subject to the Vandenberg AFB INRMP and addendum, and the conservation efforts identified in the INRMP addendum will provide a conservation benefit to Vandenberg monkeyflower. Therefore, lands within this installation are exempt from critical habitat designation under section 4(a)(3) of the Act. We are not including approximately 4,159 ac (1,683 ha) of habitat in this proposed critical habitat designation because of this exemption.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if she determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless she determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise her discretion to exclude the area only if such exclusion would not result in the extinction of the species.

When identifying the benefits of inclusion for an area, we consider the additional regulatory benefits that area would receive from the protection from adverse modification or destruction as a result of actions with a Federal nexus; the educational benefits of mapping essential habitat for recovery of the listed species; and any benefits that may result from a designation due to State or Federal laws that may apply to critical habitat.

When identifying the benefits of exclusion, we consider, among other things, whether exclusion of a specific area is likely to result in conservation; the continuation, strengthening, or encouragement of partnerships; or implementation of a management plan that provides equal to or more conservation than a critical habitat designation would provide.

In the case of Vandenberg monkeyflower, the benefits of critical habitat include public awareness of the presence of Vandenberg monkeyflower, the importance of habitat protection, and in cases where a Federal nexus exists, the potential increased habitat protection for Vandenberg monkeyflower due to the protection from adverse modification or destruction of critical habitat.

When we evaluate the existence of a conservation plan (or similar management plan) when considering the benefits of exclusion, we consider a variety of factors, including but not limited to, whether the plan is finalized, how it provides for the conservation of the essential physical or biological features, whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan will be implemented into the future, whether the conservation strategies in the plan are likely to be effective, and whether the plan contains a monitoring program or adaptive management to ensure that the conservation measures are effective and can be adapted in the future in response to new information.

After identifying the benefits of inclusion and the benefits of exclusion, we carefully weigh the two sides to evaluate whether the benefits of exclusion outweigh those of inclusion. If our analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, we then determine whether exclusion would result in extinction. If exclusion of an area from critical habitat will result in extinction, we will not exclude it from the designation.

Based on the information provided by entities seeking exclusion, as well as any additional public comments received, we will evaluate whether certain lands in the proposed critical habitat Subunits 2, 3, and 4 are appropriate for exclusion from the final designation pursuant to section 4(b)(2) of the Act. If the analysis indicates that the benefits of excluding lands from the final designation outweigh the benefits of designating those lands as critical habitat, then the Secretary may exercise her discretion to exclude the lands from the final designation.

After considering the following areas under section 4(b)(2) of the Act, we are considering excluding them from the critical habitat designation for Vandenberg monkeyflower. These areas include lands proposed for critical habitat within the Burton Mesa Ecological Reserve (including a portion of lands in Subunit 2—Santa Lucia, a portion of lands in Subunit 3—Encina, and a portion of lands in Subunit 4—La Purisima) and lands proposed for critical habitat within La Purisima Mission SHP (a portion of lands in Subunit 4—La Purisima). Table 2 below provides approximate areas (ac, ha) of these lands that meet the definition of critical habitat and are under our consideration for possible exclusion under section 4(b)(2) of the Act.

TABLE 2—AREAS CONSIDERED FOR EXCLUSION BY CRITICAL HABITAT UNIT

Subunit	Specific area	Areas meeting the definition of critical habitat in acres (hectares)	Areas considered for exclusion in acres (hectares)
Subunit 2—Santa Lucia	Burton Mesa Ecological Reserve	1,484 (601)	1,422 (576)
Subunit 3—Encina	Burton Mesa Ecological Reserve	2,000 (810)	1,460 (591)
Subunit 4—La Purisima	La Purisima Mission SHP	2,024 (819)	1,542 (624)
	Burton Mesa Ecological Reserve		250 (101)
Total		5,508 (2,230)	4,674 (1,892)

However, we specifically solicit comments on the inclusion or exclusion of these areas. In the paragraphs below, we provide a detailed analysis of our consideration to exclude these lands under section 4(b)(2) of the Act.

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts, we are preparing an analysis of the economic impacts of the proposed critical habitat designation and related factors. The critical habitat subunits, as proposed, include Federal lands under the jurisdiction of the Department of Justice for the Lompoc Penitentiary, State lands with recreational uses, and private lands.

During the development of a final designation, we will consider economic impacts based on information in our economic analysis, public comments, and other new information, and areas may be excluded from the final critical habitat designation under section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands owned or managed by the Department of Defense or Department of Homeland Security where a national security impact might exist. As discussed above under the Exemptions section, we are exempting Department of Defense lands at Vandenberg AFB because we have determined that the INRMP and addendum provide a conservation benefit to Vandenberg monkeyflower. We have also determined that the remaining lands within the proposed designation of critical habitat for the species are not owned or managed by the Department of Defense or Department of Homeland Security, and, therefore, we anticipate no impact on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts in addition to economic impacts and impacts on national security. We consider a number of factors, including whether the landowners have developed any HCPs or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

We consider a current land management or conservation plan (HCPs as well as other types) to provide adequate management or protection if it meets the following criteria:

(1) The plan is complete and provides a conservation benefit for the species and its habitat;

(2) there is a reasonable expectation that the conservation management strategies and actions will be implemented into the future, based on past practices, written guidance, or regulations; and

(3) the plan provides conservation strategies and measures consistent with currently accepted principles of conservation biology.

Portions of the proposed critical habitat subunits may warrant exclusion from designation as critical habitat under section 4(b)(2) of the Act based on partnerships with the State for management of the Burton Mesa Ecological Reserve and La Purisima Mission SHP, and the management and protection afforded by the general management plans the State has developed for the Reserve and the La Purisima Mission SHP, as discussed below.

Burton Mesa Ecological Reserve. The State Lands Commission signed a 49-year lease of the Burton Mesa Ecological Reserve on January 20, 2000. The purpose of the lease is to manage, operate, and maintain these sovereign lands for the sensitive species and habitats they support (Gevirtz *et al.* 2007, p. 3). The CDFW developed a management plan for the Reserve. This plan guides management of habitats, species, and programs to achieve the mission of CDFW to protect and enhance wildlife values (Gevirtz *et al.* 2007, p. 1). Management objectives that provide a conservation benefit to Vandenberg monkeyflower include:

(1) Minimizing damage to sensitive natural resources from ground disturbance.

(2) Minimizing the presence and impact of invasive, nonnative species.

(3) Maintaining a network of trails for public use while protecting resources and preventing unauthorized uses.

(4) Maintaining habitat continuity around the Reserve to limit the fragmentation of native vegetation on Burton Mesa.

(5) Restoring native areas that have been altered by humans to natural habitats.

(6) Monitoring the effectiveness and validity of the management actions.

(7) Encouraging public education about the ecosystem of the Reserve.

(8) Developing a fire (fuel) management plan to provide for public safety of nearby residential areas and to protect the numerous special status plants and animals on the Reserve (Gevirtz *et al.* 2007, pp. 229–265).

These management objectives would benefit Vandenberg monkeyflower by reducing the loss of suitable habitat; minimizing the presence and expansion of invasive, nonnative plants; minimizing the pathways for nonnative plants to invade suitable habitat; reducing potential trampling of individual plants during casual recreational use; and maintaining an adequate fire regime for the benefit of the native Burton Mesa chaparral vegetation. Although aspects of this general management plan address to some degree the above criteria for exclusion of lands from critical habitat designation (for instance, it provides a conservation benefit and strategies and measures consistent with currently accepted principles of conservation biology), we have concerns whether funding and staffing will be available to adequately implement this plan to protect Vandenberg monkeyflower in the future. We are considering the exclusion of State lands covered by the Reserve's plan that provide for the conservation of Vandenberg monkeyflower. We are requesting comments on the benefit to Vandenberg monkeyflower from this plan and our consideration to exclude these lands from the final designation under section 4(b)(2) of the Act (see the Information Requested section).

La Purisima Mission State Historical Park (SHP). California State Parks has guidelines for the management of natural resources and sensitive species. Based on measures included in a general management plan for La Purisima Mission SHP that was completed in 1991 (California State Parks 1991), we are considering lands covered by the plan for exclusion under section 4(b)(2) of the Act. General plans for State Parks are prepared to guide future management and development of State Park System units (California State Parks 1991, p. 10). The goal of the State Parks natural resource management program is to protect, restore, and maintain the natural resources in the State Park System. Additionally, broad resource management policies concerning State Historic Parks are stated in the Public Resources Code, the California Code of Regulations, and the Department's Resource Management Directives (California State Parks 1991, p. 54).

Although the primary goal of the La Purisima Mission SHP plan is historical preservation, there are resource management directives specific to La Purisima Mission SHP that would include the habitat where Vandenberg monkeyflower occurs, which include:

(1) Preserving Burton Mesa chaparral.

(2) Protecting and managing rare and endangered plants in perpetuity.

(3) Maintaining a network of trails for public use while protecting resources and preventing unauthorized uses.

(4) Controlling nonnative plants that have become established in La Purisima Mission SHP.

(5) Developing a wildfire management plan (Cox 2013, pers. comm.).

These management objectives would benefit Vandenberg monkeyflower by reducing the loss of suitable habitat; minimizing the presence and expansion of invasive, nonnative plants; minimizing the pathways for nonnative plants to invade suitable habitat; reducing potential trampling of individual plants during casual recreational use; and implementing wildfire management guidelines to minimize the potential impact to natural resources while suppressing fires. Although there are aspects of this general management plan that address to some degree the above criteria for exclusion of lands from critical habitat designation (for instance, it provides a conservation benefit and strategies and measures consistent with currently accepted principles of conservation biology), we have concerns whether funding and staffing will be available to adequately implement this plan to protect Vandenberg monkeyflower in the future. We are considering the exclusion of State lands covered by this general management plan that provide for the conservation of Vandenberg monkeyflower. We are requesting comments on the benefit to Vandenberg monkeyflower from La Purisima Mission SHP's general management plan (see the Information Requested section).

In preparing this proposal, we have determined that there are currently no HCPs or other management plans for Vandenberg monkeyflower, and the proposed designation does not include any tribal lands. We anticipate no impact on tribal lands, partnerships, or HCPs from this proposed critical habitat designation.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during this public comment period.

We will consider all comments and information received during this comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review—Executive Orders 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C. 801 *et seq.*), whenever an

agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include such businesses as manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and forestry and logging operations with fewer than 500 employees and annual business less than $7 million. To determine whether small entities may be affected, we will consider the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Importantly, the incremental impacts of a rule must be *both* significant and substantial to prevent certification of the rule under the RFA and to require the preparation of an initial regulatory flexibility analysis. If a substantial number of small entities are affected by the proposed critical habitat designation, but the per-entity economic impact is not significant, the Service may certify. Likewise, if the per-entity economic impact is likely to be significant, but the number of affected entities is not substantial, the Service may also certify.

Under the RFA, as amended, and following recent court decisions, Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself, and not the potential impacts to indirectly affected entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried by the Agency is not likely to adversely modify critical habitat. Therefore, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Under these circumstances, it is our position that only Federal action agencies will be directly regulated by this designation. Therefore, because Federal agencies are not small entities, the Service may certify that the proposed critical habitat rule will not have a significant economic impact on a substantial number of small entities.

We acknowledge, however, that in some cases, third-party proponents of the action subject to permitting or funding may participate in a section 7 consultation, and thus may be indirectly affected. We believe it is good policy to assess these impacts if we have sufficient data before us to complete the necessary analysis, whether or not this analysis is strictly required by the RFA. While this regulation does not directly regulate these entities, in our draft economic analysis we will conduct a brief evaluation of the potential number of third parties participating in consultations on an annual basis in order to ensure a more complete examination of the incremental effects of this proposed rule in the context of the RFA.

In conclusion, we believe that, based on our interpretation of directly regulated entities under the RFA and relevant case law, this designation of critical habitat will only directly regulate Federal agencies which are not by definition small business entities. Therefore, we certify that, if promulgated, this designation of critical habitat would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required. However, though not necessarily required by the RFA, in our draft economic analysis for this proposal we will consider and evaluate the potential effects to third parties that may be involved with consultations with Federal action agencies related to this action.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Oil extraction is still occurring on the oil field to the north of the Burton Mesa Ecological Reserve that is operated by Plains Exploration and Production Company (PXP). Multiple remnant pipelines associated with oil production remain in several locations just outside of the Reserve's boundaries (Gevirtz *et al.* 2007, p. 57). A triplet pipeline runs from the Lompoc Oil and Gas Plant to the offshore oil platform Irene, crossing Vandenberg AFB. Therefore, a Federal nexus with the Air Force or the Federal Energy Regulatory Commission may exist; however, Vandenberg AFB is not proposed as critical habitat. We do not expect the designation of this proposed critical habitat to significantly affect energy supplies, distribution, or use. This is because, under section 7 of the Act, the lead agency for a proposed project would need to consider substantial project modifications only if the project were to reach a threshold of jeopardizing the continued existence of the species or destroy or adversely modify its critical habitat, a scenario that is unlikely with Vandenberg monkeyflower. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment if warranted.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates

to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule will significantly or uniquely affect small governments because approximately 85 percent of the lands being proposed for Vandenberg monkeyflower critical habitat are on lands managed by State agencies, primarily CDFW and California State Parks. A small percentage of land (38 ac (15 ha), or 0.7 percent) proposed as critical habitat falls within the land use jurisdiction of local agencies (such as special-use districts, water districts, and community service districts). The local-agency lands proposed as critical habitat are a small percentage of the total land area proposed. Small governments would be affected only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions would not adversely affect critical habitat. Moreover, these agencies would be required to meet other regulatory mechanisms (such as CEQA) in addition to compliance with the Act. Therefore, a Small Government Agency Plan is not required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment if appropriate.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), this rule is not anticipated to have significant takings implications. As discussed above, the designation of critical habitat affects only Federal actions. Critical habitat designation does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. We have not yet completed the economic analysis for this proposed rule. Once the economic analysis is available, we will review and revise this preliminary assessment as warranted, and prepare a Takings Implication Assessment.

Federalism—Executive Order 13132

In accordance with Executive Order 13132 (Federalism), this proposed rule does not have significant Federalism effects. A Federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this proposed listing and critical habitat designation with appropriate State resource agencies in California. The designation may have some benefit to these governments because the areas that contain the physical or biological features essential to the conservation of the species are more clearly defined, and the elements of the features necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (rather than having them wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, the proposed rule identifies the elements of physical or biological features essential to the conservation of Vandenberg monkeyflower. The areas of proposed critical habitat are presented on maps, and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal**

Register on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

We determined that there are no tribal lands that are within the geographical area occupied by Vandenberg monkeyflower at the time of listing that contain the features essential to the conservation of the species, and no tribal lands outside the geographical area occupied by Vandenberg monkeyflower at the time of listing that are essential for the conservation of the species. Therefore, we are not proposing to designate critical habitat for Vandenberg monkeyflower on tribal lands.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* at Docket No. FWS–R8–ES–2013–0049 and upon request from the Ventura Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this package are the staff members of the Ventura Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. In § 17.96, amend paragraph (a) by adding the family Phrymaceae and an entry for ''*Diplacus vandenbergensis* (Vandenberg monkeyflower)'' in alphabetical order to read as follows:

§ 17.96 Critical habitat—plants.

(a) *Flowering plants.*

* * * * *

Family Phrymaceae: *Diplacus vandenbergensis* (Vandenberg monkeyflower)

(1) Critical habitat units are depicted for Santa Barbara County, California, on the maps below.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of Vandenberg monkeyflower consist of two components:

(i) Native maritime chaparral communities of Burton Mesa comprised of maritime chaparral and maritime chaparral mixed with coastal scrub, oak woodland, and small patches of native grasslands. The mosaic structure of the native plant communities (arranged in a mosaic of dominant vegetation and sandy openings (canopy gaps)), may change spatially as a result of succession, and physical processes such as windblown sand and wildfire.

(ii) Loose sandy soils on Burton Mesa. As mapped by the Natural Resources Conservation Service (NRCS), these could include the following soil series: Arnold Sand, Marina Sand, Narlon Sand, Tangair Sand, Botella Loam, Terrace Escarpments, and Gullied Land.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of any final rule designating critical habitat for Vandenberg monkeyflower.

(4) *Critical habitat map units.* Data layers defining map units were created on a base of USGS 1:24,000 maps, and critical habitat units were then mapped using Universal Transverse Mercator (UTM) Zone 15N coordinates.

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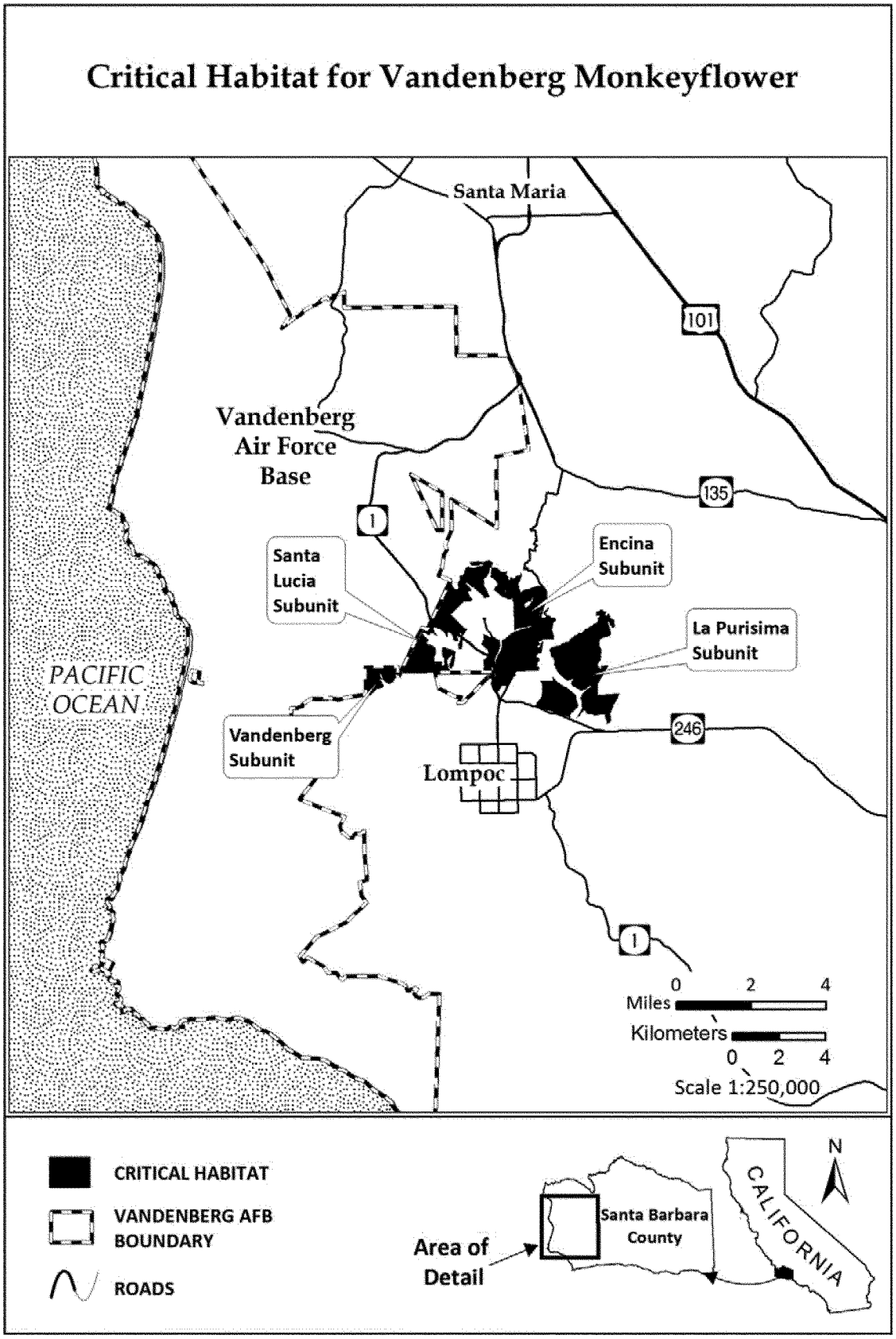
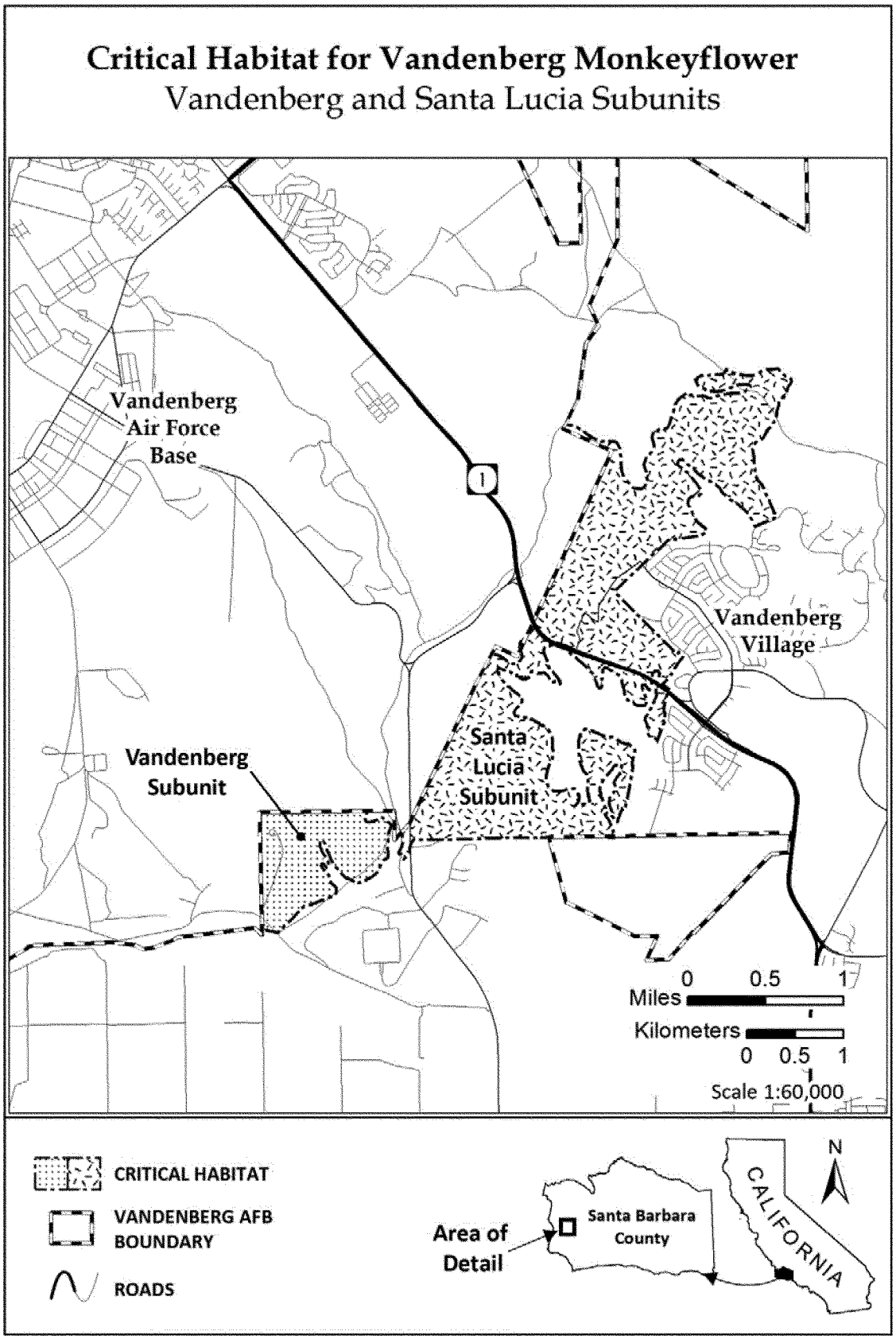
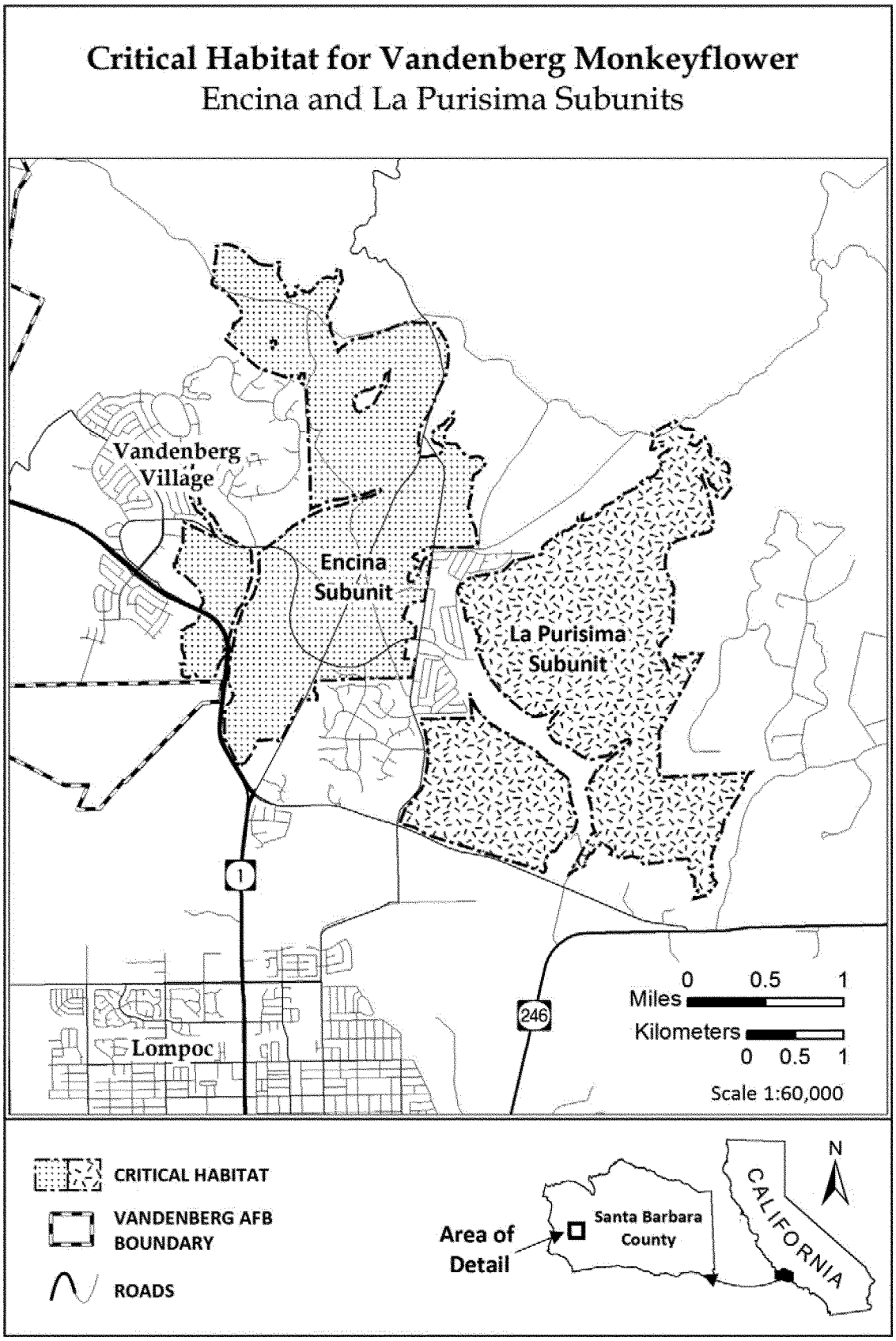
(5) *Note:* Index map follows:



(6) Unit 1, Subunit 1 (Vandenberg) and Subunit 2 (Santa Lucia): Santa Barbara County, California. Map of Unit 1, Subunits 1 and 2 follows.



(7) Unit 1, Subunit 3 (Encina) and Subunit 4 (La Purisima): Santa Barbara County, California. Map of Unit 1, Subunits 3 and 4, follows:



* * * * *

Dated: October 21, 2013.

Rachel Jacobson,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2013–25399 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–55–C

Notices

Federal Register

Vol. 78, No. 209

Tuesday, October 29, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 23, 2013.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Operating Guidelines, Forms and Waivers.

OMB Control Number: 0584–0083.

Summary of Collection: Under section 16 of the Food and Nutrition Act of 2008 (the Act), 7 U.S.C. 2025, the Secretary is authorized to pay each State agency an amount equal to 50 percent of all administrative costs involved in each State agency's operation of the Supplemental Nutrition Assistance Program (SNAP). Under corresponding SNAP regulations at 7 CFR 272.2(c), the State agency must submit to the Food and Nutrition Service (FNS) annually for approval a Budget Projection Statement (FNS–366A), which projects total costs for major areas of SNAP operations, and a Program Activity Statement (FNS–366B), which provides a summary of SNAP operations during the preceding fiscal year.

Need and Use of the Information: FNS will collect information to estimate funding needs and also provide data on the number of applications processed, number of fair hearings, and fraud control activity. FNS uses the data to estimate funding needs and to monitor State agency activity levels and performance. If the information were not collected it would disrupt budget planning and delay appropriation distributions and FNS would not be able to verify and ensure State compliance with statutory criteria.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 53.

Frequency of Responses: Recordkeeping; Reporting: Annually.

Total Burden Hours: 2,866.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2013–25372 Filed 10–28–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 24, 2013.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Foreign Agricultural Service

Title: Certificate for Quota Eligibility (CQE).

OMB Control Number: 0551–0014.

Summary of Collection: 5(a)(i) of the Harmonized Tariff Schedule of the United State authorize the Secretary to establish a raw-cane sugar tariff-rate quota (TRQ). 5(b)(1) authorizes the U.S. Trade Representative to allocate the raw-cane sugar tariff-rate quota among supplying countries. Certificates of Quota Eligibility (CQE) are issued to the 40 countries that receive TRQ allocations to export sugar to the United States. The CQE is completed by the

certifying authority in the foreign country that certifies that the sugar being exported to the United States was produced in the foreign country that has the TRQ allocation. The Foreign Agriculture will collect information using form FAS–961.

Need and Use of the Information: FAS will collect the following information: (1) Country of origin or area of the eligible raw cane sugar; (2) quota period; (3) quantity of raw cane sugar to be exported; (4) details of the shipment (shipper, vessel, port of loading); and (5) additional details if available at the time of shipment (consignee, address of consignee, expected date of departure, expected date of arrival in the U.S., expected port of arrival). The information will help determine if the quantity to be imported is eligible to be entered under the TRQ.

Description of Respondents: Business or other for-profit.

Number of Respondents: 40.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 204.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2013–25548 Filed 10–28–13; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

[FNS–2013–0033]

Request for Information: Supplemental Nutrition Assistance Program (SNAP) Enhancing Retail Food Store Eligibility; Extension of Comment Period

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice; Extension of Comment Period.

SUMMARY: Sections 3(k), (p) and (r), Section 7, and Section 9 of the Food and Nutrition Act of 2008 (''the Act''), and Title 7 Parts 271, 274, and 278 of the Code of Federal Regulations (''the regulations'') provide factors for determining the eligibility of retail food stores to participate in the Supplemental Nutrition Assistance Program (''SNAP''). This notice requests information from any and all interested parties on opportunities to enhance retailer definitions and requirements in a manner that improves access to healthy food choices for SNAP participants as well as program integrity, and ensures that only those retailers that effectuate the purpose of SNAP are authorized to accept benefits. The Food and Nutrition Service (''FNS'') considers access to a variety of healthy foods at SNAP retailers to be fundamental to the effectiveness of this critical nutrition assistance program. FNS is requesting information to understand what policy changes and, as needed, statutory changes, should be considered for retailer authorizations. FNS will use this information in determining how to make positive progress in the available healthy choices for program participants at authorized SNAP retail stores. The comment period is being extended to provide additional time for interested parties to review this request for information.

DATES: The comment period for the notice that was published on August 20, 2013 (78 FR 51136) has been extended from October 21, 2013 to November 6, 2013. To be assured of consideration, comments must be postmarked on or before November 6, 2013.

ADDRESSES: Comments may be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* Follow the online instructions for submitting comments electronically. Comments can also be mailed or delivered to: Shanta Swezy, Chief, Retailer Management and Issuance Branch, Retailer Policy and Management Division, Supplemental Nutrition Assistance Program, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 426, Alexandria, Virginia 22302.

All comments submitted in response to this notice will be included in the record and will be made available to the public at *www.regulations.gov.* Please be advised that the substance of the comments and the identity of the individuals or entities commenting will be subject to public disclosure.

FOR FURTHER INFORMATION CONTACT: Shanta Swezy, Chief, Retailer Management and Issuance Branch, Food and Nutrition Service, (703) 305–2238.

SUPPLEMENTARY INFORMATION: At the end of fiscal year (FY) 2012, over 246,000 retailers were authorized to redeem SNAP benefits. This is an increase of almost 100,000 authorized stores since 2005. According to the most recent data available (2012), 82 percent of all benefits redeemed were redeemed at supermarkets, large grocers and superstores. Approximately 18 percent of benefits were redeemed at smaller stores, including convenience stores, small grocers and farmers' markets. Less than one percent were redeemed by authorized treatment programs, group homes, homeless meal providers, communal dining facilities and shelters as provided for in statute. A 2009 FNS study on benefit use indicates that 96.3 percent of all SNAP beneficiaries shopped at supermarkets or superstores at least once each month.

According to Sections 3(k), (p) and (r), and Section 9 of the Act, and Title 7, Parts 271 and 278 of the regulations, to be eligible to participate in SNAP, stores must sell food for home preparation and consumption and meet one of the criteria below:

(A) Offer for sale, on a continuous basis (any given day of operation), at least three varieties of qualifying foods in each of the following four staple food groups, with perishable foods in at least two of the categories:

- Meat, poultry or fish
- Bread or cereal
- Vegetables or fruits
- Dairy products

or

(B) More than one-half (50 percent) of the total dollar amount of all things (food, nonfood, gas and services) sold in the store must be from the sale of eligible staple foods.

The last major changes to the store eligibility requirements took place in the early 1990's as a result of congressional action. Today, a store that consistently stocks as few as 12 total food items from the required staple foods categories could technically be licensed to participate in SNAP. Store authorization data collected from retailers by USDA indicates that over 90,000 currently authorized SNAP retailers have substantial (over 50 percent) sales that stem from ineligible items.

In addition to providing minimal access to healthy food, retailers that do not provide sufficient healthful offerings often tend to be those stores that present the greatest integrity challenges for USDA. The sale or exchange of SNAP benefits for cash is referred to as ''trafficking'', an illegal activity punishable by law. According to the latest FNS trafficking study covering the period 2009–2011, 99.5 percent of all trafficking stores involve retailers *other than* supermarkets, superstores and large grocers. Further, 84.5 percent of all benefit dollars trafficked involve retailers *other than* supermarkets, superstores and large grocers. The large number of smaller stores—roughly 222,000 authorized store locations nationwide—redeemed 15 percent of SNAP recipient's benefits and present the greatest integrity challenge for FNS; the trafficking rate in these store types was 7.6 percent. The store violation rate was 12.45 percent. A 2006 report by the Government Accountability Office

(GAO) suggested that the minimal stocking requirements in SNAP contribute to corrupt retailers entering the program, and noted that FNS regulations lacked clarity as to what constitutes sufficient stocking requirements.

FNS is concerned that there are a large and growing number of authorized retailers that do not provide healthful food offerings to SNAP recipients and that engage in fraud. These retailers represent a management challenge for the program that must be balanced against the need to ensure effective access to healthful, nutritious food for SNAP households. FNS has an interest in assuring that all authorized retailers will play by the rules and further the purpose of SNAP.

FNS' objectives are to improve the availability of more healthful foods without compromising access to nutritious food for SNAP participants, or unnecessarily burdening the retailers that redeem SNAP benefits, and to improve the integrity of the program. The Agency is seeking public input regarding the following questions, with particular attention to impacts of each on program integrity, healthy food choices, access to food and retailer operations:

1. Is ensuring that SNAP retailers provide SNAP clients access to healthy food choices a reasonable priority for establishing SNAP store eligibility criteria?

2. Are there store types that clearly meet all of the Program goals and, consequently, should always be eligible for SNAP participation?

3. Conversely, are there store types that do not effectively improve access to food choices (e.g. stores that sell low amounts of food when compared to the amounts of distilled liquor, tobacco and/or lottery tickets sold) and, therefore, should always be ineligible for SNAP participation?

4. Would a different definition of the ''staple foods [1]'' required in SNAP authorized stores help to ensure that these stores offer more healthy food choices? If so, what kinds of changes would be most effective? Specifically, almost all foods can be counted towards meeting staple food requirements, including those high in added sugar, sodium or solid fats. Should foods high in these components be counted as staple foods when determining store authorization requirements?

5. How should prepared foods with multiple ingredients, such as chicken pot pie or other frozen dinners, or single serving meat jerky packages, be treated with regards to ''staple foods'' categories?

6. Do twelve items (the minimum amount necessary to meet SNAP authorization criterion A, by virtue of needing three varieties in the four different staple food categories) provide adequate variety for a retailer to further the Program's purpose? If not, what would be a more appropriate requirement?

7. Currently, retailers who are authorized under criterion A are required to stock perishable items (e.g., fresh, frozen or refrigerated fruits and vegetables; dairy; meats, poultry and fish; bread or cereal) in two categories. Should perishable items be required in more than two categories?

8. Are 50 percent of sales in staple foods, as currently required for criterion B, sufficient to ensure that a SNAP authorized store furthers the program's purpose, given the current definition of ''staple foods''? Would this percentage be sufficient if the definition of ''staple foods'' is changed to exclude items high in added sugar, sodium or solid fats?

9. Should stores whose primary business (as evidenced by marketing, inventory or sales) is not the sale of food, be eligible to participate in SNAP?

10. Restaurants are generally prohibited from being SNAP retailers, and hot foods cannot be purchased with SNAP benefits. However, there are authorized retailers who primarily sell food for immediate consumption, often on premises, but also sell their products cold and heat them for SNAP recipients immediately after purchase for a nominal fee. These stores qualify today based on the array of raw ingredients, such as unbaked pizza or raw fish. Should such stores be eligible for participation in SNAP?

11. Should all retailers who meet SNAP eligibility criteria be authorized, even when sufficient store access for recipients is not a concern?

12. If store access were a concern in an area where no store meets basic eligibility criteria for SNAP authorization, how should FNS select the stores to authorize that best serve the needs of the client population? Should FNS employ an evaluation and scoring system? If so, what criteria should make up such a system?

13. How should integrity and management priorities be balanced against healthy food choice criteria in the SNAP authorization process? What elements could be used to assess integrity risks, and how should they be applied?

14. Are there any other ways in which the criteria for retailer eligibility should be changed? If so, how?

Dated: October 23, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[1] *Statutory, Regulatory and Policy Definitions of ''Food'', ''Staple Food'' and ''Accessory Food''*:

Food and Nutrition Act of 2008 7 U.S.C. 2012 Section 3 Definitions:

(k) *''Food'' means* (1) any food or food product for home consumption except alcoholic beverages, tobacco, and hot foods or hot food products ready for immediate consumption other than those authorized pursuant to clauses (3), (4), (5), (7), (8), and (9) of this subsection, (2) seeds and plants for use in gardens to produce food for the personal consumption of the eligible household, (3) in the case of those persons who are sixty years of age or over or who receive supplemental security income benefits or disability or blindness payments under title I, II, X, XIV, or XVI of the Social Security Act [(42 U.S.C. 1381 et seq.)], and their spouses, meals prepared by and served in senior citizens' centers, apartment buildings occupied primarily by such persons, public or private nonprofit establishments (eating or otherwise) that feed such persons, private establishments that contract with the appropriate agency of the State to offer meals for such persons at concessional prices, and meals prepared for and served to residents of federally subsidized housing for the elderly, (4) in the case of persons sixty years of age or over and persons who are physically or mentally handicapped or otherwise so disabled that they are unable adequately to prepare all of their meals, meals prepared for and delivered to them (and their spouses) at their home by a public or private nonprofit organization or by a private establishment that contracts with the appropriate State agency to perform such services at concessional prices, (5) in the case of narcotics addicts or alcoholics, and their children, served by drug addiction or alcoholic treatment and rehabilitation programs, meals prepared and served under such programs, (6) in the case of certain eligible households living in Alaska, equipment for procuring food by hunting and fishing, such as nets, hooks, rods, harpoons, and knives (but not equipment for purposes of transportation, clothing, or shelter, and not firearms, ammunition, and explosives) if the Secretary determines that such households are located in an area of the State where it is extremely difficult to reach stores selling food and that such households depend to a substantial extent upon hunting and fishing for subsistence, (7) in the case of disabled or blind recipients of benefits under title I, II, X, XIV, or XVI of the Social Security Act, or are 3–2 individuals described in paragraphs (2) through (7) of subsection (j), who are residents in a public or private nonprofit group living arrangement that serves no more than sixteen residents and is certified by the appropriate State agency or agencies under regulations issued under section 1616(e) of the Social Security Act or under standards determined by the Secretary to be comparable to standards implemented by appropriate State agencies under such section [(42 U.S.C. 1382e(e))], meals prepared

and served under such arrangement, (8) in the case of women and children temporarily residing in public or private nonprofit shelters for battered women and children, meals prepared and served, by such shelters, and (9) in the case of households that do not reside in permanent dwellings and households that have no fixed mailing addresses, meals prepared for and served by a public or private nonprofit establishment (approved by an appropriate State or local agency) that feeds such individuals and by private establishments that contract with the appropriate agency of the State to offer meals for such individuals at concessional prices.

(r)(1) Except as provided in paragraph (2), *''staple foods'' means* foods in the following categories:

(A) Meat, poultry, or fish.

(B) Bread or cereals.

(C) Vegetables or fruits.

(D) Dairy products.

(2) *''Staple foods'' do not includ*e accessory food items, such as coffee, tea, cocoa, carbonated and un-carbonated drinks, candy, condiments, and spices.

7 CFR Part 271 General Information and Definitions: Staple food means those food items intended for home preparation and consumption in each of the following food categories: Meat, poultry, or fish; bread or cereals; vegetables or fruits; and dairy products. Commercially processed foods and prepared mixtures with multiple ingredients shall only be counted in one staple food category. For example, foods such as cold pizza, macaroni and cheese, multi-ingredient soup, or frozen dinners, shall only be counted as one staple food item and will normally be included in the staple food category of the main ingredient as determined by FNS. Hot foods are not eligible for purchase with food stamps and, therefore, do not qualify as staple foods for the purpose of determining eligibility under § 278.1(b)(1) of this chapter. Accessory food items including, but not limited to, coffee, tea, cocoa, carbonated and un-carbonated drinks, candy, condiments, and spices shall not be considered staple foods for the purpose of determining eligibility of any firm. However, accessory foods that are offered for sale in authorized retail food stores are eligible food items which may be purchased with food stamp benefits.

USDA FNS Policy: ''*Accessory food* items include coffee, tea, cocoa, carbonated and un-carbonated drinks, candy, condiments and spices. *All foods not identified as accessory in the Act and regulations must be considered staple foods''.*

[FR Doc. 2013–25451 Filed 10–28–13; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2013–0003]

Availability of FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of a compliance guide to assist livestock slaughter establishments in complying with the regulatory requirements for humane handling and slaughter of livestock. FSIS encourages operators of livestock slaughter establishments to follow this guidance.

DATES: The Agency must receive comments by December 30, 2013.

ADDRESSES: A downloadable version of the compliance guide is available to view and print at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance.* No hard copies of the compliance guide have been published.

FSIS invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov/.* Follow the on-line instructions at that site for submitting comments.

Mail, including CD–ROMs, etc.: Send to Docket Room Manager, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163B, Washington, DC 20250–3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8–163B, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2013–0003. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205–0495, or by Fax: (202) 720–2025.

SUPPLEMENTARY INFORMATION: The Humane Methods of Slaughter Act (HMSA) of 1978 (7 U.S.C. 1901 et seq.) requires the use of humane methods for handling and slaughtering livestock. The HMSA states that ''the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions for persons engaged in the slaughtering industry; brings about improvement of products and economies in slaughtering operations; and produces other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce.''

The HMSA is referenced in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 603) and is implemented by FSIS humane handling and slaughter regulations found at 9 CFR part 313. Establishments are required to meet the humane handling and slaughter requirements in the regulations the entire time they hold livestock in connection with slaughter.

On September 9, 2004, FSIS announced that livestock slaughter establishments should implement and maintain a systematic approach to humane handling and slaughter to best ensure compliance with the HMSA, FMIA, and the implementing regulations (69 FR 54625). A systematic approach is a comprehensive way of evaluating how livestock enter and move through an establishment. The 2004 notice outlined four steps establishments should take to develop and maintain a systematic approach. The guidance summarizes these four steps and states that under a systematic approach, establishments should:

(1) Assess the ability of their livestock handling and slaughter practices to minimize distress and injury to livestock;

(2) Design facilities and implement handling practices that minimize distress and injury to livestock;

(3) Periodically evaluate facilities and handling methods to ensure that they continue to minimize distress and injury to livestock; and

(4) When necessary, modify facilities and handling methods to ensure that they continue to minimize distress and injury to livestock.

The guidance also explains that if an establishment takes this systematic approach and incorporates three additional features, FSIS would consider it a ''robust'' systematic approach. These three features are:

(1) The establishment develops written procedures that it will implement to stay in compliance with the regulations or to come back into compliance should it fail to implement the program as written or fail to prevent noncompliance;

(2) The establishment maintains written records that demonstrate that the program is being implemented as written, and that the program is effectively preventing identified potential noncompliances; and

(3) These written procedures and records are made available for FSIS review upon request.

FSIS believes developing a written plan is a step toward a robust systematic approach to humane handling because a written plan can effectively address the four aspects of a systematic approach.

The Agency has developed a compliance guide to assist establishments in developing, implementing, and maintaining a systematic approach to humane handling and slaughter of livestock to comply with the regulatory requirements. Although the guide sets out recommendations rather than requirements, FSIS encourages livestock slaughter establishments to follow this guidance. This guide represents FSIS's thinking, and FSIS will update it as necessary to reflect comments received any additional information that becomes available.

USDA Nondiscrimination Statement

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To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call (202) 720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register.*

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service.* Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on: October 23, 2013.

Alfred V. Almanza,

Administrator.

[FR Doc. 2013–25373 Filed 10–28–13; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Crescent Ranger District; Oregon; Withdrawal of Notice for Preparation of an Environmental Impact Statement for the Marsh Project

AGENCY: Forest Service, USDA.

ACTION: Notice of withdrawal.

SUMMARY: The Crescent Ranger District is withdrawing their intent to prepare an Environmental Impact Statement (EIS) for the Marsh project. The original Notice of Intent (NOI) was published in the **Federal Register** on April 26, 2013 (Vol. 78, No.81, p 24717–24718). The Forest Service has determined that an EIS is not required for this project as currently proposed and therefore, it was decided to document the project in an environmental assessment.

FOR FURTHER INFORMATION CONTACT: Tim Foley, Team Leader, Crescent Ranger District, P.O. Box 208, Crescent, Oregon, 97733, phone (541) 433–3200.

Dated: July 31, 2013.

Holly Jewkes,

Crescent District Ranger.

[FR Doc. 2013–25584 Filed 10–28–13; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972 (5 U.S.C. App. II) (FACA), and the Forest and Rangeland Renewable Resources Planning Act of 1974 (16 U.S.C. 1600 et seq.) (RPA), the National Forest Management Act of 1976 (16 U.S.C. 1612) (NFMA), and the Federal Public Lands Recreation Enhancement Act (Pub. L. 108–447) (REA).

The purpose of the Board is to provide advice and recommendations on a broad range of forest issues such as forest plan revisions or amendments and forest health, including fire and mountain pine beetle epidemics, travel management, forest monitoring and evaluation, recreation fees, and site-specific projects having forest-wide implications.

The meeting is open to the public. The purpose of the meeting is to: (1) To provide an orientation to the Board regarding Forest Funding, including appropriations and trends; (2) provide an update to the Board regarding Cave Management and White Nose Syndrome in Bats; and (3) discuss Motorized Travel Permit Fees.

DATES: The meeting will be held November 20, 2013, at 1:00 p.m.

ADDRESSES: The meeting will be held at the Forest Service Mystic Ranger District Office, 8221 South Highway 16, Rapid City SD. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Supervisor's Office, Black Hills National Forest, 1019 North Fifth Street, Custer, SD. Please call ahead to Scott Jacobson,

Committee Management Officer, at 605–673–9216, to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Scott Jacobson, Committee Management Officer, Black Hills National Forest Supervisor's Office, 605–673–9216, *sjjacobson@fs.fed.us.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The following business will be conducted: (1) Orientation to Forest Funding including appropriations and trends; (2) an update on Cave Management and White Nose Syndrome in Bats; and (3) a discussion regarding Motorized Trail Permit Fees. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by November 8, 2013, to be scheduled on the agenda. Written comments and time requests for oral comments must be sent to Scott Jacobson, Supervisor's Office, Black Hills National Forest, 1019 North Fifth Street, Custer, SD 57730, or by email to *sjjacobson@fs.fed.us,* or via facsimile to 605–673–9208. A summary of the meeting will be posted at *http://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees* within 45 days of the meeting.

Meeting Accommodations: If you require sign language interpreting, assistive listening devices, or other reasonable accommodation, please request this in advance of the meeting by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: October 23, 2013.

Dennis L. Jaeger,

Acting Forest Supervisor.

[FR Doc. 2013–25525 Filed 10–28–13; 8:45 am]

BILLING CODE 3410–11–P

APPALACHIAN STATES LOW-LEVEL RADIOACTIVE WASTE COMMISSION

Annual Meeting

Time and Date: 10 a.m.–12 p.m. October 31, 2013.

Place: Harrisburg Hilton and Towers, One North Second Street, Harrisburg, PA 17101.

Status: The meeting will be open to the public.

Matters To Be Considered:

Portions Open To The Public: The primary purpose of this meeting is to

(1) Review the independent auditors' report of Commission's financial statements for fiscal year 2012–2013; (2) Review the Low-Level Radioactive Waste (LLRW) generation information for 2012; (3) Consider a proposed budget for fiscal year 2014–2015; (4) Review recent regional and national developments regarding LLRW management and disposal; and (5) Elect the Commission's Officers.

Portions Closed To The Public: Executive Session, if deemed necessary, will be announced at the meeting.

Contact Person For More Information: Rich Janati, Administrator of the Commission, at 717–787–2163.

Rich Janati,

Administrator, Appalachian Compact Commission.

[FR Doc. 2013–25670 Filed 10–25–13; 11:15 am]

BILLING CODE 0000–00–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–916]

Laminated Woven Sacks From the People's Republic of China: Final Results of Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 1, 2013, the Department of Commerce (the ''Department'') initiated the first five-year (''sunset'') review of the antidumping duty order on laminated woven sacks from the People's Republic of China (''PRC'') pursuant to section 751(c) of the Tariff Act of 1930, as amended (the ''Act'').[1] As a result of this sunset review, the Department finds that revocation of the antidumping duty order on laminated woven sacks from the PRC would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: *Effective Date:* October 29, 2013.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6905.

SUPPLEMENTARY INFORMATION:

Background

On July 30, 2013, the Department received an adequate substantive response from domestic interested party Laminated Woven Sacks Committee (''Petitioner'') within the deadline specified in 19 CFR 351.218(d)(3)(i).[2] We received no responses from respondent interested parties. As a result, the Department conducted an expedited (120-day) sunset review of the order, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2).

Analysis of Comments Received

All issues raised in this sunset review are addressed in the ''Issues and Decision Memorandum for the Expedited First Sunset Review of the Antidumping Duty Order on Laminated woven sacks from the People's Republic of China'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, dated concurrently with, and hereby adopted by, this notice (''Decision Memorandum''). The issues discussed in the Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the order was to be revoked. Parties may find a complete discussion of all issues raised in the review and the corresponding recommendations in this public memorandum which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (''IA ACCESS''). Access to IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Decision Memorandum can be access directly on the Web at *http://ia.ita.doc.gov/frn.* The signed Decision Memorandum and the electronic versions of the Decision Memorandum are identical in content.

[1] *See Initiation of Five-Year (''Sunset'') Review,* 78 FR 39256 (July 1, 2013).

[2] *See* Petitioners' July 30, 2013, submission.

Scope of the Order

The merchandise covered by the order[3] is laminated woven sacks. Laminated woven sacks are bags or sacks consisting of one or more plies of fabric consisting of woven polypropylene strip and/or woven polyethylene strip, regardless of the width of the strip; with or without an extrusion coating of polypropylene and/or polyethylene on one or both sides of the fabric; laminated by any method either to an exterior ply of plastic film such as biaxially-oriented polypropylene (''BOPP'') or to an exterior ply of paper that is suitable for high quality print graphics.[4] Effective July 1, 2007, laminated woven sacks are classifiable under Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings 6305.33.0050 and 6305.33.0080. Laminated woven sacks were previously classifiable under HTSUS subheading 6305.33.0020.[5] The HTSUS subheadings are provided for convenience and customs purposes only; the written product description of the scope of the order is dispositive.

Final Results of Review

We determine that revocation of the order would be likely to lead to continuation or recurrence of dumping at the following weighted-average percentage margins:

Exporter	Weighted-average dumping margin (percent)
Zibo Aifudi Plastic Packaging Co., Ltd.	20.19
Polywell Plastic Product Factory	20.19
Zibo Linzi Worun Packing Product Co., Ltd.	20.19
Shandong Qikai Plastics Product Co., Ltd.	20.19
Changle Baodu Plastic Co. Ltd.	20.19
Zibo Linzi Shuaiqiang Plastics Co. Ltd.	20.19
Zibo Linzi Qitianli Plastic Fabric Co. Ltd.	20.19
Shandong Youlian Co. Ltd.	20.19
Zibo Linzi Luitong Plastic Fabric Co. Ltd.	20.19
Wenzhou Hotson Plastics Co. Ltd.	20.19
Jiangsu Hotson Plastics Co. Ltd.	20.19
Cangnan Color Make The Bag	20.19
Zibo Qigao Plastic Cement Co. Ltd.	20.19
PRC-Wide Entity (including Shandong Shouguang Jianyuanchun Co., Ltd. (''SSJ''); Han Shing Chemical Co., Ltd.; Ningbo Yong Feng Packaging Co., Ltd.; and Shandong Qilu Plastic Fabric Group, Ltd.)	47.64

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return of destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This sunset review and notice are in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: October 23, 2013.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2013–25601 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–DS–P

[3] *See Notice of Antidumping Duty Order: Laminated Woven Sacks From the People's Republic of China,* 73 FR 45941 (August 7, 2008) (''*Order*'').

[4] *See* Decision Memorandum for a complete description of the Scope of the Order.

[5] Additional HTSUS considerations apply. *See* Decision Memorandum.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–865]

Certain Hot-Rolled Carbon Steel Flat Products From the People's Republic of China: Final No Shipments Determination of Antidumping Duty Administrative Review; 2011–2012

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 15, 2013, the Department of Commerce (the ''Department'') published the *Preliminary Results* of the 2011–2012 administrative review of the antidumping duty order on certain hot-rolled carbon steel flat products (''hot-rolled steel'') from the People's Republic of China (''PRC'').[1] The period of review is November 1, 2011, through October 31, 2012. We received no comments from interested parties. Therefore, the Department continues to find that Baosteel Group Corporation, Shanghai Baosteel International Economic & Trading Co., Ltd., and Baoshan Iron and Steel Co., Ltd. (collectively, ''Baosteel'') had no reviewable transactions of subject merchandise to the United States during the POR.

DATES: *Effective Date:* October 29, 2013

FOR FURTHER INFORMATION CONTACT: Steven Hampton, AD/CVD Operations, Office 5, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington DC 20230; telephone (202) 482–0116.

SUPPLEMENTARY INFORMATION:

Background

On July 15, 2013, the Department published the *Preliminary Results* of the administrative review of the antidumping duty order on hot-rolled steel from the PRC. We invited interested parties to comment on the *Preliminary Results.* No party provided comments. The Department has conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (''the Act'').

[1] *See Certain Hot-Rolled Carbon Steel Flat Products From the People's Republic of China: Preliminary Results of 2011–2012 Antidumping Duty Administrative Review,* 78 FR 42039 (July 15, 2013) (''*Preliminary Results*'').

Scope of the Order

The products covered by the order are certain hot-rolled carbon steel flat products of a rectangular shape, of a width of 0.5 inch or greater, neither clad, plated, nor coated with metal and whether or not painted, varnished, or coated with plastics or other non-metallic substances, in coils (whether or not in successively superimposed layers), regardless of thickness, and in straight lengths of a thickness of less than 4.75 mm and of a width measuring at least 10 times the thickness. Universal mill plate (*i.e.,* flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 mm, but not exceeding 1,250 mm, and of a thickness of not less than 4.0 mm, not in coils and without patterns in relief) of a thickness not less than 4.0 mm is not included within the scope of the order. Specifically included within the scope of the order are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (''IF'')) steels, high strength low alloy (''HSLA'') steels, and the substrate for motor lamination steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium or niobium (also commonly referred to as columbium), or both, added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. Steel products included in the scope of the order, regardless of definitions in the Harmonized Tariff Schedule of the United States (''HTSUS''), are products in which: i) iron predominates, by weight, over each of the other contained elements; ii) the carbon content is two percent or less, by weight; and, iii) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

1.80 percent of manganese, or
2.25 percent of silicon, or
1.00 percent of copper, or
0.50 percent of aluminum, or
1.25 percent of chromium, or
0.30 percent of cobalt, or
0.40 percent of lead, or
1.25 percent of nickel, or
0.30 percent of tungsten, or
0.10 percent of molybdenum, or
0.10 percent of niobium, or
0.15 percent of vanadium, or
0.15 percent of zirconium.

All products that meet the physical and chemical description provided above are within the scope of the order unless otherwise excluded. The following products, for example, are outside or specifically excluded from the scope of the order:

- Alloy hot-rolled steel products in which at least one of the chemical elements exceeds those listed above (including, *e.g.,* American Society for Testing and Materials (''ASTM'') specifications A543, A387, A514, A517, A506).
- Society of Automotive Engineers (''SAE'')/American Iron & Steel Institute (''AISI'') grades of series 2300 and higher.
- Ball bearing steels, as defined in the HTSUS.
- Tool steels, as defined in the HTSUS.
- Silico-manganese (as defined in the HTSUS) or silicon electrical steel with a silicon level exceeding 2.25 percent.
- ASTM specifications A710 and A736.
- USS abrasion-resistant steels (USS AR 400, USS AR 500).
- All products (proprietary or otherwise) based on an alloy ASTM specification (sample specifications: ASTM A506, A507).
- Non-rectangular shapes, not in coils, which are the result of having been processed by cutting or stamping and which have assumed the character of articles or products classified outside chapter 72 of the HTSUS.

The merchandise subject to the order is classified in the HTSUS at subheadings: 7208.10.15.00, 7208.10.30.00, 7208.10.60.00, 7208.25.30.00, 7208.25.60.00, 7208.26.00.30, 7208.26.00.60, 7208.27.00.30, 7208.27.00.60, 7208.36.00.30, 7208.36.00.60, 7208.37.00.30, 7208.37.00.60, 7208.38.00.15, 7208.38.00.30, 7208.38.00.90, 7208.39.00.15, 7208.39.00.30, 7208.39.00.90, 7208.40.60.30, 7208.40.60.60, 7208.53.00.00, 7208.54.00.00, 7208.90.00.00, 7211.14.00.90, 7211.19.15.00, 7211.19.20.00, 7211.19.30.00, 7211.19.45.00, 7211.19.60.00, 7211.19.75.30, 7211.19.75.60, and 7211.19.75.90. Certain hot-rolled carbon steel flat products covered by the order, including: vacuum degassed fully stabilized; high strength low alloy; and the substrate for motor lamination steel may also enter under the following tariff numbers: 7225.11.00.00, 7225.19.00.00, 7225.30.30.50, 7225.30.70.00, 7225.40.70.00, 7225.99.00.90, 7226.11.10.00, 7226.11.90.30, 7226.11.90.60, 7226.19.10.00, 7226.19.90.00, 7226.91.50.00, 7226.91.70.00, 7226.91.80.00, and 7226.99.00.00. Subject merchandise may also enter under 7210.70.30.00, 7210.90.90.00, 7211.14.00.30, 7212.40.10.00, 7212.40.50.00, and 7212.50.00.00. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Final Determination of No Shipments

In the *Preliminary Results,* the Department preliminarily determined that Baosteel did not have any reviewable transactions of subject merchandise during the POR because there was no evidence on the record indicating that Baosteel had entries of subject merchandise during the POR.[2] We stated, consistent with the refinement to the Department's assessment practice in non-market economy (''NME'') cases, that we would not to rescind the review in these circumstances but, rather, would complete the review with respect to Baosteel and issue appropriate instructions to U.S. Customs and Border Protection (''CBP'') based on the final results of the review.[3] As stated above, we did not receive any comments on our *Preliminary Results.* Therefore, we continue to determine that Baosteel had no reviewable transactions of subject merchandise during the POR. Consistent with our ''automatic assessment'' clarification, the Department will issue appropriate instructions to CBP based on our final results.[4]

Assessment

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. The Department announced a refinement to its assessment practice in NME cases.[5] Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the NME-wide rate. In addition, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case

[2] *See Preliminary Results,* 78 FR at 42040.

[3] *Id.*

[4] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) (''*Assessment Practice Refinement''*); *see also* the ''Assessment'' section of this notice, below.

[5] *See* Assessment Practice Refinement.

number (*i.e.,* at that exporter's rate) will be liquidated at the NME-wide rate.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 90.83 percent; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to the administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results and this notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: October 23, 2013.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2013–25594 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–850]

Certain Large Diameter Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Over 4½ Inches) From Japan: Final Results of Antidumping Duty Administrative Review; 2011–2012

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 10, 2013, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain large diameter carbon and alloy seamless standard, line, and pressure pipe (over 4½ inches) from Japan. For these final results, we continue to find that no shipments were made by JFE Steel Corporation (JFE), Nippon Steel Corporation (Nippon), NKK Tubes (NKK), or Sumitomo Metal Industries, Ltd. (SMI), and that entries of subject merchandise made by Canadian Natural Resources Limited (CNRL) should be liquidated without regard to antidumping duties.

DATES: *Effective Date:* October 29, 2013.

FOR FURTHER INFORMATION CONTACT: Nancy Decker or Joshua Morris, AD/CVD Operations, Office 1, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0196, and (202) 482–1779, respectively.

Background

On July 10, 2013, the Department published the preliminary results of the administrative review of the antidumping duty order on certain large diameter carbon and alloy seamless standard, line, and pressure pipe (over 4½ inches) from Japan.[1] We invited interested parties to comment on the *Preliminary Results.* We received no comments.

The Department has conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the order are large diameter seamless carbon and alloy (other than stainless) steel standard, line, and pressure pipes produced, or equivalent, to the American Society for Testing and Materials (ASTM) A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, and the American Petroleum Institute (API) 5L specifications and meeting the physical parameters described below, regardless of application. The scope of the order also includes all other products used in standard, line, or pressure pipe applications and meeting the physical parameters described below, regardless of specification, with the exception of the exclusions discussed below. Specifically included within the scope of the order are seamless pipes greater than 4.5 inches (114.3 mm) up to and including 16 inches (406.4 mm) in outside diameter, regardless of wall-thickness, manufacturing process (hot finished or cold-drawn), end finish (plain end, beveled end, upset end, threaded, or threaded and coupled), or surface finish.

The seamless pipes subject to the order are currently classifiable under the subheadings 7304.10.10.30, 7304.10.10.45, 7304.10.10.60, 7304.10.50.50, 7304.19.10.30, 7304.19.10.45, 7304.19.10.60, 7304.19.50.50, 7304.31.60.10, 7304.31.60.50, 7304.39.00.04, 7304.39.00.06, 7304.39.00.08, 7304.39.00.36, 7304.39.00.40, 7304.39.00.44, 7304.39.00.48, 7304.39.00.52, 7304.39.00.56, 7304.39.00.62, 7304.39.00.68, 7304.39.00.72, 7304.51.50.15, 7304.51.50.45, 7304.51.50.60, 7304.59.20.30, 7304.59.20.55, 7304.59.20.60, 7304.59.20.70, 7304.59.60.00, 7304.59.80.30, 7304.59.80.35, 7304.59.80.40, 7304.59.80.45, 7304.59.80.50, 7304.59.80.55, 7304.59.80.60, 7304.59.80.65, and 7304.59.80.70 of the Harmonized Tariff Schedule of the United States (HTSUS).

Specifications, Characteristics, and Uses: Large diameter seamless pipe is used primarily for line applications such as oil, gas, or water pipeline, or utility distribution systems. Seamless pressure pipes are intended for the conveyance of water, steam, petrochemicals, chemicals, oil products,

[1] *See Certain Large Diameter Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Over 4 ½ Inches) From Japan: Preliminary Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 41366 (July 10, 2013) and accompanying Decision Memorandum (*Preliminary Results*).

natural gas and other liquids and gasses in industrial piping systems. They may carry these substances at elevated pressures and temperatures and may be subject to the application of external heat. Seamless carbon steel pressure pipe meeting the ASTM A–106 standard may be used in temperatures of up to 1000 degrees Fahrenheit, at various American Society of Mechanical Engineers (ASME) code stress levels. Alloy pipes made to ASTM A–335 standard must be used if temperatures and stress levels exceed those allowed for ASTM A–106. Seamless pressure pipes sold in the United States are commonly produced to the ASTM A–106 standard.

Seamless standard pipes are most commonly produced to the ASTM A–53 specification and generally are not intended for high temperature service. They are intended for the low temperature and pressure conveyance of water, steam, natural gas, air and other liquids and gasses in plumbing and heating systems, air conditioning units, automatic sprinkler systems, and other related uses. Standard pipes (depending on type and code) may carry liquids at elevated temperatures but must not exceed relevant ASME code requirements. If exceptionally low temperature uses or conditions are anticipated, standard pipe may be manufactured to ASTM A–333 or ASTM A–334 specifications.

Seamless line pipes are intended for the conveyance of oil and natural gas or other fluids in pipe lines. Seamless line pipes are produced to the API 5L specification. Seamless water well pipe (ASTM A–589) and seamless galvanized pipe for fire protection uses (ASTM A–795) are used for the conveyance of water.

Seamless pipes are commonly produced and certified to meet ASTM A–106, ASTM A–53, API 5L–B, and API 5L–X42 specifications. To avoid maintaining separate production runs and separate inventories, manufacturers typically triple or quadruple certify the pipes by meeting the metallurgical requirements and performing the required tests pursuant to the respective specifications. Since distributors sell the vast majority of this product, they can thereby maintain a single inventory to service all customers.

The primary application of ASTM A–106 pressure pipes and triple or quadruple certified pipes in large diameters is for use as oil and gas distribution lines for commercial applications. A more minor application for large diameter seamless pipes is for use in pressure piping systems by refineries, petrochemical plants, and chemical plants, as well as in power generation plants and in some oil field uses (on shore and off shore) such as for separator lines, gathering lines and metering runs. These applications constitute the majority of the market for the subject seamless pipes. However, ASTM A–106 pipes may be used in some boiler applications.

The scope of the order includes all seamless pipe meeting the physical parameters described above and produced to one of the specifications listed above, regardless of application, with the exception of the exclusions discussed below, whether or not also certified to a non-covered specification. Standard, line, and pressure applications and the above-listed specifications are defining characteristics of the scope of the order. Therefore, seamless pipes meeting the physical description above, but not produced to the ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, and API 5L specifications shall be covered if used in a standard, line, or pressure application, with the exception of the specific exclusions discussed below.

For example, there are certain other ASTM specifications of pipe which, because of overlapping characteristics, could potentially be used in ASTM A–106 applications. These specifications generally include ASTM A–161, ASTM A–192, ASTM A–210, ASTM A–252, ASTM A–501, ASTM A–523, ASTM A–524, and ASTM A–618. When such pipes are used in a standard, line, or pressure pipe application, such products are covered by the scope of the order.

Specifically excluded from the scope of the order are:

A. Boiler tubing and mechanical tubing, if such products are not produced to ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, and API 5L specifications and are not used in standard, line, or pressure pipe applications.

B. Finished and unfinished oil country tubular goods (OCTG), if covered by the scope of another antidumping duty order from the same country. If not covered by such an OCTG order, finished and unfinished OCTG are included in the scope when used in standard, line or pressure applications.

C. Products produced to the A–335 specification unless they are used in an application that would normally utilize ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, and API 5L specifications.

D. Line and riser pipe for deepwater application, *i.e.,* line and riser pipe that is: (1) Used in a deepwater application, which means for use in water depths of 1,500 feet or more; (2) intended for use in and is actually used for a specific deepwater project; (3) rated for a specified minimum yield strength of not less than 60,000 psi; and (4) not identified or certified through the use of a monogram, stencil, or otherwise marked with an API specification (*e.g.,* API 5L).

With regard to the excluded products listed above, the Department will not instruct U.S. Customs and Border Protection (CBP) to require end-use certification until such time as petitioner or other interested parties provide to the Department a reasonable basis to believe or suspect that the products are being utilized in a covered application. If such information is provided, we will require end-use certification only for the product(s) (or specification(s)) for which evidence is provided that such products are being used in a covered application as described above. For example, if, based on evidence provided by petitioner, the Department finds a reasonable basis to believe or suspect that seamless pipe produced to the A–335 specification is being used in an A–106 application, we will require end-use certifications for imports of that specification. Normally we will require only the importer of record to certify to the end use of the imported merchandise. If it later proves necessary for adequate implementation, we may also require producers who export such products to the United States to provide such certification on invoices accompanying shipments to the United States.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the merchandise subject to the scope is dispositive.

Final Results of Review

We have made no changes to our findings announced in the *Preliminary Results.* Consistent with our findings in the *Preliminary Results,*[2] we find that JFE, Nippon, NKK, and SMI had no shipments for the period June 1, 2011, through May 31, 2012.

Also consistent with the *Preliminary Results,*[3] we find that CNRL had no sales to unaffiliated customers in the United States, or to unaffiliated customers for exportation to the United States. Although CNRL entered subject

[2] *See Preliminary Results* and accompanying Decision Memorandum at 6–8.

[3] *Id.* at 8–13.

merchandise for consumption during the period of review (POR), the merchandise was not sold in any form, either in the form as entered or as further manufactured; it was exported back to CNRL in Canada. As a result, consistent with our decision in *OCTG from Japan,*[4] antidumping duties would not be applied to CNRL's subject merchandise under current law and practice. Accordingly, we will instruct CBP to liquidate the entries at issue without regard to antidumping duties.

Assessment Rates

Because we found that CNRL did not sell subject merchandise to an unaffiliated customer in the United States, or to unaffiliated customers for exportation to the United States, but exported all the subject merchandise back to CNRL in Canada we will instruct CBP to liquidate its entries covered by this review without regard to antidumping duties.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to POR entries by JFE, Nippon, NKK, and SMI because these companies certified that they made no POR shipments of subject merchandise for which they had knowledge of U.S. destination and we are making a final determination of no shipments. We will instruct CBP to liquidate these entries at the all-others rate established in the less-than-fair-value investigation (68.88 percent) if there is no rate for the intermediary involved in the transaction. For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results and this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: October 23, 2013.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2013–25603 Filed 10–28–13; 8:45 am]

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[4] In *OCTG from Japan,* the subject merchandise entered the United States under a temporary import bond. Upon re-exportation, pursuant to the North American Free Trade Agreement, the entries were treated as if they had entered the United States for consumption. The Department determined that the subject merchandise was not sold in any form, and liquidated without regard to duties. *See Oil Country Tubular Goods From Japan: Preliminary Results and Rescission {sic} in Part of Antidumping Duty Administrative Review,* 64 FR 48589, 48590–91 (September 7, 1999) (*OCTG from Japan*).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–857]

Welded Large Diameter Line Pipe From Japan: Continuation of Antidumping Duty Order

AGENCY: Enforcement and Compliance, Formerly Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (the Department) and the U.S. International Trade Commission (USITC) that revocation of the antidumping duty order on welded large diameter line pipe (LDLP) from Japan would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation of this antidumping duty order.

DATES: *Effective Date:* October 29, 2013.

FOR FURTHER INFORMATION CONTACT: John Drury or Angelica Mendoza, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0195 and (202) 482–3019, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 6, 2001, the Department published the antidumping duty order on LDLP from Japan.[1] On October 1, 2012, the Department initiated the second sunset review of the antidumping duty order on LDLP from Japan pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2]

As a result of this sunset review, the Department determined that revocation of the antidumping duty order on LDLP from Japan would likely lead to continuation or recurrence of dumping and, therefore, notified the USITC of the magnitude of the margins likely to prevail should the order be revoked.[3]

On October 2, 2013, the USITC determined, pursuant to section 751(c) of the Act, that revocation of the antidumping duty order on LDLP from Japan would be likely to lead to a continuation or recurrence of material injury to an industry in the United Sates within a reasonably foreseeable time.[4]

Scope of the Order

The product covered by this order is certain welded carbon and alloy line pipe, of circular cross section and with an outside diameter greater than 16 inches, but less than 64 inches, in diameter, whether or not stenciled. This product is normally produced according to American Petroleum Institute (API) specifications, including Grades A25, A, B, and X grades ranging from X42 to X80, but can also be produced to other specifications. The product currently is classified under U.S. Harmonized Tariff Schedule (HTSUS) item numbers 7305.11.10.30, 7305.11.10.60, 7305.11.50.00, 7305.12.10.30, 7305.12.10.60, 7305.12.50.00, 7305.19.10.30. 7305.19.10.60, and 7305.19.50.00. Although the HTSUS item numbers are provided for

[1] *See Antidumping Duty Order: Welded Large Diameter Line Pipe from Japan,* 66 FR 63368 (December 6, 2001).

[2] *See Initiation of Five-Year (''Sunset'') Review,* 77 FR 59897 (October 1, 2012).

[3] *See Welded Large Diameter Line Pipe From Japan: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order,* 78 FR 10134 (February 13, 2013).

[4] *See LDLP from Japan,* 78 FR 60897 (October 2, 2013), and USITC Publication 4427 (September 2013). As explained in the memorandum from the Assistant Secretary for Enforcement and Compliance, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 1, through October 16, 2013. *See* Memorandum for the Record from Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Shutdown of the Federal Government'' (October 18, 2013). Therefore, all deadlines in this segment of the proceeding have been extended by 16 days. As a result, this notice of continuation of the order is timely.

convenience and customs purposes, the written description of the scope is dispositive. Specifically not included within the scope of this investigation is American Water Works Association (AWWA) specification water and sewage pipe and the following size/grade combinations; of line pipe:

Having an outside diameter greater than or equal to 18 inches and less than or equal to 22 inches, with a wall thickness measuring 0.750 inch or greater, regardless of grade.

Having an outside diameter greater than or equal to 24 inches and less than 30 inches, with wall thickness measuring greater than 0.875 inches in grades A, B, and X42, with wall thickness measuring greater than 0.750 inches in grades X52 through X56, and with wall thickness measuring greater than 0.688 inches in grades X60 or greater.

Having an outside diameter greater than or equal to 30 inches and less than 36 inches, with wall thickness measuring greater than 1.250 inches in grades A, B, and X42, with wall thickness measuring greater than 1.000 inches in grades X52 through X56, and with wall thickness measuring greater than 0.875 inches in grades X60 or greater.

Having an outside diameter greater than or equal to 36 inches and less than 42 inches, with wall thickness measuring greater than 1.375 inches in grades A, B, and X42, with wall thickness measuring greater than 1.250 inches in grades X52 through X56, and with wall thickness measuring greater than 1.125 inches in grades X60 or greater.

Having an outside diameter greater than or equal to 42 inches and less than 64 inches, with a wall thickness measuring greater than 1.500 inches in grades A, B, and X42, with wall thickness measuring greater than 1.375 inches in grades X52 through X56, and with wall thickness measuring greater than 1.250 inches in grades X60 or greater.

Having an outside diameter equal to 48 inches, with a wall thickness measuring 1.0 inch or greater, in grades X–80 or greater.

In API grades X80 or above, having an outside diameter of 48 inches to and including 52 inches, and with a wall thickness of 0.90 inch or more.

In API grades X100 or above, having an outside diameter of 48 inches to and including 52 inches, and with a wall thickness of 0.54 inch or more.

An API grade X–80 having an outside diameter of 21 inches and wall thickness of 0.625 inch or more.

Continuation of the Order

As a result of the determinations by the Department and the USITC that revocation of the antidumping duty order on LDLP from Japan would be likely to lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping duty order on LDLP from Japan.

U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of this order will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next sunset review of this order not later than 30 days prior to the fifth anniversary of the effective date of continuation.

This five-year (sunset) review and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: October 23, 2013.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2013–25607 Filed 10–28–13; 8:45 am]

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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 130909789–3789–01]

Request for Comments on the Preliminary Cybersecurity Framework

AGENCY: National Institute of Standards and Technology (NIST), Department of Commerce.

ACTION: Notice; request for comments.

SUMMARY: The National Institute of Standards and Technology (NIST) seeks comments on the preliminary version of the Cybersecurity Framework (''preliminary Framework''). The preliminary Framework was developed by NIST using information collected through the Request for Information (RFI) that was published in the **Federal Register** on February 26, 2013, and a series of open public workshops. The preliminary Framework was developed in response to NIST responsibilities directed in Executive Order 13636, ''Improving Critical Infrastructure Cybersecurity'' (''Executive Order''). Under the Executive Order, the Secretary of Commerce is tasked to direct the Director of NIST to lead the development of a framework to reduce cyber risks to critical infrastructure (the ''Cybersecurity Framework'' or ''Framework''). The Framework will consist of standards, methodologies, procedures and processes that align policy, business, and technological approaches to address cyber risks. The preliminary Framework is available electronically from the NIST Web site at: *http://www.nist.gov/itl/cyberframework.cfm.*

DATES: Comments must be received by 5:00 p.m. Eastern Time December 13, 2013.

ADDRESSES: Both written and electronic comments should be submitted using the comment template form available electronically from the NIST Web site at: *http://www.nist.gov/itl/cyberframework.cfm.* Written comments concerning the preliminary Framework may be sent to: Information Technology Laboratory, ATTN: Adam Sedgewick, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930. Electronic comments concerning the preliminary Framework should be submitted in Microsoft Word or Excel formats to: *csfcomments@nist.gov,* with the Subject line: Preliminary Cybersecurity Framework Comments.

The preliminary Cybersecurity Framework is available electronically from the NIST Web site at: *http://www.nist.gov/itl/cyberframework.cfm.*

FOR FURTHER INFORMATION CONTACT: Diane Honeycutt, telephone: 301–975–8443, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930 or via email: *dhoneycutt@nist.gov.* Please direct media inquiries to NIST's Public Affairs Office at (301) 975–NIST.

SUPPLEMENTARY INFORMATION: The national and economic security of the United States depends on the reliable functioning of critical infrastructure,[1] which has become increasingly dependent on information technology. Recent trends demonstrate the need for improved capabilities for defending against malicious cyber activity. Such activity is increasing, and its consequences can range from theft through disruption to destruction. Steps

[1] For the purposes of this notice the term ''critical infrastructure'' has the meaning given the term in 42 U.S.C 5195c(e), ''systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters.''

must be taken to enhance existing efforts to increase the protection and resilience of this infrastructure, while maintaining a cyber environment that encourages efficiency, innovation, and economic prosperity, while protecting privacy and civil liberties.

Under the Executive Order,[2] the Secretary of Commerce is tasked to direct the Director of NIST to lead the development of a framework to reduce cyber risks to critical infrastructure (the ''Cybersecurity Framework'' or ''Framework''). The Cybersecurity Framework will consist of standards, methodologies, procedures and processes that align policy, business, and technological approaches to address cyber risks. Given the diversity of sectors in critical infrastructure, the Framework development process was designed to initially identify cross-sector security standards and guidelines that are immediately applicable or likely to be applicable to critical infrastructure, to increase visibility and adoption of those standards and guidelines, and to find potential areas for improvement (i.e., where standards/guidelines are nonexistent or where existing standards/guidelines are inadequate) that need to be addressed through future collaboration with industry and industry-led standards bodies. The Cybersecurity Framework will incorporate voluntary consensus standards and industry best practices to the fullest extent possible and will be consistent with voluntary international consensus-based standards when such international standards advance the objectives of the Executive Order. The Cybersecurity Framework will be designed for compatibility with existing regulatory authorities and regulations.

The Cybersecurity Framework will provide a prioritized, flexible, repeatable, performance-based, and cost-effective approach, including information security measures and controls to help owners and operators of critical infrastructure and other interested entities to identify, assess, and manage cybersecurity-related risk while protecting business confidentiality, individual privacy and civil liberties. To enable technical innovation and account for organizational differences, the Cybersecurity Framework will not prescribe particular technological solutions or specifications. It will include guidance for measuring the performance of an entity in implementing the Cybersecurity Framework and will include methodologies to identify and mitigate impacts of the Framework and associated information security measures and controls on business confidentiality and to protect individual privacy and civil liberties.

As a non-regulatory Federal agency, NIST developed the preliminary Framework in a manner that is consistent with its mission to promote U.S. innovation and industrial competitiveness through the development of standards and guidelines in consultation with stakeholders in both government and industry. The preliminary Framework seeks to provide owners and operators of critical infrastructure the ability to implement security practices in the most effective manner while allowing organizations to express requirements to multiple authorities and regulators. Issues relating to harmonization of existing relevant standards and integration with existing frameworks were also considered. While the focus is on the Nation's critical infrastructure, the preliminary Framework was developed in a manner to promote wide adoption of practices to increase cybersecurity across all sectors and industry types.

The preliminary Framework was developed through an open public review and comment process that included information collected through Request for Information (RFI), 78 FR 13024 (February 26, 2013), and a series of public workshops. Comments received in response to the RFI are available at *http://csrc.nist.gov/cyberframework/rfi_comments.html.*

NIST held four open public workshops to provide the public with additional opportunities to provide input. The first workshop was conducted on April 3, 2013, at the Department of Commerce in Washington, DC The second workshop was conducted on May 29–31, 2013, at Carnegie Mellon University in Pittsburgh, Pennsylvania. The third workshop was conducted on July 10–12, 2013, at the University of California, San Diego. The fourth workshop was conducted on September 11–13, 2013, at the University of Texas at Dallas. Agenda, discussion materials, and presentation slides for each of these workshops are available at *http://www.nist.gov/itl/cyberframework.cfm.*

Throughout the process, NIST issued public updates on the development of the Cybersecurity Framework. NIST issued the first update on June 18, 2013, and it is available at *http://www.nist.gov/itl/upload/nist_cybersecurity_framework_update_061813.pdf.* NIST issued the second update on July 24, 2013, and it is available at *http://www.nist.gov/itl/upload/NIST-Cybersecurity-Framework-Update-072413.pdf.*

The preliminary Framework incorporates existing consensus-based standards to the fullest extent possible, consistent with requirements of the National Technology Transfer and Advancement Act of 1995,[3] and guidance provided by Office of Management and Budget Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.''[4] Principles articulated in the Executive Office of the President memorandum M–12–08 ''Principles for Federal Engagement in Standards Activities to Address National Priorities''[5] are followed. The preliminary Framework is also consistent with, and supported by the broad policy goals of, the Administration's 2010 ''National Security Strategy,''[6] 2011 ''Cyberspace Policy Review,''[7] ''International Strategy for Cyberspace''[8] of May 2011 and HSPD–7 ''Critical Infrastructure Identification, Prioritization, and Protection.''[9]

Request for Comments:

NIST seeks public comments on the preliminary Cybersecurity Framework. The draft report is available electronically from the NIST Web site at: *http://www.nist.gov/itl/cyberframework.cfm.* The comment templates are available at the same address, and are required for both written and electronic comments. Interested parties should submit comments in accordance with the **DATES** and **ADDRESSES** sections of this notice. All comments will be posted at *http://csrc.nist.gov/cyberframework/preliminary_framework_comments.html* without change or redaction, so commenters should not include information they do not wish to be posted (e.g., personal or business information).

[2] Exec. Order No. 13636, Improving Critical Infrastructure Cybersecurity, 78 FR 11739 (February 19, 2013).

[3] Public Law 104–113 (1996), codified in relevant part at 15 U.S.C. 272(b).

[4] *http://www.whitehouse.gov/omb/circulars_a119.*

[5] *http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf.*

[6] *http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf.*

[7] *http://www.whitehouse.gov/assets/documents/Cyberspace_Policy_Review_final.pdf.*

[8] *http://www.whitehouse.gov/sites/default/files/rss_viewer/international_strategy_for_cyberspace.pdf.*

[9] *http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy04/m-04-15.pdf.*

Dated: October 23, 2013.

Patrick Gallagher,

Under Secretary of Commerce for Standards and Technology.

[FR Doc. 2013–25566 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC866

Fisheries of the Northeast Region

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of a determination of overfishing or an overfished condition.

SUMMARY: This action serves as a notice that NMFS, on behalf of the Secretary of Commerce (Secretary), has determined that Georges Bank (GB) cod and Gulf of Maine (GOM) cod are subject to overfishing and continue to be in an overfished condition.

NMFS, on behalf of the Secretary, notifies the appropriate fishery management council (Council) whenever it determines that overfishing is occurring, a stock is in an overfished condition, a stock is approaching an overfished condition, or when a rebuilding plan has not resulted in adequate progress toward ending overfishing and rebuilding affected fish stocks.

FOR FURTHER INFORMATION CONTACT: Mark Nelson, (301) 427–8565.

SUPPLEMENTARY INFORMATION: Pursuant to sections 304(e)(2) and (e)(7) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1854(e)(2) and (e)(7), and implementing regulations at 50 CFR 600.310(e)(2), NMFS, on behalf of the Secretary, must notify Councils whenever it determines that a stock or stock complex is: overfished; approaching an overfished condition; or an existing rebuilding plan has not ended overfishing or resulted in adequate rebuilding progress. NMFS also notifies Councils when it determines a stock or stock complex is subject to overfishing. Section 304(e)(2) further requires NMFS to publish these notices in the **Federal Register**.

The 2013 Stock Assessment Workshop (SAW) 55, showed that overfishing was occurring on both Georges Bank cod and Gulf of Maine cod, and that both stocks remain in an overfished condition. The New England Fishery Management Council has been notified of the results of SAW 55 and has taken action to end overfishing and rebuild these two stocks through Framework 48.

Dated: October 18, 2013.

Emily H. Menashes,

Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–25605 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC938

New England Fishery Management Council (NEFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scientific and Statistical Committee (SSC) on November 15, 2013 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Friday, November 15, 2013 at 8:30 a.m.

ADDRESSES: *Meeting address:* The meeting will be held at the Omni Hotel, 1 West Exchange Street, Providence, RI 02903; telephone: (401) 598–8000; fax: (401) 598–8200.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The NEFMC's Scientific and Statistical Committee (SSC) will meet to specify overfishing levels (OFLs) and develop Acceptable Biological Catch (ABC) recommendations for Atlantic sea scallops for fishing years 2014 and 2015 (default) and for the Northeast Skate Complex for fishing years 2014 through 2016. The Committee will consider information provided to it by the Council's Scallop Plan Development Team (PDT) and by the Skate PDT. The Committee will also review the 2012 update assessment for Gulf of Maine (GOM) haddock and the work of the Groundfish PDT in order to reconsider ABC and OFL for GOM haddock for fishing years 2013–15.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 24, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–25569 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC939

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scallop Committee on November 14, 2013 to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, November 14, 2013 at 9 a.m.

ADDRESSES: *Meeting address:* The meeting will be held at the Omni Providence Hotel, 1 West Exchange Street, Providence, RI 02048; telephone: (401) 598–8000; fax: (401) 598–8200.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION: The Committee will continue development of potential alternatives for FY2014 and FY2015 (default) specifications being considered in Framework 25. Specifications include days-at-sea allocations, access area allocations, individual fishing quota (IFQ) allocations for the general category fishery, a hard total allowable catch (TAC) for the Northern Gulf of Maine (NGOM) area and target TAC for vessels with a general category incidental catch permit. The Committee will also finalize other measures being considered: (1) Measures for unused 2012 and 2013 Closed Area I access area trips; and (2) accountability measures for Southern New England/Mid Atlantic (SNE/MA) windowpane flounder. The Committee will make final recommendations for the Council to consider for 2014 Council work priorities. Finally, there will be a presentation from the Northeast Regional Ocean Council (NROC) about regional ocean planning efforts, specifically fishing characterization maps that have been developed. Other issues may be discussed.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 24, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–25570 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Climate Assessment and Development Advisory Committee (NCADAC)

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: This notice sets forth the schedule of a forthcoming meeting of the DoC NOAA National Climate Assessment and Development Advisory Committee (NCADAC).

Time and Date: The meeting will be held Monday, November 18, 2013 from 3:15 p.m.–5:00 p.m. Eastern time.

Place: This meeting will be a conference call. Public access and materials will be available at the office of the U.S. Global Change Research Program, Conference Room A, Suite 250, 1717 Pennsylvania Avenue NW., Washington, DC 20006. The public will not be able to dial into the call. Please check the National Climate Assessment Web site for additional information at *http://www.globalchange.gov/what-we-do/assessment.*

Status: The meeting will be open to public participation with a 5-minute public comment period from 4:45–4:55 p.m. The NCADAC expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of two minutes. Written comments should be received in the NCADAC DFO's office by Wednesday, November 13, 2013 to provide sufficient time for NCADAC review. Written comments received by the NCADAC DFO after Wednesday, November 13, 2013 will be distributed to the NCADAC, but may not be reviewed prior to the meeting date.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for special accommodations may be directed no later than 12 p.m. on Wednesday, November 13, 2013 to Dr. Cynthia Decker, SAB Executive Director, SSMC3, Room 11230, 1315 East-West Hwy., Silver Spring, MD 20910.

Matters To Be Considered: Please refer to the Web page *http://www.nesdis.noaa.gov/NCADAC/Meetings.html* for the most up-to-date meeting agenda, when available.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Designated Federal Officer, National Climate Assessment and Development Advisory Committee, NOAA, Rm. 11230, 1315 East-West Highway, Silver Spring, Maryland 20910. (Phone: 301–734–1156, Fax: 301–713–1459, Email: *Cynthia.Decker@noaa.gov.*

SUPPLEMENTARY INFORMATION: The National Climate Assessment and Development Advisory Committee was established in December 2010. The committee's mission is to synthesize and summarize the science and information pertaining to current and future impacts of climate change upon the United States; and to provide advice and recommendations toward the development of an ongoing, sustainable national assessment of global change impacts and adaptation and mitigation strategies for the Nation. Within the scope of its mission, the committee's specific objective is to produce a National Climate Assessment.

Dated: October 23, 2013.

Jason Donaldson,

Chief Financial Officer/Chief Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2013–25608 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC371

Marine Mammals; Issuance of Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permits.

SUMMARY: Notice is hereby given that six individuals and institutions have been issued Letters of Confirmation for activities conducted under the General Authorization for Scientific Research on marine mammals. See **SUPPLEMENTARY INFORMATION** for a list of names and address of recipients.

ADDRESSES: The Letters of Confirmation and related documents are available for review upon written request or by appointment in the following office:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)427–8401; fax (301)713–0376.

FOR FURTHER INFORMATION CONTACT: Office of Protected Resources, Permits and Conservation Division, (301)427–8401.

SUPPLEMENTARY INFORMATION: The requested Letters of Confirmation have been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216). The General Authorization allows for bona fide scientific research that may result only in taking by level B harassment of marine mammals. The following Letters of Confirmation (LOC) were issued in Fiscal Year 2013.

File No. 17235: Issued to the Virginia Aquarium and Marine Science Center, Virginia Beach, VA on November 21, 2012, authorizes close approach, photo-identification, video, behavioral observations, and passive acoustic recordings of 17 cetacean species and 4 pinniped species in inland and offshore waters of Maryland, Virginia, and North Carolina. The focus species is bottlenose dolphins (*Tursiops truncatus*) and the primary study area is off Virginia Beach. Objectives for the bottlenose dolphin project are to: (1) Collect and maintain a long-term record of bottlenose dolphins in coastal waters of Virginia and (2) provide data to the Mid-Atlantic Bottlenose Dolphin Catalog to test the hypothesized stock structure for this species. Other objectives include to: (1) Collect distribution, group size, and photo-id data on cetaceans and pinnipeds in the larger study area and (2) identify and monitor pinniped haul out sites in Virginia and North Carolina and to track the abundance and residency of individual seals. The LOC expires on November 30, 2017.

File No. 17418: Issued to James Ha, Ph.D., University of Washington, Seattle, WA on February 19, 2013, authorizes close approach, photo-identification, behavioral observations, and focal follows of bottlenose dolphins in the Middle Keys, Florida. Specifically, the study area ranges from Lignumvitae Key to the northeast shore of Big Pine Key and includes bay and ocean waters out to two miles. Objectives are to: (1) Begin an in-depth population demographic study of bottlenose dolphins in the area and (2) identify foraging strategies and determine what percentage of resident dolphins is influenced by anthropogenic sources of food. The LOC was originally supposed to expire on February 28, 2018. However, on July 25, 2013, Dr. Ha requested that his LOC be terminated with an immediate effective date, so LOC No. 17418 is no longer valid.

File No. 17988: Issued to Jessica Weiss Taylor of the Outer Banks Center for Dolphin Research, Kill Devil Hills, NC, on April 5, 2013, for research activities including vessel surveys, close approach, photo-identification, and behavioral observations, including focal follows of bottlenose dolphins in waters of North Carolina. Specifically the study area comprises the Roanoke, Croatan, Currituck, Albemarle, and Pamlico Sounds and the adjacent Atlantic Ocean to a maximum distance of 5 miles offshore. Objectives are to: (1) Investigate patterns of seasonal and year-round residency in the northern Outer Banks; (2) estimate local abundances of dolphins in the northern Outer Banks seasonally and year-round; (3) identify and characterize any biological and/or ecological stressors on bottlenose dolphins in the northern Outer Banks; (4) describe the social structure of bottlenose dolphin populations in the northern Outer Banks through examination of social networks and male pair bonds; and (5) promote awareness of bottlenose dolphin conservation throughout the local and visiting community. The LOC expires on April 15, 2018.

File No. 13427: Originally issued to the Pacific Whale Foundation [Responsible Party: Gregory D. Kaufman], Wailuku, HI, on June 4, 2008, authorizes the close vessel approach, photo-identification, focal follows, and acoustic recordings of 16 cetacean species within the waters of Maui County, Hawaii to estimate the abundance and distribution of odontocete species in the area. This study was modified on June 11, 2013, to extend the duration of the LOC until June 15, 2014, add a Co-investigator, and remove authorization to take the endangered Hawaiian insular stock of false killer whales (*Pseudorca crassidens*). This LOC was cancelled on June 20, 2013, when a new LOC (File No. 18101) was issued to the Pacific Whale Foundation.

File No. 18101: Issued to the Pacific Whale Foundation [Responsible Party: Gregory D. Kaufman], Wailuku, HI, on June 20, 2013, authorizes close vessel approaches, photo-identification, focal follows, and acoustic recordings of 15 cetacean species within the waters of Maui County, Hawaii to estimate the abundance and distribution of odontocete species in the area. The LOC replaces No. 13427 and expires on June 21, 2018.

File No. 18152: Issued to Barbara Brunnick, Ph.D., Jupiter, FL, on September 11, 2013, for research activities including vessel surveys, close approach, photo-identification, and behavioral observations of bottlenose dolphins. The research objective is to continue developing a photo-identification catalog and database to address questions regarding the local abundance, population ecology, life history, habitat utilization, social structure, habitat health, and residency patterns of Atlantic spotted (*Stenella frontalis*) and bottlenose dolphins. If other dolphin and whale species are encountered, the applicant may collect information on them. This LOC replaces File No. 13386 and expires on September 10, 2018.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: October 23, 2013.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–25458 Filed 10–28–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2013–OS–0207]

Proposed Collection; Comment Request

AGENCY: Defense Acquisition University, DoD.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Defense Acquisition University announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by December 30, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Center Director, Student Information System, Performance and Resource Management, Defense Acquisition University, 9820 Belvoir Road, Ft. Belvoir, VA 22060, or call the Center Director for the Student Information System, Performance and Resource Management, at 703–805–4288.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Acquisition University, Student Information System (SIS); OMB Control Number 0704–TBD.

Needs and Uses: The information collection requirement is necessary to permit an individual to register for a DAU training course. The information is used to evaluate the individual's eligibility for a course and to notify the individual of approval or disapproval of the request. It is also used to notify the training facility of assignments to classes, for training schedule analysis and forecasts, cost analysis, budget estimates, and financial planning.

Affected Public: Individuals associated with the Army, Navy, Air Force, other defense-wide agencies, the federal government, and defense contractors.

Annual Burden Hours: 7,500.

Number of Respondents: 90,000.

Responses per Respondent: 1.

Average Burden per Response: 5 minutes.

Frequency: On Occasion.

Respondents are university applicants and instructors who willingly provide personal information to take courses administered by the Defense Acquisition University. Failure to provide required information results in the individual being denied access to DAU and its course offerings. The data is used by DoD and college officials to: Provide for the administration of and a record of academic performance of current, former, and nominated students; verify grades; select instructors; make decisions to admit students to programs and classes, and to release students from programs; serve as a basis for studies to determine improved criteria for selecting students into classes; forecast demand for future course offerings, and to develop statistics relating to duty assignments and qualifications based on DoD mandated training needs.

Dated: October 24, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–25519 Filed 10–28–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Department of Defense Military Family Readiness Council

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal Advisory Committee meeting of the Department of Defense Military Family Readiness Council will take place. The purpose of this meeting is to refine the Council recommendations that will be included in the 2013 Military Family Readiness Council reports to the congressional defense committees and the Secretary of Defense.

DATES: Friday, November 22, 2013, from 1:00 p.m. to 3:30 p.m.

ADDRESSES: Pentagon Conference Center B6 (escorts will be provided from the Pentagon Metro entrance).

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Ms. Betsy Graham, Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), 4800 Mark Center Drive, Alexandria, VA 22350–2300, Room 3G15. Telephones (571) 372–0880; (571) 372–0881 and/or email: OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to the availability of space. Persons desiring to attend may contact Ms. Melody McDonald at 571–372–0880 or email OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil* no later than 5:00 p.m., on Friday, November 15, 2013 to arrange for escort inside the Pentagon to the Conference Room area.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, interested persons may submit a written statement for consideration by the Council. Persons desiring to submit a written statement to the Council must notify the point of contact listed in **FOR FURTHER INFORMATION CONTACT** no later than 5:00 p.m., Tuesday November 5, 2013.

Friday, November 22, 2013 Meeting Agenda

Welcome & Administrative Remarks

Review and summary of fiscal year 2013 Military Family Readiness Council proceedings

Presentation, deliberation and vote on fiscal year 2013 recommendations

Closing Remarks

Note: Exact order may vary.

Dated: October 24, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–25512 Filed 10–28–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID USAF–2013–0027]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by November 29, 2013.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB Number: Victim/Witness Feedback Request; OMB Control Number 0701–TBD.

Type of Request: New Collection.

Number of Respondents: 16.

Responses per Respondent: 1.

Annual Responses: 16.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 4 hours.

Needs and Uses: The information collection is requested, not required. It is necessary to provide this select group the opportunity to comment on their experiences as victims/witnesses in trial proceedings, and to help inform and modify processes and procedures that pertain to others in the same category in the future.

Affected Public: Individuals or Households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD Information Management Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: October 23, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–25401 Filed 10–28–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. IC13–19–000 and IC13–20–000]

Commission Information Collection Activities (FERC–511 and FERC–515); Comment Request

AGENCY: Federal Energy Regulatory Commission.

ACTION: Request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1)(D), the Federal Energy Regulatory Commission (Commission or FERC) is submitting the information collections, FERC–511 (Transfer of Hydropower License [1]) and FERC–515 (Rules of Practice and Procedure: Declaration of Intention), to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission issued Notices in the **Federal Register** (for FERC–511 at 78 FR 49490, 8/14/2013, and for FERC–515 at 78 FR 49489, 8/14/2013) requesting public comments. FERC received no comments.

DATES: Comments on the collections of information are due November 29, 2013.

ADDRESSES: Comments filed with OMB, identified by the OMB Control Nos. 1902–0069 (FERC–511) and 1902–0079 (FERC–515) should be sent via email to the Office of Information and Regulatory Affairs at *oira_submission@omb.gov*, Attention: Federal Energy Regulatory Commission Desk Officer. The OMB Desk Officer may also be reached via telephone at 202–395–4718.

A copy of the comments should also be sent to the Federal Energy Regulatory Commission, identified by the Docket Nos. IC13–19–000 and IC13–20–000, by either of the following methods:

- eFiling at Commission's Web site: *http://www.ferc.gov/docs-filing/efiling.asp.*
- Mail/Hand Delivery/Courier: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov*, or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in these dockets or in viewing/downloading comments and issuances in these dockets may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION: Ellen Brown may be reached by email at *DataClearance@FERC.gov*, telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION: This notice is combined for administrative purposes only. The FERC–511 and FERC–515 will remain separate information collections with separate OMB Control Numbers.

FERC–511

Title: Transfer of Hydropower License.

OMB Control No.: 1902–0069.

Type of Request: Three-year extension of the FERC–511 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission uses the information collected under the requirements of FERC–511 to implement the statutory provisions of Sections 4(e) and 8 of the Federal Power Act (FPA).[2] Section 4(e) authorizes the Commission to issue licenses for the construction, operation and maintenance of reservoirs, powerhouses, and transmission lines or other facilities necessary for the development and improvement of

[1] This collection was formerly called the ''Application for Transfer of License''; the reporting requirements are not being revised.

[2] 16 U.S.C. 797(e) and 801.

navigation and for the development, transmission, and utilization of power.[3] Section 8 of the FPA provides that the voluntary transfer of any license is made only with the written approval of the Commission. Any successor to the licensee may assign the rights of the original licensee but is subject to all of the conditions of the license. The information filed with the Commission is a mandatory requirement contained in the format of a written application for transfer of license, executed jointly by the parties of the proposed transfer. The sale or merger of a licensed hydroelectric project may occasion the transfer of a license. The Commission's staff uses the information collection to determine the qualifications of the proposed transferee to hold the license and to prepare the transfer of the license order. Approval by the Commission of transfer of a license is contingent upon the transfer of title to the properties under license, delivery of all license instruments, and evidence that such transfer is in the public interest. The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR Part 9.

Type of Respondents: Hydropower Project Licensees.

Estimate of Annual Burden:[4] The Commission estimates the total annual Public Reporting Burden for this information collection as:

FERC–511—TRANSFER OF HYDROPOWER LICENSE

Number of respondents (A)	Number of responses per respondent (B)	Total number of responses (A) × (B) = (C)	Average burden hours per response (D)	Estimated total annual burden (C) × (D)
23	1	23	40	920

The total estimated annual cost burden to respondents is $64,496 [(920 hours/2080 hours per year) * $145,818/year[5] = $64,496].

FERC–515

Title: Rules of Practice and Procedure: Declaration of Intention.

OMB Control No.: 1902–0079.

Type of Request: Three-year extension of the FERC–515 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission uses the information collected under the requirements of FERC–515 to implement the statutory provisions of Section 23(b) of the FPA.[6] Section 23(b) authorized the Commission to make a determination as to whether it has jurisdiction over a proposed water project[7] not affecting navigable waters[8] but across, along, over, or in waters over which Congress has jurisdiction under its authority to regulate commerce with foreign nations and among the several States. Section 23(b) requires that any person intending to construct project works on such waters must file a declaration of their intention with the Commission. If the Commission finds the proposed project will have an impact on interstate or foreign commerce, then the entity intending to construct the project must obtain a Commission license or exemption before starting construction.[9] The information is collected in the form of a written application, containing sufficient details to allow the Commission staff to research the jurisdictional aspects of the project. This research includes examining maps and land ownership records to establish whether or not there is Federal jurisdiction over the lands and waters affected by the project. A finding of non-jurisdictional by the Commission eliminates a substantial paperwork burden for the applicant who might otherwise have to file for a license or exemption application. The Commission implements these filing requirements under 18 CFR Part 24.

Type of Respondents: Persons intending to construct project works on certain waters described above.

Estimate of Annual Burden: The Commission estimates the total annual Public Reporting Burden for this information collection as:

FERC–515—RULES OF PRACTICE AND PROCEDURE: DECLARATION OF INTENTION

Number of respondents (A)	Number of responses per respondent (B)	Total number of responses (A) × (B) = (C)	Average burden hours per response (D)	Estimated total annual burden (C) × (D)
10	1	10	80	800

The total estimated annual cost burden to respondents is $56,084 [(800 hours/2080 hours per year) * $145,818/year[10] = $56,084].

Comments on FERC–511 and FERC–515: Comments are invited on: (1) Whether the collections of information are necessary for the proper performance of the functions of the

[3] Refers to facilities across, along, from, or in any of the streams or other bodies of water over which Congress has jurisdiction under its authority to regulate commerce with foreign nations and among the several States, or upon any part of public lands and reservations of the United States, or for the purpose of utilizing the surplus water or water power from any Government dam.

[4] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[5] FY (Fiscal Year) 2013 Estimated Average Annual Cost per FTE, including salary plus benefits, is $145,818. There are 2,080 hours per workyear.

[6] 16 U.S.C. 817.

[7] Dams or other project works. (See 16 U.S.C. 817.)

[8] See 16 U.S.C. 796(8) for the definition of ''Navigable Waters.''

[9] Upon a finding of non-jurisdictional by the Commission, and if no public lands or reservations are affected, permission is granted upon compliance with State laws.

[10] FY (Fiscal Year) 2013 Estimated Average Annual Cost per FTE, including salary plus benefits, is $145,818. There are 2,080 hours per workyear.

Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collections; and (4) ways to minimize the burden of the collections of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: October 21, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–25438 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 349–181]

Alabama Power Company; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-project use of project lands and waters.

b. *Project No.:* 349–181.

c. *Date Filed:* August 19, 2013.

d. *Applicant:* Alabama Power Company.

e. *Name of Project:* Martin Dam Hydroelectric Project.

f. *Location:* Tallapoosa River in Tallapoosa County, Alabama.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Applicant Contact:* Melissa Crabbe, Alabama Power Company, 600 18th Street North, Birmingham, AL 35203–8180, (205) 257–2428.

i. *FERC Contact:* Rebecca Martin, (202) 502–6012, *Rebecca.Martin@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* November 21, 2013.

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may be paper-filed. To paper-file, mail an original and seven copies to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–349–181) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Application:* The licensee requests Commission approval to allow Central Elmore Water and Sewer Authority (CEWSA) to increase its authorized water withdrawal, from Martin Reservoir, from 10 million gallons per day (mgd) to 11 mgd. According to projected withdrawals, CEWSA is not scheduled to exceed the current 10 mgd withdrawal cap until October 2031. The proposed increase in water withdrawals would not require any changes to the withdrawal structures or to CEWSA's use of Martin Project lands.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field (P–349) to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions To Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by a proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: October 21, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–25440 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC14–9–000.

Applicants: Lower Mount Bethel Energy, LLC.

Description: Section 203 Application of Lower Mount Bethel Energy, LLC.

Filed Date: 10/18/13.

Accession Number: 20131018–5191.

Comments Due: 5 p.m. ET 11/8/13.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG14–8–000.

Applicants: Yellow Jacket Energy, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Yellow Jacket Energy, LLC.
Filed Date: 10/18/13.
Accession Number: 20131018–5148.
Comments Due: 5 p.m. ET 11/8/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1246–004; ER10–1982–005; ER10–1253–004; ER10–1252–004; ER13–764–004; ER12–2498–004; ER12–2499–004.
Applicants: Consolidated Edison Energy, Inc., Consolidated Edison Solutions, Inc., Consolidated Edison Company of New York, Inc., Orange and Rockland Utilities, Inc., CED White River Solar, LLC, Alpaugh 50, LLC, Alpaugh North, LLC.
Description: Notice of non-material change status of Consolidated Edison Energy, Inc., et al.
Filed Date: 10/21/13.
Accession Number: 20131021–5055.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER10–2374–004; ER10–1533–005.
Applicants: Puget Sound Energy, Inc., Macquarie Energy LLC.
Description: Amendment to June 28, 2013 Triennial Updated Market Power Analysis in the Northwest Region of Puget Sound Energy, Inc., et al.
Filed Date: 10/18/13.
Accession Number: 20131018–5195.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER11–3262–002.
Applicants: Trans Bay Cable LLC.
Description: Response to September 19, 2013 Data Request Letter, Docket ER11–3262–002 to be effective N/A.
Filed Date: 10/21/13.
Accession Number: 20131021–5003.
Comments Due: 5 p.m. ET 11/12/13.

Docket Number: ER13–2225–001.
Applicants: Entergy Arkansas, Inc.
Description: Amendment to EWOM NITSA to be effective 5/1/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5000.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–128–000.
Applicants: Entergy Texas, Inc.
Description: ETI Notice of Cancellation of System Agreement to be effective 10/18/2018.
Filed Date: 10/18/13.
Accession Number: 20131018–5159.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–129–000.
Applicants: Entergy Gulf States Louisiana, L.L.C.
Description: Wholesale Distribution Service Tariff to be effective 12/19/2013.
Filed Date: 10/18/13.
Accession Number: 20131018–5161.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–130–000.
Applicants: Entergy Louisiana, LLC.
Description: Wholesale Distribution Service Tariff to be effective 12/19/2013.
Filed Date: 10/18/13.
Accession Number: 20131018–5164.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–131–000.
Applicants: Entergy Mississippi, Inc.
Description: Wholesale Distribution Service Tariff to be effective 12/19/2013.
Filed Date: 10/18/13.
Accession Number: 20131018–5166.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–132–000.
Applicants: Entergy Texas, Inc.
Description: Wholesale Distribution Service Tariff to be effective 12/19/2013.
Filed Date: 10/18/13.
Accession Number: 20131018–5167.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–133–000.
Applicants: Entergy Arkansas, Inc.
Description: WDS and LBA Agreements with AECC to be effective 12/19/2013.
Filed Date: 10/18/13.
Accession Number: 20131018–5169.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–134–000.
Applicants: Entergy Arkansas, Inc.
Description: EAI Cert Concurrence to MISO Coordination Agreement to be effective 12/19/2013.
Filed Date: 10/18/13.
Accession Number: 20131018–5173.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–135–000.
Applicants: Cleco Power LLC.
Description: Cleco WDS and Service Agreements to be effective 12/19/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5006.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–136–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Midcontinent Independent System Operator, Inc. submits filing outlining the market power analysis recommendations of the Independent Market Monitor performed pursuant to Section 63.4.1.g of MISO's Tariff.
Filed Date: 10/18/13.
Accession Number: 20131018–5196.
Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–137–000.
Applicants: Duke Energy Progress, Inc.
Description: Cancellation of Duke Energy Progress, Inc. OATT to be effective 12/20/2013 under ER14–137 Filing Type: 410.
Filed Date: 10/21/13.
Accession Number: 20131021–5034.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–138–000.
Applicants: Duke Energy Progress, Inc.
Description: OATT Name Change to be effective 12/20/201.
Filed Date: 10/21/13.
Accession Number: 20131021–5035.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–139–000.
Applicants: ArcLight Energy Marketing, LLC.
Description: ArcLight Energy Marketing, LLC submits AEM CIS and Tariff Revisions to be effective 12/20/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5068.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–140–000.
Applicants: Panther Creek Power Operating, LLC.
Description: Panther Creek Power Operating, LLC submits Panther Tariff Revisions to be effective 12/20/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5069.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–141–000.
Applicants: Scrubgrass Generating Company, L.P.
Description: Scrubgrass Generating Company, L.P. submits Scrubgrass CIS & Tariff Revisions to be effective 12/20/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5094.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–142–000.
Applicants: Ameren Energy Generating Company.
Description: Ameren Energy Generating Company submits Notice of Cancellation and Amendment Filing to be effective 10/11/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5102.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–143–000.
Applicants: AmerenEnergy Medina Valley Cogen, L.L.C.
Description: AmerenEnergy Medina Valley Cogen, L.L.C. submits Notice of Succession to be effective 10/11/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5105.
Comments Due: 5 p.m. ET 11/12/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's

Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 21, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25528 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2238–007; *ER10–2239–007; ER10–2237–006; ER10–1821–007; ER11–4475–007; ER12–896–003; ER12–911–006.*

Applicants: Indigo Generation LLC, Larkspur Energy LLC, Wildflower Energy LP, Goshen Phase II LLC, Rockland Wind Farm LLC, Mariposa Energy, LLC, CPV Sentinel, LLC.

Description: Notice of Non-Material Change in Status of the DGC Companies.

Filed Date: 10/18/13.

Accession Number: 20131018–5112.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER13–342–002.

Applicants: CPV Shore, LLC.

Description: CPV Shore Submits Notice of Change in Status.

Filed Date: 10/18/13.

Accession Number: 20131018–5110.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER13–585–000.

Applicants: New England Power Pool Participants Committee, ISO New England Inc.

Description: Notice of Effective Date-ER13–585–000 to be effective N/A.

Filed Date: 10/18/13.

Accession Number: 20131018–5095.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–120–000.

Applicants: BTG Pactual Commodities (US) LLC.

Description: BTG Pactual Commodities (US) LLC Market-Based Rate Tariff to be effective 11/18/2013.

Filed Date: 10/17/13.

Accession Number: 20131018–5000.

Comments Due: 5 p.m. ET 11/7/13.

Docket Numbers: ER14–121–000.

Applicants: Pacific Gas and Electric Company.

Description: Notices of Termination of Pacific Gas and Electric Company for Pristine Sun Funds 5 & 6, LLC, Service Agreement Nos. 200 and 201 under PG&E FERC Electric Tariff Volume No. 4.

Filed Date: 10/18/13.

Accession Number: 20131018–5111.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–122–000.

Applicants: Entergy Mississippi, Inc.

Description: EAI–MEAM Interconnection Agreement to be effective 12/19/2013.

Filed Date: 10/18/13.

Accession Number: 20131018–5115.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–123–000.

Applicants: Arizona Public Service Company.

Description: Rate Schedule No. 33—WAPA Triangle-Exhibit A, Revision No. 48 to be effective 12/18/2013.

Filed Date: 10/18/13.

Accession Number: 20131018–5125.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–124–000.

Applicants: Entergy Arkansas, Inc.

Description: Wholesale Distribution Service Tariff to be effective 12/19/2013.

Filed Date: 10/18/13.

Accession Number: 20131018–5136.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–125–000.

Applicants: Southwest Power Pool, Inc.

Description: Removal of NERCs Administration of Reliability-Grid Management Tools to be effective 12/17/2013.

Filed Date: 10/18/13.

Accession Number: 20131018–5143.

Comments Due: 5 p.m. ET 11/8/13.

Docket Numbers: ER14–126–000.

Applicants: Yellow Jacket Energy, LLC.

Description: Application for Market-Based Rate Authority to be effective 10/18/2013.

Filed Date: 10/18/13.

Accession Number: 20131018–5147.

Comments Due: 5 p.m. ET 11/8/13.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES14–2–000.

Applicants: AEP Generation Resources Inc.

Description: Amendment and clarification to October 15, 2013 Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of AEP Generation Resources Inc.

Filed Date: 10/17/13.

Accession Number: 20131017–5138.

Comments Due: 5 p.m. ET 11/5/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 18, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25532 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1999–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35: 10–17–13 Attachment VV Compliance to be effective 9/27/2013.

Filed Date: 10/17/13.

Accession Number: 20131017–5103.

Comments Due: 5 p.m. ET 11/7/13.

Docket Numbers: ER13–2063–001.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corporation submits tariff filing per 35.17(b): 2013–10–17_MandatoryMSGDelay to be effective 4/1/2014.

Filed Date: 10/17/13.

Accession Number: 20131017–5109.

Comments Due: 5 p.m. ET 11/7/13.

Docket Numbers: ER13–2118–001.

Applicants: NedPower Mount Storm, LLC.

Description: NedPower Mount Storm, LLC submits tariff filing per 35: Compliance Filing—Amendment to Previous Filing of 080613 to be effective 10/18/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5105.
Comments Due: 5 p.m. ET 11/7/13.

Docket Numbers: ER14–116–000.
Applicants: American Electric Power Service Corporation, Ohio Power Company, AEP Ohio Transmission Company, Inc., PJM Interconnection, L.L.C.
Description: AEP submits 39th Revised Service Agreement No. 1336 to be effective 6/10/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5099.
Comments Due: 5 p.m. ET 11/7/13.

Docket Numbers: ER14–117–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 10–17–13 Attachment WW to be effective 12/17/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5104.
Comments Due: 5 p.m. ET 11/7/13.

Docket Numbers: ER14–118–000.
Applicants: NaturEner Glacier Wind Energy 1, LLC.
Description: NaturEner Glacier Wind Energy 1, LLC submits tariff filing per 35.15: Notice of Cancellation of Temporary Use Agreement to be effective 10/18/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5107.
Comments Due: 5 p.m. ET 11/7/13.

Docket Numbers: ER14–119–000.
Applicants: San Diego Gas & Electric Company.
Description: San Diego Gas & Electric Company submits tariff filing per 35.13(a)(2)(iii: SDG&E Concurrence to LGIA Between CAISO, SDG&E, and Mesquite Solar 1, LLC to be effective 1/1/2014.
Filed Date: 10/17/13.
Accession Number: 20131017–5117.
Comments Due: 5 p.m. ET 11/7/13.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES14–4–000.
Applicants: MidAmerican Energy Company.
Description: Application for Authorization under Section 204 of MidAmerican Energy Company under ES14–4.
Filed Date: 10/17/13.
Accession Number: 20131017–5098.
Comments Due: 5 p.m. ET 11/7/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 17, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25531 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP14–53–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Negotiated Rate—Integrys to be effective 11/1/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5106.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–54–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Negotiated Rate—Castleton LPS RO to be effective 10/17/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5108.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–55–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Negotiated Rate—NJR LPS RO to be effective 10/17/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5111.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–56–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Negotiated Rate—NJR to be effective 10/17/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5113.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–57–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Negotiated Rate—Renaissance LPS RO to be effective 10/17/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5115.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–58–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: 10/17/13 Negotiated Rates—JP Morgan Ventures Energy Corp (HUB) 6025–89 to be effective 11/1/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5118.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–59–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: 10/17/13 Negotiated Rates—Rainbow Energy Marketing Corp. (HUB) 7400–89 to be effective 11/1/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5119.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–60–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: 10/17/13 Negotiated Rates—Tenaska Gas Storage, LLC (HUB) 1175–89 to be effective 11/1/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5121.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–61–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: 10/17/13 Negotiated Rates—United Energy Trading, LLC (HUB) 5095–89 to be effective 11/1/2013.
Filed Date: 10/17/13.
Accession Number: 20131017–5122.
Comments Due: 5 p.m. ET 10/29/13.

Docket Numbers: RP14–62–000.
Applicants: Eastern Shore Natural Gas Company.
Description: Eastern Shore Storage Tracker Filing to be effective 10/1/2013.
Filed Date: 10/18/13.
Accession Number: 20131018–5064.
Comments Due: 5 p.m. ET 10/30/13.

Docket Numbers: RP14–63–000.
Applicants: Centra Pipelines Minnesota Inc.
Description: Revised Index of Shippers Oct 2013 to be effective 12/1/2013.

Filed Date: 10/18/13.
Accession Number: 20131018–5092.
Comments Due: 5 p.m. ET 10/30/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 21, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25534 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP14–44–000.
Applicants: Energy West Development, Inc.
Description: Compliance filing to GT& C section 18 to be effective 12/2/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5007.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–45–000.
Applicants: East Tennessee Natural Gas, LLC.
Description: Eastman Chemical 410456 Negotiated Rate to be effective 11/1/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5095.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–46–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Tariff Revision and Clarification Filing October 2013 to be effective 11/16/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5125.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–47–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Negotiated Rate—Tenaska LPS RO to be effective 10/16/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5131.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–48–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Tenaska LPS RO Negotiated Rate to be effective 10/16/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5141.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–49–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Negotiated Rate Tenaska to be effective 10/16/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5146.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–50–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Volume No. 2—Cabot Oil & Gas and Southwestern Energy Svs-Neg Rate and Non Conf to be effective 11/1/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5158.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–51–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Tennessee Gas Pipeline Company, L.L.C. submits tariff filing per 154.204: Volume No. 2—Anadarko Energy Services and MMGS—Neg and Non Conforming Agmts to be effective 11/1/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5158.
Comments Due: 5 p.m. ET 10/28/13.

Docket Numbers: RP14–52–000.
Applicants: Shell U.S. Gas & Power, LLC.
Description: Petition of Shell U.S. Gas & Power, LLC. for Declaratory Order and Request for Expedited Consideration.
Filed Date: 10/16/13.
Accession Number: 20131016–5178.
Comments Due: 5 p.m. ET 11/15/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 17, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25533 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–107–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 10–16–13 MISO Revs to Scheds 7–8–9–26 to be effective 12/19/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5122.
Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–108–000.
Applicants: Entergy Arkansas, Inc., Entergy Gulf States Louisiana, L.L.C., Entergy Mississippi, Inc., Entergy New Orleans, Inc., Entergy Texas, Inc., Entergy Louisiana, LLC.
Description: Entergy Operating Companies' Reactive Power Revenue Requirement to be effective 1/1/2014.
Filed Date: 10/16/13.
Accession Number: 20131016–5124.
Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–109–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 10–16–13 SA6503 Gaylord SSR to be effective 10/1/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5128.
Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–110–000.
Applicants: Entergy Gulf States Louisiana, L.L.C.
Description: Nelson 6 Marketing Agreement to be effective 12/16/2013.
Filed Date: 10/16/13.
Accession Number: 20131016–5150.

Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–111–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: 10–16–2013 Schedule 43D Gaylord SSR Consumers to be effective 10/1/2013.

Filed Date: 10/16/13.

Accession Number: 20131016–5151.

Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–112–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: 10–16–2013 SA 6504 Straits SSR Consumers Energy to be effective 10/1/2013.

Filed Date: 10/16/13.

Accession Number: 20131016–5153.

Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–113–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: 10–16–2013 Schedule 43E Straits SSR Consumers to be effective 10/1/2013.

Filed Date: 10/16/13.

Accession Number: 20131016–5155.

Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–114–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: 10–16–13 MISO EAI Coordination Agreement to be effective 12/19/2013.

Filed Date: 10/16/13.

Accession Number: 20131016–5157.

Comments Due: 5 p.m. ET 11/6/13.

Docket Numbers: ER14–115–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: 10–17–13 Missouri Unexecuted SAs 2546 2547 2548 to be effective 12/19/2013.

Filed Date: 10/16/13.

Accession Number: 20131017–5000.

Comments Due: 5 p.m. ET 11/6/13.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES14–3–000.

Applicants: FirstEnergy Service Company.

Description: Application for Authorization under Section 204(a) of the Federal Power Act to Issue Short-Term Debt Securities of FirstEnergy Service Company on Behalf of Allegheny Generating Company.

Filed Date: 10/16/13.

Accession Number: 20131016–5177.

Comments Due: 5 p.m. ET 11/6/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 17, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25530 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP14–64–000

Applicants: Ameren Energy Generating Company, AmerenEnergy Medina Valley Cogen, L.L.C., Main Line Generation, LLC

Description: Joint Petition of Ameren Energy Generating Company, AmerenEnergy Medina Valley Cogen, L.L.C., and Main Line Generation, LLC for Temporary Waiver of Capacity Release Regulations and Policies, and Request for Expedited Treatment

Filed Date: 10/21/13

Accession Number: 20131021–5156

Comments Due: 5 p.m. ET 10/28/13

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP12–813–003.

Applicants: Gulf South Pipeline Company, LP.

Description: Second Compliance Filing to be effective 7/24/2013.

Filed Date: 10/21/13.

Accession Number: 20131021–5027.

Comments Due: 5 p.m. ET 11/4/13.

Docket Numbers: RP12–814–003.

Applicants: Gulf Crossing Pipeline Company LLC.

Description: Second Compliance Filing—Demand Charge Credits to be effective 7/24/2013.

Filed Date: 10/21/13.

Accession Number: 20131021–5028.

Comments Due: 5 p.m. ET 11/4/13.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 22, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25537 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC14–10–000.

Applicants: AmerenEnergy Medina Valley Cogen, L.L.C., Rockland Capital.

Description: Joint Application of AmerenEnergy Medina Valley Cogen, L.L.C., et. al. for Authorization under Section 203 of the FPA and Request for Expedited Consideration.

Filed Date: 10/21/13.

Accession Number: 20131021–5164.

Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: EC14–11–000.

Applicants: Fibrominn LLC.

Description: Application for Disposition of Jurisdictional Facilities and Request for Confidential Treatment, Expedited Consideration and Waivers of Fibrominn LLC.

Filed Date: 10/21/13.

Accession Number: 20131021–5167.

Comments Due: 5 p.m. ET 11/12/13.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG14–9–000.
Applicants: Gibson City Energy Center, LLC.
Description: Notice of Self-Certification as an Exempt Wholesale Generator of Gibson City Energy Center, LLC.
Filed Date: 10/21/13.
Accession Number: 20131021–5152.
Comments Due: 5 p.m. ET 11/12/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–3987–004.
Applicants: Mesquite Solar 1, LLC.
Description: Notice of Non-Material Change in Status of Mesquite Solar 1, LLC.
Filed Date: 10/21/13.
Accession Number: 20131021–5169.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER12–2263–002.
Applicants: Arizona Public Service Company.
Description: Rate Schedule No. 217, Exhibit B Corrections to be effective 10/1/2012.
Filed Date: 10/21/13.
Accession Number: 20131021–5138.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER12–2570–002; ER10–3041–002.
Applicants: Panther Creek Power Operating, LLC, Westwood Generation, LLC.
Description: Notice of Non-Material Change in Status of Panther Creek Operating, LLC, et al.
Filed Date: 10/21/13.
Accession Number: 20131021–5160.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–107–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 10–21–13 Scheds 7–8–9 Entergy to be effective 12/19/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5113.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–144–000.
Applicants: New York Independent System Operator, Inc.
Description: NYISO revisions re: minimum participation criteria for the NYISO markets to be effective 12/19/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5109.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–145–000.
Applicants: Idaho Power Company.
Description: OATT Order No. 764 Compliance Filing to be effective 11/12/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5111.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–146–000.
Applicants: Nevada Power Company.
Description: Rate Schedule No. 139 Interim Joint Dispatch Agreement to be effective 1/1/2014.
Filed Date: 10/21/13.
Accession Number: 20131021–5116.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–147–000.
Applicants: Sierra Pacific Power Company.
Description: Rate Schedule No. 63—Concurrence in NPC RS No. 139 Interim Joint Dispatch Agmt to be effective 1/1/2014.
Filed Date: 10/21/13.
Accession Number: 20131021–5117.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–148–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 10–21–2013 Entergy NITSAs PTPs Succession to be effective 12/19/2013.
Filed Date: 10/21/13.
Accession Number: 20131021–5140.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–149–000.
Applicants: NV Energy, Inc.
Description: NV Energy OATT to be effective 1/1/2014.
Filed Date: 10/21/13.
Accession Number: 20131022–5000.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–150–000.
Applicants: Arizona Public Service Company.
Description: Rate Schedule No. 217—Bouse Switchyard—Exhibit B.BSE, Revision No. 4 to be effective 12/16/2013.
Filed Date: 10/21/13.
Accession Number: 20131022–5001.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–151–000.
Applicants: PJM Interconnection, L.L.C.
Description: 3rd Quarter 2013 Updates to PJM Operating Agreement and RAA Membership Lists to be effective 9/30/2013.
Filed Date: 10/22/13.
Accession Number: 20131022–5020.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–152–000.
Applicants: Elgin Energy Center, LLC.
Description: Market-Based Rate Application to be effective 12/23/2013.
Filed Date: 10/22/13.
Accession Number: 20131022–5041.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–153–000.
Applicants: Gibson City Energy Center, LLC.
Description: Market-Based Rate Application to be effective 12/23/2013.
Filed Date: 10/22/13.
Accession Number: 20131022–5042.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–154–000.
Applicants: Grand Tower Energy Center, LLC.
Description: Market-Based Rate Application to be effective 12/23/2013.
Filed Date: 10/22/13.
Accession Number: 20131022–5044.
Comments Due: 5 p.m. ET 11/12/13.

Docket Numbers: ER14–155–000.
Applicants: PacifiCorp.
Description: Moon Lake Revised Wheeling Agreement Rev 4 to be effective 12/21/2013.
Filed Date: 10/22/13.
Accession Number: 20131022–5061.
Comments Due: 5 p.m. ET 11/12/13.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES14–5–000.
Applicants: PacifiCorp.
Description: Application for Authorization to Issue and Sell up to $1.5 Billion of Promissory Notes or Other Evidences of Unsecured Short-Term Indebtedness of PacifiCorp.
Filed Date: 10/22/13.
Accession Number: 20131022–5081.
Comments Due: 5 p.m. ET 11/12/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 22, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25529 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL14–5–000; ER13–2428–000 (Not consolidated)]

Notice of Complaint; Frankfort Electric and Water Plant Board; Cities of Barbourville, Bardstown, Bardwell, Benham, Berea, Corbin, Falmouth, Madisonville, Nicholasville, Paris, and Providence, Kentucky v. Kentucky Utilities Company

Take notice that on October 17, 2013, pursuant to section 206 of the Federal Power Act (FPA) and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Frankfort Electric and Water Plant Board and the Cities of Barbourville, Bardstown, Bardwell, Benham, Berea, Corbin, Falmouth, Madisonville, Nicholasville, Paris, and Providence, Kentucky (Complainants or Kentucky Municipals) filed a formal complaint against the Kentucky Utilities Company, (Respondents), seeking an investigation and refund effective date under FPA section 206 and ask that the proceeding be consolidated with Docket no. ER13–2428–000.

The Kentucky Municipals certify that copies of the complaint were served on the contacts for the Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on November 6, 2013.

Dated: October 21, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–25441 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13563–001]

Juneau Hydropower, Inc.; Notice of Subsequent Draft License Application (DLA) and Draft Preliminary Draft Environmental Assessment (PDEA) and Request for Preliminary Terms and Conditions

Take notice that the following Draft License Application (DLA) and draft Preliminary Draft Environmental Assessment (PDEA) have been filed with the Commission and are available for public inspection.

a. *Type of Application:* Major Unconstructed Project.

b. *Project No.:* 13563–001.

c. *Date Filed:* October 15, 2013.

d. *Applicant:* Juneau Hydropower, Inc.

e. *Name of Project:* Sweetheart Lake Hydroelectric Project.

f. *Location:* At the confluence of Sweetheart Lake and Gilbert Bay, in the City and Borough of Juneau, Alaska. The project would occupy 1,886.76 acres of federal lands within the Tongass National Forest, administered by the US Forest Service.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Duff Mitchell, Business Manager, Juneau Hydropower, Inc., P.O. Box 22775, Juneau, AK 99802; 907–789–2775, email: *duff.mitchell@juneauhydro.com*.

i. *FERC Contact:* John Matkowski, 202–502–8576, *john.matkowski@ferc.gov*.

j. *Status of Project:* With this notice the Commission is soliciting (1) preliminary terms, conditions, and recommendations on the draft PDEA, and (2) comments on the DLA.

k. *Deadline for filing:* 90 days from the issuance of this notice.

All comments on the draft PDEA and DLA should be sent to the addresses noted above in Item (h), and filed with the Commission.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–13563–001.

All comments must bear the heading Preliminary Comments, Preliminary Recommendations, Preliminary Terms and Conditions, or Preliminary Prescriptions.

l. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Juneau Hydropower, Inc. has mailed a copy of the draft PDEA and DLA to interested entities and parties. Copies of these documents are available for review at the Juneau Public Library, 292 Marine Way, Juneau, Alaska 99801, or at the Juneau Hydropower, Inc. Web site, *http://www.juneauhydro.com*.

m. With this notice, we are initiating consultation with the Alaska State Historic Preservation Officer, as required by section 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

Dated: October 22, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–25437 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF14–1–000]

Southwestern Power Administration; Notice of Filing

Take notice that on October 3, 2013, the Deputy Secretary of the Department of Energy, pursuant to the authority vested by sections 301(b), 302(a), 402(e), 641, 642, 643, and 644, of the Department of Energy Organization Act (Pub. L. 95–91), and by Delegation Order Nos. 00–037.00 (December 6, 2001) and 00–001.00E (June 6, 2013), confirmed, approved, and placed in effect on an interim basis in Rate Order SWPA–66, Southwestern Power Administration Integrated System Rates for the period October 1, 2013 through September 30, 2017.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on November 4, 2013.

Dated: October 18, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25535 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF14–2–000]

Southwestern Power Administration; Notice of Filing

Take notice that on October 3, 2013, the Deputy Secretary of the Department of Energy, pursuant to the authority vested by sections 301(b), 302(a), 402(e), 641, 642, 643, and 644, of the Department of Energy Organization Act (Pub. L. 95–91), and by Delegation Order Nos. 00–037.00 (December 6, 2001) and 00–001.00E (June 6, 2013), confirmed, approved, and placed in effect on an interim basis in Rate Order SWPA–67, Southwestern Power Administration annual rate for the sale of power and energy from the Rayburn Project to the Sam Rayburn Dam Electric Cooperative, Inc.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on November 4, 2013.

Dated: October 18, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25536 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13579–002; Project No. 14491–000]

FFP Qualified Hydro 14, LLC, Western Minnesota Municipal Power Agency; Notice Announcing Filing Priority for Preliminary Permit Applications

On October 21, 2013, the Commission held a drawing to determine priority between competing preliminary permit applications with identical filing times. In the event that the Commission concludes that neither of the applicants' plans is better adapted than the other to develop, conserve, and utilize in the public interest the water resources of the region at issue, the priority established by this drawing will serve as the tiebreaker. Based on the drawing, the order of priority is as follows:

1. FFP Qualified Hydro 14, LLC—Project No. 13579–002
2. Western Minnesota Municipal Power Agency—Project No. 14491–000

Dated: October 23, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–25527 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt

of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e) (1) (v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped chronologically, in ascending order. These filings are available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC, Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866)208–3676, or for TTY, contact (202)502–8659.

Docket No.	Filed date	Presenter or requester
Exempt:		
1. CP12–509–000	09–17–13	Hon. John Cornyn.
2. CP13–14–000	09–19–13	Asm. Clifford W. Crouch.[1]
3. CP13–492–000	09–23–13	Gov. John A. Kitzhaber.
4. AD13–7–000	09–24–13	Committee on Energy & Commerce.
5. ER13–2140–000	09–25–13	Hon. Robert P. Casey, Jr.
6. ER13–897–000, *et al*	10–03–13	Kentucky Public Service Commission.
7. CP13–483–000; CP13–492–000	10–07–13	FERC Staff.[2]
8. ER13–2140–000	10–07–13	Hon. Robert P. Casey, Jr.
9. CP13–483–000; CP13–492–000	10–11–13	FERC Staff.[3]

[1] Letters submitted individually to the Chairman, to each Commissioner, and to the Secretary.
[2] Telephone record.
[3] Telephone record.

Dated: October 21, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–25442 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at Southwest Power Pool Regional Entity Trustee, Regional State Committee and Board of Directors Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meetings of the Southwest Power Pool, Inc. (SPP) Regional Entity Trustee (RE), Regional State Committee (RSC) and Board of Directors, as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

All meetings will be held at the SPP Corporate Offices, 201 Worthen Drive, Little Rock, AR 722111. The phone number is (501) 312–9000.

SPP RE

October 28, 2013 (8:00 a.m.–12:00 p.m.)

SPP RSC

October 28, 2013 (1:00 p.m.–5:00 p.m.)

SPP Board of Directors

October 29, 2013 (8:00 a.m.–3:00 p.m.)

The discussions may address matters at issue in the following proceedings:

Docket No. ER06–451, *Southwest Power Pool, Inc.*

Docket No. ER11–4105, *Southwest Power Pool, Inc.*

Docket No. ER12–140, *Southwest Power Pool, Inc.*

Docket No. ER12–550, *Southwest Power Pool, Inc.*

Docket No. ER12–909, *Southwest Power Pool, Inc.*

Docket No. ER12–1017, *Southwest Power Pool, Inc.*

Docket No. ER12–1018, *Southwest Power Pool, Inc.*

Docket No. ER12–1179, *Southwest Power Pool, Inc.*

Docket No. ER12–1401, *Southwest Power Pool, Inc.*

Docket No. ER12–1586, *Southwest Power Pool, Inc.*

Docket No. ER12–1779, *Southwest Power Pool, Inc.*

Docket No. ER12–2292, *Southwest Power Pool, Inc.*

Docket No. ER12–2366, *Southwest Power Pool, Inc.*

Docket No. EL12–2, *Southwest Power Pool, Inc.*

Docket No. EL12–47, *Southwest Power Pool, Inc.*

Docket No. EL12–51, *Southwest Power Pool, Inc.*

Docket No. EL12–60, *Southwest Power Pool, Inc., et al.*

Docket No. ER12–1813, *The Empire District Electric Co.*

Docket No. ER12–1071, *Entergy Arkansas, Inc.*

Docket No. EL12–59, *Golden Spread Electric Cooperative, Inc.*

Docket No. ER09–548, *ITC Great Plains, LLC*

Docket No. ER12–480, *Midwest Independent Transmission System Operator, Inc.*

Docket No. EL11–34, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER09–36, *Prairie Wind Transmission, LLC*
Docket No. ER09–35, *Tallgrass Transmission, LLC*
Docket No. EL12–28, *Xcel Energy Services Inc., et al.*
Docket No. EL13–15, *Southwestern Public Service Company*
Docket No. EL13–35, *Southwestern Public Service Company*
Docket No. ER13–366, *Southwest Power Pool, Inc.*
Docket No. ER13–367, *Southwest Power Pool, Inc.*
Docket No, ER13–1032, *Southwest Power Pool, Inc.*
Docket No. ER13–1173, *Southwest Power Pool, Inc.*
Docket No. ER13–1768, *Southwest Power Pool, Inc.*
Docket No. ER13–1769, *Southwest Power Pool, Inc.*
Docket No. ER13–1819, *Southwest Power Pool, Inc.*
Docket No. ER13–1937, *Southwest Power Pool, Inc.*
Docket No. ER13–1939, *Southwest Power Pool, Inc.*
Docket No. ER13–2031, *Southwest Power Pool, Inc.*
Docket No. ER13–2033, *Southwest Power Pool, Inc.*
Docket No. ER13–2270, *Southwest Power Pool, Inc.*
Docket No. ER13–2271, *Southwest Power Pool, Inc.*
Docket No. ER13–2272, *Southwest Power Pool, Inc.*
Docket No. ER13–2274, *Southwest Power Pool, Inc.*
Docket No. ER13–2275, *Southwest Power Pool, Inc.*
Docket No. ER13–2276, *Southwest Power Pool, Inc.*
Docket No. ER13–2281, *Southwest Power Pool, Inc.*
Docket No. ER13–2282, *Southwest Power Pool, Inc.*
Docket No. ER13–2284, *Southwest Power Pool, Inc.*
Docket No. ER13–2335, *Southwest Power Pool, Inc.*
Docket No. ER13–2358, *Southwest Power Pool, Inc.*
Docket No. ER13–2359, *Southwest Power Pool, Inc.*
Docket No. ER13–2430, *Southwest Power Pool, Inc.*
Docket No. ER13–2433, *Southwest Power Pool, Inc.*
Docket No. ER13–2438, *Southwest Power Pool, Inc.*
Docket No. ER13–2439, *Southwest Power Pool, Inc.*
Docket No. ER13–2440, *Southwest Power Pool, Inc.*
Docket No. ER14–27, *Southwest Power Pool, Inc.*
Docket No. ER14–60, *Southwest Power Pool, Inc.*
Docket No. ER14–67, *Southwest Power Pool, Inc.*

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov*.

Dated: October 22, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–25439 Filed 10–28–13; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9902–14–OAR]

Acid Rain Program: Notice of Annual Adjustment Factors for Excess Emissions Penalty

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of annual adjustment factors for excess emissions penalty.

SUMMARY: The Acid Rain Program under title IV of the Clean Air Act provides for automatic excess emissions penalties in dollars per ton of excess emissions for sources that do not meet their annual Acid Rain emissions limitations. This notice states the dollars per ton excess emissions penalty amounts, which must be adjusted for each compliance year commensurate with changes in the Consumer Price Index (CPI), for compliance years 2013 and 2014.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Clean Air Markets Division (6204J), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460, at (202) 343–9077 or *miller.robertl@epa.gov.*

SUPPLEMENTARY INFORMATION: The Acid Rain Program under title IV of the Clean Air Act limits annual sulfur dioxide and nitrogen oxide emissions of fossil fuel-fired utility units. Under the Acid Rain Program, affected sources must hold enough allowances to cover their sulfur dioxide emissions, and certain coal-fired sources must meet an emission limit for nitrogen oxides. Under 40 CFR 77.6, sources that do not meet these requirements must pay a penalty without demand to the Administrator based on the number of excess tons emitted times $2,000 as adjusted by an annual adjustment factor, which must be published in the **Federal Register**.

The annual adjustment factor for adjusting the penalty for excess emissions of sulfur dioxide and nitrogen oxides under 40 CFR 77.6(b) for compliance year 2013 is 1.8489. This value is derived using the CPI for 1990 and 2012 (defined respectively at 40 CFR 72.2 as the CPI for August of the year before the specified year for all urban consumers) and results in an automatic penalty of $3,698 per excess ton of sulfur dioxide or nitrogen oxides emitted for 2013.

The annual adjustment factor for adjusting the penalty for such excess emissions under 40 CFR 77.6(b) for compliance year 2014 is 1.8770. This value is derived using the CPI for 1990 and 2013 and results in an automatic penalty of $3,754 per excess ton of sulfur dioxide or nitrogen oxides emitted for 2014.

Dated: September 30, 2013.

Reid P. Harvey,

Director, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 2013–25579 Filed 10–28–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: The Federal Communications Commission (FCC), as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act (PRA) of 1995. Comments are requested concerning whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology;

and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 30, 2013. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to the Federal Communications Commission via email to *PRA@fcc.gov* and *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0454.

Title: Sections 43.51, 64.1001, 64.1002, Regulations of International Accounting Rates.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 5 respondents; 20 responses.

Estimated Time per Response: 1–5 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 151, 154(i), 154(j), 201, 214, 303(r) and 309.

Total Annual Burden: 205 hours.

Annual Cost Burden: $3,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general, there is no need for confidentiality with this collection of information.

Needs and Uses: This collection will be submitted as an extension (no change in reporting or recordkeeping requirements) after this 60-day comment period to the Office of Management and Budget (OMB) in order to obtain the full three-year clearance.

The information is used by the Commission staff in carrying out its duties under the Communications Act. The information collections are necessary for the Commission to maintain effective oversight of U.S. carriers that are affiliated with, or involved in certain co-marketing or similar arrangements with, foreign carriers that have market power. Additionally, the information collections are necessary to analyze market trends to determine whether amendment of the Commission's existing rules or proposals of new rules are necessary to promote effective competition and prevent anti-competitive behavior between American and foreign carriers.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director

[FR Doc. 2013–25564 Filed 10–28–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 30, 2013. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0865.

Title: Wireless Telecommunications Bureau Universal Licensing System Recordkeeping and Third Party Disclosure Requirements.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Individuals or households, Not-for-profit institutions, and State, Local or Tribal Government.

Number of Respondents and Responses: 62,490 respondents; 168,908 responses.

Estimated Time per Response: .166 hours (10 minutes)—4 hours.

Frequency of Response: Recordkeeping and third-party disclosure requirements; On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 154(i) and 309(j).

Total Annual Burden: 88,927 hours.

Annual Cost Burden: None.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality: This information collection contains personally identifiable information (PII). The FCC has a system of records notice (SORN), FCC/WTB–1, ''Wireless Services Licensing Records,'' to cover the collection, maintenance, use(s), and destruction of this PII, which respondents may provide to the FCC as part of the information collection requirement(s). This SORN was published in the **Federal Register** on April 5, 2006 (71 FR 17234, 17269).

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB) as an extension after this 60 day comment period to obtain the full three-year clearance from them.

The purpose of this information collection is to continually streamline

and simplify processes for wireless applicants and licensees, who previously used a myriad of forms for various wireless services and types of requests, in order to provide the Commission information that has been collected in separate databases, each for a different group of services. Such processes have resulted in unreliable reporting, duplicate filings for the same licensees/applicants, and higher cost burdens to licensees/applicants. By streamlining the Universal Licensing System (ULS), the Commission eliminates the filing of duplicative applications for wireless carriers; increases the accuracy and reliability of licensing information; and enables all wireless applicants and licensees to file all licensing-related applications and other filings electronically, thus increasing the speed and efficiency of the application process. The ULS also benefits wireless applicants/licensees by reducing the cost of preparing applications, and speeds up the licensing process in that the Commission can introduce new entrants more quickly into this already competitive industry. Finally, ULS enhances the availability of licensing information to the public, which has access to all publicly available wireless licensing information on-line, including maps depicting a licensee's geographic service area.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2013–25436 Filed 10–28–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Thursday, October 31, 2013 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes for September 12, 2013
Election of Officer
Draft Advisory Opinion 2013–11: Citizens for Joe Miller
Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shawn Woodhead Werth,

Secretary and Clerk of the Commission.

[FR Doc. 2013–25641 Filed 10–25–13; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 12, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *D. Robert Downing,* Indianola, Iowa; to acquire voting shares of Central South Bancorporation, Inc., and thereby indirectly acquire voting shares of Peoples Savings Bank, both in Indianola, Iowa.

2. *David H. McKee, individually, and as special voting trustee of the McKee Family Trust, and as a member of the McKee Norris Family Control Group,* all of Indianapolis, Indiana; to acquire voting shares of Midstate Financial Corporation, and thereby indirectly acquire voting shares of Hendricks County Bank and Trust Company, both in in Brownsburg, Indiana.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *The Richard W. Agee Marital Trust, the Eloise R. Agee Irrevocable Trust; and Rex A. Marquart, as trustee of both trusts,* all of Lincoln, Nebraska; to acquire voting shares of First Minden Financial Corporation, and thereby indirectly acquire voting shares of First Bank and Trust Company, both in Minden, Nebraska.

Board of Governors of the Federal Reserve System, October 23, 2013.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2013–25368 Filed 10–28–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 22, 2013.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Adams Dairy Bancshares, Inc.,* Blue Springs, Missouri; to become a bank holding company by acquiring 100 percent of the voting shares of Adams Dairy Bank, Blue Springs, Missouri.

Board of Governors of the Federal Reserve System, October 23, 2013.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2013–25369 Filed 10–28–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0032; Docket 2012–0076; Sequence 66]

Federal Acquisition Regulation; Submission for OMB Review; Contractor Use of Interagency Fleet Management System Vehicles

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning contractor use of interagency fleet management system vehicles. A notice was published in the **Federal Register** at 78 FR 23935, on April 23, 2013. No comments were received.

DATES: Submit comments on or before November 29, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles, by any of the following methods:

- Regulations.gov: *http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles'' on your attached document.

- Fax: 202–501–4067.
- Mail: General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., 2nd Floor, Washington, DC 20405–0001. ATTN: Hada Flowers/IC 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles.

Instructions: Please submit comments only and cite Information Collection 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles, in all correspondence related to this collection. Submit comments regarding this burden estimate and any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA (202) 501–1448 or email at *Curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

If it is in the best interest of the Government, the contracting officer may authorize cost-reimbursement contractors to obtain, for official purposes only, interagency fleet management system (IFMS) vehicles and related services. Federal Acquisition Regulation (FAR) 51.205 and the clause at FAR 52.251–2, Interagency Fleet Management System (IFMS) Vehicles and Related Services are to be used in solicitations and contracts when a cost reimbursement contract is contemplated and the contracting officer may authorize the contractor to use interagency fleet management system (IFMS) vehicles and related services.

Before a contracting officer may authorize cost-reimbursement contractors to obtain IFMS vehicles and related services, the contracting officer must have, among other requirements:

- A written statement that the contractor will assume, without the right of reimbursement from the Government, the cost or expense of any use of the IFMS vehicles and services not related to the performance of the contract;
- Evidence that the contractor has obtained motor vehicle liability insurance covering bodily injury and property damage, with limits of liability as required or approved by the agency, protecting the contractor and the Government against third-party claims arising from the ownership, maintenance, or use of an IFMS vehicle; and
- Considered any recommendations of the contractor. The information is used by the Government to determine whether it is in the Government's best interest to authorize a cost-reimbursement contractor, for official purposes only, to use IFMS vehicles and related services.

Authorized contractors shall submit requests for IFMS vehicles and related services in writing to the appropriate GSA point of contact in accordance with the FAR. Contractors' requests for vehicles or related services must include:

- Two copies of the agency authorization;
- The number of vehicles and related services required and period of use;
- A list of employees who are authorized to request the vehicles or related services;
- A listing of equipment authorized to be serviced; and
- Billing instructions and address.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

B. Annual Reporting Burden

There is no centralized database in the Federal Government that captures information on agencies' use of the IFMS for this information collection; however, agencies annually report motor vehicle fleet data using the GSA Federal Automotive Statistical Tool (FAST), a web-based reporting tool cosponsored by GSA and the Department of Energy.

For this information collection requirement data from Fiscal Year (FY) 2012 was retrieved from the Federal Procurement Data System (FPDS) to determine the number of agencies that awarded cost reimbursable contracts that may utilize IFMS to provide vehicles to contractors for official purposes only. FPDS identified approximately 120 contracting agencies

that awarded cost reimbursable contracts in FY 2012. Of these agencies, it is estimated that approximately fifty percent, or 60, contracting agencies may utilize IFMS to provide vehicles to contractors for official purposes only. It is further estimated that each of the 60 agencies would average approximately 3 contractor requests per year to utilize the IFMS, for a total estimate of approximately 180 contactor requests per year. The requests should be limited because certain travel costs are allowable under cost-reimbursement contracts, including the costs of contractor-owned or -leased automobiles. FAR 31.205–46(d) provides that these costs are allowable, if reasonable, to the extent that the automobiles are used for company business. Consequently, the FY 2012 FPDS data will serve as the basis for the number of respondents per year. One burden hour was estimated per response to read and prepare information. This represents an increase from what was published in the **Federal Register** on March 5, 2010 (75 FR 10267). No public comments were received in prior years that have challenged the validity of the Government's estimate.

Estimated respondents/yr: 180.

Number of responses annually: 1.0.

Total annual responses: 180.

Estimated hrs/response: 1.0.

Estimated total burden/hrs: 180.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street, NW., 2nd Floor, Washington, DC 20405–0001, telephone (202) 501–4755. Please cite OMB Control No. 9000–0032, Contractor Use of Interagency Fleet Management System Vehicles, in all correspondence.

Dated: October 22, 2013.

Karlos Morgan,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–25213 Filed 10–28–13; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[Notice-WWI–2013–02; Docket No. 2013–0007; Sequence 2]

World War One Centennial Commission; Notification of Upcoming Public Advisory Meeting

AGENCY: World War One Centennial Commission.

ACTION: Meeting notice.

SUMMARY: Notice of this meeting is being provided according to the requirements of the Federal Advisory Committee Act, 5 U.S.C. App. 10(a)(2). This notice provides the schedule and agenda for the November 15, 2013, meeting of the World War One Centennial Commission (the Commission). The meeting is open to the public and the site is accessible to individuals with disabilities.

DATES: *Meeting date:* The meeting will be held on Friday, November 15, 2013 starting at 9:30 a.m. Eastern Standard Time (EST), and ending no later than 5:30 p.m. The meeting will be in open session from 9:30 a.m. until 12:00 p.m. The afternoon session will address administrative issues and will not be open to the public.

FOR FURTHER INFORMATION CONTACT: Daniel S. Dayton, Designated Federal Officer, c/o The Foundation for the Commemoration of the World Wars, 701 Pennsylvania Avenue NW., #123, Washington, DC 20004–2608 202–380–0725 (note: this is not a toll-free number).

Contact Daniel S. Dayton at 202–380–0725 to register to comment during the meeting's 30 minute public comment period. Registered speakers/organizations will be allowed 5 minutes and will need to provide written copies of their presentations. Requests to comment at the meeting must be received by 5:00 p.m. Eastern Standard Time (EST), November 12, 2013. Written comments may be provided to Mr. Dayton at *daniel.dayton@dhs.gov* until November 12, 2013. Please contact Mr. Dayton at the email address above to obtain meeting materials.

SUPPLEMENTARY INFORMATION:

Background

The World War One Centennial Commission was established by Public Law 112–272, as a commission to ensure a suitable observance of the centennial of World War I, to provide for the designation of memorials to the service of members of the United States Armed Forces in World War I, and for other purposes. Under this authority, the Committee will plan, develop, and execute programs, projects, and activities to commemorate the centennial of World War I, encourage private organizations and State and local governments to organize and participate in activities commemorating the centennial of World War I, facility and coordinate activities throughout the United States relating to the centennial of World War I, serve as a clearinghouse for the collection and dissemination of information about events and plans for the centennial of World War I, and develop recommendations for Congress and the President for commemorating the centennial of World War I.

Agenda: Friday November 15, 2013.

- Introductions and plans for today's meeting—DFO
- Committee Reports
- Old Business
- New Business
- 30 minute public comment period for individuals pre-registered per instructions above. Each individual will be able to speak for no more than 5 minutes.
- Closing comments

Meeting Access: The Committee will convene its meeting at: The Law offices of Jones-Day, 51 Louisiana Avenue NW., Washington, DC, 20001–2113. Persons attending this meeting are requested to refrain from using perfume, cologne, and other fragrances (see *http://www.access-board.gov/about/policies/fragrance.htm* for more information).

Dated: October 18, 2013.

Daniel S. Dayton,

Designated Federal Official, World War I Centennial Commission.

[FR Doc. 2013–25434 Filed 10–28–13; 8:45 am]

BILLING CODE 6820–95–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Feed Materials Production Center (FMPC) in Fernald, Ohio, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On September 30, 2013, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Feed Materials Production Center (FMPC) in Fernald, Ohio, who were not employed by National Lead of Ohio, NLO, or the Department of Energy or its predecessor agencies, who worked at FMPC from January 1, 1951, through December 31, 1983, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work

days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on October 30, 2013, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2013–25518 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Feed Materials Production Center (FMPC) in Fernald, Ohio, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On September 30, 2013, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Feed Materials Production Center (FMPC) in Fernald, Ohio, from January 1, 1954, through December 31, 1967, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on October 30, 2013, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2013–25517 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Pantex Plant in Amarillo, Texas, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On September 30, 2013, the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Pantex Plant in Amarillo, Texas, from January 1, 1984, through December 31, 1991, for a number of work days aggregating at least 250 work days, occurring either solely under this employment, or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on October 30, 2013, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2013–25521 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition to Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from Baker Brothers, in Toledo, Ohio, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). On September 30, 2013, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All Atomic Weapons Employees and Department of Energy employees, contractors and subcontractors who worked at the Baker Brothers site in Toledo, Ohio, during the applicable covered residual radiation and remediation period from January 1, 1945, through December 31, 1996.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q.

John Howard

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2013–25508 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition To Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from the Pantex Plant in Amarillo, Texas, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA). On September 30, 2013, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Pantex Plant in Amarillo, Texas, from January 1, 1951, through December 31, 1957.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2013–25516 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–0612]

Agency Forms Undergoing Paperwork Reduction Act

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System (OMB #0920–0612, exp. 1/31/2014)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The WISEWOMAN program (Well-Integrated Screening and Evaluation for Women Across the Nation), administered by the Centers for Disease Control and Prevention (CDC), was established to examine ways to improve the delivery of services for women who have limited access to health care and elevated risk factors for cardio vascular disease (CVD). The program focuses on reducing CVD risk factors and provides screening services for selected risk factors such as elevated blood cholesterol, hypertension, and abnormal blood glucose levels. The program also provides women with referrals to lifestyle programs and medical care. The WISEWOMAN program currently provides services to approximately 45,000 women who are jointly enrolled in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), also administered by CDC. CDC collects information from WISEWOMAN awardees through the ''WISEWOMAN Reporting System'' (OMB No. 0920–0612, exp. 1/31/2014).

New WISEWOMAN cooperative agreements were awarded in 2013 and CDC seeks to continue information collection for three years, with revisions. The new funding period will reflect an increased emphasis on efficient oversight of program awardees and documenting program outcomes. As a result, the WISEWOMAN information collection will be revised to support updated program goals. Revisions to be implemented include a reduction in the frequency of progress report submission—from twice per year to once per year—and changes to the content of the Minimum Data Element (MDE) submissions. This will result in an overall net decrease in respondent burden. The first reports based on the revised reporting requirements will be submitted to CDC in April 2014.

The hardcopy progress report provides a narrative summary of each awardee's objectives and the activities undertaken to meet program goals, including public education and outreach. The estimated burden per response is 16 hours.

The MDE include information that describes risk factors for the women served in each program and the number and type of lifestyle program sessions they attend. MDE information has previously been submitted to CDC in two electronic transmissions. The burden for Screening and Assessment MDE was estimated at 16 hours per response and the burden for Lifestyle Program MDE was estimated at 8 hours per response.

Upon OMB approval of the proposed Revision, the MDE will be submitted as a single electronic file with a combined estimated burden per response of 24 hours. The total number of MDE variables will increase from 66 to 85. The number of variables relating to Lifestyle Programs will decrease and the number of variables relating to Screening and Assessment will increase.

CDC will continue to use the information collected from WISEWOMAN awardees to support continuous program monitoring and improvement activities, evaluation, and assessment of program outcomes. The overall program evaluation is designed to demonstrate how WISEWOMAN can obtain more complete health data on vulnerable populations, promote public education about disease incidence, cardiovascular disease risk-factors, health promotion, to improve the availability of screening and diagnostic services for under-served women, ensure the quality of services provided to under-served women, and develop strategies for improved interventions. Participation in this information collection is required as a condition of cooperative agreement funding. There are no costs to respondents other than their time.

The total annualized burden hours are 1,344.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response
WISEWOMAN Awardees	Screening and Assessment and Lifestyle Program MDE.	21	2	24
	Annual Progress Report	21	1	16

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–25450 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)

Cancellation: This notice was published in the **Federal Register** on October 2, 2013, Volume 78, Number 191, page 60876. The meeting previously scheduled to convene on October 24, 2013, has been cancelled.

Contact Person for More Information: Gayle Hickman, Committee Management Specialist, Office Chief of Staff, CDC, 1600 Clifton Road NE., Mail Stop D–14, Atlanta, Georgia 30303, Telephone: (404) 639–7158, Fax: (404) 639–7212, Email: *ghickman@cdc.gov.*

This notice is published less than the required 15 days prior to the start of the announced meeting, in accordance with Section 102–3.150(b) of the GSA Final Rule (2001) that allows for exceptions to the meeting notification time requirement. Section 102–3.150(b) states the following: ''In exceptional circumstances, the agency or an independent Presidential advisory committee may give less than 15 calendar days' notice, provided that the reasons for doing so are included in the advisory committee meeting notice published in the **Federal Register**.''

In this case, the agency is giving less than 15 days' notice due to the recent furlough status of United States Federal Government, including the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, from October 1–16, 2013.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–25429 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Time and Date: 10:00 a.m.–5:00 p.m. Eastern Time, November 20, 2013.

Place: Teleconference.

Status: Open to the public, without a verbal public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1–866–659–0537 and the passcode is 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Discussed: The agenda for the Subcommittee meeting includes: Dose reconstruction program quality management and assurance activities, including: Current findings from NIOSH internal dose reconstruction blind reviews; and discussion of dose reconstruction cases under review (set 9, and Portsmouth, Hanford, and Oak Ridge National Laboratory cases from sets 10–13).

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore Katz, Designated Federal Official, NIOSH, CDC, 1600 Clifton Road NE., Mailstop E–20, Atlanta Georgia 30333, Telephone: (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email: *ocas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–25431 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH or Institute)

Cancellation: This notice was published in the **Federal Register** on September 12, 2013, Volume 78, Number 177, Pages 56235–56236.

Contact Person for More Information: Price Connor, Ph.D., NIOSH Health Scientist, CDC, 2400 Executive Parkway, Mailstop E–20, Atlanta, Georgia 30345, Telephone: (404)498–2511, Fax: (404)498–2571.

This notice is published less than the required 15 days prior to the start of the announced meeting, in accordance with Section 102–3.150(b) of the GSA Final Rule (2001) that allows for exceptions to the meeting notification time requirement. Section 102–3.150(b) states the following: ''In exceptional circumstances, the agency or an independent Presidential advisory committee may give less than 15 calendar days' notice, provided that the reasons for doing so are included in the advisory committee meeting notice published in the **Federal Register**.''

In this case, the agency is giving less than 15 days' notice due to the recent furlough status of United States Federal Government, including the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, from October 1–16, 2013.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–25426 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women (ACBCYW)

Cancellation: This notice was published in the **Federal Register** on September 18, 2013, Volume 78, Number 181, page 57391. The meeting previously scheduled to convene on October 31, 2013, has been cancelled.

Contact Person for More Information: Temeika L. Fairley, Ph.D., Designated Federal Official, Office of the Director, Division of Cancer Prevention and Control, CDC, 5770 Buford Hwy NE., Mail Stop F–70, Atlanta, Georgia 30341, Telephone: (770) 488–4518, Fax: (770) 488–4760, Email: *tfairley@cdc.gov.*

This notice is published less than the required 15 days prior to the start of the announced meeting, in accordance with Section 102–3.150(b) of the GSA Final Rule (2001) that allows for exceptions to the meeting notification time requirement. Section 102–3.150(b) states the following: ''In exceptional circumstances, the agency or an independent Presidential advisory committee may give less than 15 calendar days' notice, provided that the reasons for doing so are included in the advisory committee meeting notice published in the **Federal Register**.''

In this case, the agency is giving less than 15 days' notice due to the recent furlough status of United States Federal Government, including the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, from October 1–16, 2013.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–25430 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention—Health Disparities Subcommittee (HDS)

Notice of Cancellatiion: This notice was published in the **Federal Register** on October 22, 2013, Volume 78, Number 204, page 62635. The meeting previously scheduled to convene on October 28, 2013 has been cancelled.

Contact Person for More Information: Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, Health Disparities Subcommittee, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE., M/S K–77, Atlanta, GA 30333; Telephone (770) 488–8200, Email: *LEL1@cdc.gov.*

This notice is published less than the required 15 days prior to the start of the announced meeting, in accordance with Section 102–3.150(b) of the GSA Final Rule (2001) that allows for exceptions to the meeting notification time requirement. Section 102–3.150(b) states the following: ''In exceptional circumstances, the agency or an independent Presidential advisory committee may give less than 15 calendar days' notice, provided that the reasons for doing so are included in the advisory committee meeting notice published in the **Federal Register**.''

In this case, the agency is giving less than 15 days' notice due to the recent furlough status of United States Federal Government, including the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, from October 1–16, 2013.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–25428 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control, (BSC, NCIPC)

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces, the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.–4:30 p.m. Eastern Time, November 15, 2013.

Place: Teleconference.

Status: The meeting is open to the public; the toll free dial in number is 1–877–937–9818 and the passcode is 7551384.

Purpose: The board makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention goals and provides evidence in injury prevention-related research and programs. The board provides advice on the appropriate balance of intramural and extramural research, and provides advice on the structure, progress and performance of intramural programs. The Board of Scientific Counselors is also designed to provide guidance on extramural scientific program matters, including the: (1) Review of extramural research concepts for funding opportunity announcements; (2) conduct of Secondary Peer Review of extramural research grants, cooperative agreements, and contracts applications received in response to the funding opportunity announcements as it relates to the Center's programmatic balance and mission; (3) submission of secondary review recommendations to the Center Director of applications to be considered for funding support; (4) review of research portfolios, and (5) review of program proposals. The board shall provide guidance on the National Center of Injury Prevention and Control's programs and research activities by conducting scientific peer review of intramural research and programs within the National Center for Injury Prevention and Control; by ensuring adherence to Office of Management and Budget requirements for intramural peer review; and by monitoring the overall direction, focus, and success of the National Center for Injury Prevention and Control.

Matters to be Discussed: The BSC, NCIPC will discuss the recommendations provided by the expert panel on the Health Communication Portfolio Review that has been conducted and to discuss research strategies needed to guide the Center's focus. The BSC members will also discuss potential topics for the upcoming Portfolio Review. There will be 15 minutes allotted for public comments at the end of the open session.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Designated Federal Official, NCIPC, CDC, 4770 Buford Highway NE., Mailstop F–63, Atlanta, Georgia 30341, Telephone: (770) 488–1430.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–25427 Filed 10–28–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Request for Nominations for Voting Members on a Public Advisory Committee; Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Tobacco Products Scientific Advisory Committee, Office of Science, Center for Tobacco Products.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before December 30, 2013, will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after December 30, 2013, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically to *cv@oc.fda.gov* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership, the primary contact is:* Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose Option 5), FAX: 240–276–3655, email: *TPSAC@fda.hhs.gov.*

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: *http://www.fda.gov/Advisory Committees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Tobacco Products Scientific Advisory Committee. Elsewhere in this issue of the **Federal Register,** FDA is publishing a separate document announcing the Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner of Food and Drugs.

II. Criteria for Voting Members

The Committee shall consist of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The Committee shall include nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members shall be physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology,

toxicology, pharmacology, addiction, or any other relevant specialty.

In addition to the voting members, the committee shall include three nonvoting members who are identified with industry interests. These members shall include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 21, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–25541 Filed 10–28–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Transplantation, Tolerance, and Tumor Immunology Study Section, October 3, 2013, 8:30 a.m. to October 4, 2013, 12:00 p.m., Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037 which was published in the **Federal Register** on September 9, 2013, 78 FR 174 pgs. 55086–55087.

The meeting will be held at the Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005. The meeting will start on November 21, 2013 at 8:00 a.m. and will end on November 22, 2013 at 1:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25553 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, October 11, 2013, 10:00 a.m. to 5:00 p.m., National Institutes of Health, Two Democracy Plaza, Suite 959, 6707 Democracy Boulevard, Bethesda, MD 20892, which was published in the **Federal Register** on July 26, 2013, 78 FR 45254.

The meeting notice is amended to change the date from October 22, 2013, to November 19–20, 2013 at 8:00 a.m. to 6:00 p.m. The location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25470 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, October 22, 2013, 11:00 a.m. to 5:00 p.m., National Institutes of Health, Two Democracy Plaza, Suite 951, 6707 Democracy Boulevard, Bethesda, MD 20892, which was published in the **Federal Register** on September 10, 2013, 78 FR 55268.

The meeting notice is amended to change the date from October 22, 2013, to December 11, 2013. The time and location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25468 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Tumor Cell Biology Study Section, October 16, 2013, 08:00 a.m. to October 17, 2013, 05:00 p.m., Hotel Kabuki, 1625 Post Street, San Francisco, CA 94115 which was published in the **Federal Register** on September 17, 2013, 78 FR 57169.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on November 16, 2013 at 8:00 a.m. and end on November 17, 2013 at 7:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25494 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 11, 2013, 08:00 a.m. to October 11, 2013, 05:00 p.m., Doubletree Hotel Washington, 1515 Rhode Island Ave. NW., Washington, DC 20005 which was published in the **Federal Register** on September 11, 2013, 78 FR Pgs. 55752–55753.

The meeting will be held at National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892. The meeting will start on November 15, 2013 at 9:00 a.m. and end on November 15, 2013 at 4:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25492 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Prokaryotic Cell and Molecular Biology Study Section, October 25, 2013, 08:00 a.m. to October 25, 2013, 06:00 p.m., Avenue Hotel Chicago, 160 E. Huron Street, Chicago, IL 60611 which was published in the **Federal Register** on October 01, 2013, 78 FR 60296.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 on December 17, 2013, starting at 10:00 a.m. and ending at 07:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25471 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute and the Board of Scientific Counselors for Basic Sciences National Cancer Institute.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual other conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

Date: November 12, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brian E. Wojcik, Ph.D., Executive Secretary, Institute Review Office, Office of the Director, National Cancer Institute, 9609 Medical Center Boulevard, Room 3W414, Rockville, MD 20850–9711, 240–276–5665, *wojcikb@mail.nih.gov.*

Name of Committee: Board of Scientific Counselors for Basic Sciences National Cancer Institute.

Date: November 13, 2013.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Florence E. Farber, Ph.D., Executive Secretary, Institute Review Office, National Cancer Institute, NIH, 9609 Medical Center Boulevard, Room 3W240, Rockville, MD 20850–9711, 240–276–5666, *ff6p@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: October 23, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25477 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Emerging Technologies and Training in Neurosciences Overflow.

Date: November 4, 2013.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Yuan Luo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–915–6303, *luoy2@mail.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular Hematology.

Date: November 4–5, 2013.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bukhtiar H Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301–806–7314, *shahb@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Genes, Genomes and Genetics.

Date: November 5–6, 2013.

Time: 8:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center

for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, Bethesda, MD 20892, *belangerm@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Oral, Dental and Craniofacial Sciences.

Date: November 6–7, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell, Computational and Molecular Biology.

Date: November 6, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Hotel Capital View, 2800 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Maria DeBernardi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7892, Bethesda, MD 20892, 301–435–1355, *debernardima@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Orthopedic and Skeletal Biology.

Date: November 6–7, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Baljit S Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, *moongabs@mail.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular and Surgical Devices.

Date: November 6, 2013.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Inatitutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301.435.1049, *lij21@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Diabetes and Metabolism.

Date: November 6, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–1044, *campdm@mail.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurobiology of Brain Disease.

Date: November 6, 2013.

Time: 12:01 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Boris P Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government Shutdown of October 2013.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25498 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Child Psychopathology and Developmental Disabilities Study Section, October 17, 2013, 8:00 a.m. to October 18, 2013, 5:00 p.m., The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854 which was published in the **Federal Register** on September 23, 2013, 78 FR Pgs. 58324–58325.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892. The meeting will start on November 18, 2013 at 8:00 a.m. and will end on November 20, 2013 at 10:00 a.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25556 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular Genetics B Study Section, October 02, 2013, 07:00 p.m. to October 03, 2013, 06:00 p.m., Handlery Union Square Hotel, 351 Geary Street, San Francisco, CA 94102 which was published in the **Federal Register** on September 03, 2013, 78 FR Pgs. 54259–54261.

The meeting will start on November 16, 2013 at 7:00 a.m. and end on November 16, 2013 at 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25485 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Surgery, Anesthesiology and Trauma Study Section, October 02, 2013, 08:00 a.m. to October 03, 2013, 05:00 p.m., The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL, 60611 which was published in the **Federal Register** on September 03, 2013, 78 FR Pgs. 54259–54261.

The meeting will start on December 9, 2013 at 8:00 a.m. and end on December 10, 2013 at 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25474 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Biomedical Imaging Technology B Study Section, October 07, 2013, 08:00 a.m. to October 08, 2013, 05:00 p.m., Hilton Alexandria Mark Center, 5000 Seminary Road, Alexandria, VA, 22311 which was published in the **Federal Register** on September 10, 2013, 78 FR 55269.

The meeting will start on November 24, 2013 at 06:00 p.m. and end on November 25, 2013 at 06:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25495 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 25, 2013, 01:00 p.m. to October 25, 2013, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 01, 2013, 78 FR 60297.

The meeting will start on November 20, 2013 at 08:00 a.m. and end on November 21, 2013 at 05:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25487 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 29, 2013, 10:00 a.m. to October 29, 2013, 03:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on October 03, 2013, 78 FR 61376.

The meeting will be held on November 12, 2013, from 01:00 p.m. to 04:30 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 24, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25507 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, October 07, 2013, 1:00 p.m. to October 07, 2013, 4:00 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on September 3, 2013, 78 FR 55088.

The meeting will be held on November 4, 2013 from 1:00 p.m. until 4:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25467 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: November 21–22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Helen Lin, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Blvd., Suite 800, Bethesda, MD 20817, 301–594–4952, *linh1@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 24, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25552 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Science Education Awards (R25).

Date: November 18–20, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

Contact Person: Jay R. Radke, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *jay.radke@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25464 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biobehavioral Regulation, Learning and Ethology.

Date: November 7, 2013.

Time: 9:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Serena Chu, PhD., Scientific Review Officer, BBBP IRG: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301–500–5829, *sechu@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 23, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25555 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Clinical Oncology Study Section, October 07, 2013, 08:00 a.m. to October 07, 2013, 07:00 p.m., Holiday Inn Riverwalk, 217 N Saint Mary's Street, San Antonio, TX, 78205 which was published in the **Federal Register** on September 11, 2013, 78 FR 55752.

The meeting will be held at the Crowne Plaza Tysons Corner Hotel. 1960 Chain Bridge Road, McLean, VA 22102, on November 18, 2013, starting at 08:00 a.m. and ending at 06:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25503 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation.

Date: November 12, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tomas Drgon, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152,

MSC 7770, Bethesda, MD 20892, 301–435–1017 *tdrgon@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Clinical Studies and Epidemiology Study Section.

Date: November 12, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Hilary D Sigmon, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 357–9236, *sigmonh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Area Review: Cardiovascular and Respiratory Sciences.

Date: November 12, 2013.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Olga A Tjurmina, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 451–1375, *ot3d@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Psychological Function in Adulthood and Aging.

Date: November 12, 2013.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dana Jeffrey Plude, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Structural Bases of the Functions of RNA-Protein Machines.

Date: November 13–14, 2013.

Time: 7:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kathryn M Koeller, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–2681, *koellerk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–13–239: Native American Research Centers for Health (NARCH) (S06).

Date: November 13–15, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Wenchi Liang, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301–435–0681, *liangw3@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology and Bioengineering.

Date: November 13–14, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kenneth Ryan, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–1789, *kenneth.ryan@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Lymphatics in Health and Disease in the Digestive, Urinary, Cardiovascular and Pulmonary Systems.

Date: November 13, 2013.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bonnie L Burgess-Beusse, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301–435–1783, *beusseb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 24, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25496 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Vascular Cell and Molecular Biology Study Section, October 17, 2013, 08:00 a.m. to October 18, 2013, 12:00 p.m., Doubletree Hotel Washington, 1515 Rhode Island Ave. NW., Washington, DC 20005 which was published in the **Federal Register** on September 23, 2013, 78 FR184 Pgs. 58323–58324.

The meeting will be held on December 3, 2013, at 7:30 a.m. and will end at 7:30 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25475 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Environmental Health Sciences Review Committee.

Date: November 14, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Rall Building 101, Conference Room B, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Linda K Bass, PhD., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training Nat'l Institute of Environmental Health Sciences P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to

Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 23, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25497 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Infectious Diseases and Microbiology.

Date: November 12–13, 2013.

Time: 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: Alexander D Politis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435–1150, *politisa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Microtubule Networks and Virus Trafficking.

Date: November 13–14, 2013.

Time: 8:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael H Chaitin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435–0910, *chaitinm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Systematic Functional Annotation of the Mitochondrial Proteome.

Date: November 13, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Rass M Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodegeneration.

Date: November 18, 2013.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Toby Behar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435–4433, *behart@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cell Biology.

Date: November 19, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Raya Mandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217, MSC 7840, Bethesda, MD 20892, 301–402–8228, *rayam@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Translational Research in Diabetes, Obesity and Endocrine Disorders.

Date: November 19, 2013.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, 301–408–9901, sheardn@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Neuroscience.

Date: November 19, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Rare Disease Therapeutics.

Date: November 19, 2013.

Time: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1741, *pannierr@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25463 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Musculoskeletal Tissue Engineering Study Section, October 17, 2013, 08:00 a.m. to October 18, 2013, 05:30 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on September 23, 2013, 78 FR 58325.

The meeting will be held at the DoubleTree by Hilton, Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814, on November 18, 2013, starting at 08:00 a.m. and ending at 07:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25514 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cancer Immunopathology and Immunotherapy Study Section, October 03, 2013, 08:00 a.m. to October 03, 2013, 06:00 p.m., Washington Marriott at Metro Center, 775 12th Street NW., District of Columbia, DC 20005 which was published in the **Federal Register** on September 10, 2013, 78 FR 55269.

The meeting will be held at the Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814, on November 5, 2013, starting at 08:00 a.m. and ending at 06:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25501 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Structure and Function of Opioid Receptors.

Date: November 19–20, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7760, Bethesda, MD 20892, (301) 435–1747, *rosenzweign@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Translational Research in Diabetes and Obesity.

Date: November 20, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *gary.hunnicutt@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special: Pilot: Clinical Studies in Nephrology and Urology.

Date: November 20–21, 2013.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301–435–1198, *sahaia@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Endocrinology, Metabolism and Reproduction.

Date: November 20, 2013.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Basic and Integrative Bioengineering.

Date: November 20, 2013.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Paul Sammak, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, MSC 7892, Bethesda, MD 20892, 301–435–0601, *sammakpj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

Date: November 20, 2013.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–1044, *campdm@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Causal Variants for Autoimmune and Musculoskeletal Diseases.

Date: November 20, 2013.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Cheryl M Corsaro, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, (301) 435–1045, *corsaroc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Cell Biology.

Date: November 21–22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Asthma and Lung Host Defense.

Date: November 21–22, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240–498–7546, *diramig@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Integrative Omics Data Analysis for Discovery in Lung Diseases.

Date: November 21, 2013.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Dominique Lorang-Leins, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5108, MSC 7766, Bethesda, MD 20892, 301.326.9721, *Lorangd@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Nursing Related Clinical and Intervention Studies.

Date: November 21, 2013.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, HDM IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301–615–7401, *wup4@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25489 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Myocardial Ischemia and Metabolism Study Section, October 02, 2013, 08:00 a.m. to October 03, 2013, 05:00 p.m., Hotel Kabuki, 1625 Post Street, San Francisco, CA 94115 which was published in the **Federal Register** on September 03, 2013, 78 FR 54260.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on December 17, 2013 at 10:00 a.m. and end on December 19, 2013 at 06:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25499 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 24, 2013, 2:00 p.m. to 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 01, 2013, 78 FR Pgs. 60296–60297.

The meeting will be held on October 29, 2013 at 2:00 p.m. to 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25482 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psycho/Neuropathology, Lifespan Development, and Science, Education.

Date: November 13, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: John H Newman, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 267–9270, *newmanjh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bioengineering Sciences and Technologies: AREA Review.

Date: November 13–14, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ping Fan, MD, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301–408–9971, *fanp@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25561 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular and Integrative Signal Transduction Study Section, October 10, 2013, 08:00 a.m. to October 11, 2013, 05:30 p.m., Sheraton Gunter Hotel, 205 East Houston Street, San Antonio, TX, 78205 which was published in the **Federal Register** on September 11, 2013, 78 FR 55752.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on November 6, 2013 at 10:00 a.m. and end on November 7, 2013 at 05:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25515 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Synthetic and Biological Chemistry A Study Section, October 21, 2013, 08:00 a.m. to October 22, 2013, 12:00 p.m., Hotel Palomar, 2121 P Street NW., Washington, DC, 20037 which was published in the **Federal Register** on September 26, 2013, 78 FR 59361.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on December 18, 2013 at 09:00 a.m. and end on December 20, 2013 at 05:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25502 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 24, 2013, 01:00 p.m. to October 24, 2013, 04:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 01, 2013, 78 FR 60298.

The meeting will be held on November 12, 2013 from 03:30 p.m. to 06:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25472 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Development—2 Study Section, October 10, 2013, 08:00 a.m. to October 10, 2013, 06:00 p.m., Doubletree Hotel Washington, 1515 Rhode Island Ave NW., Washington, DC 20005 which was published in the **Federal Register** on September 11, 2013, 78 FR Pgs. 55752–55753.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on December 12, 2013 at 9:00 a.m. and end on December 12, 2013 at 7:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25484 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Biobehavioral Regulation, Learning and Ethology Study Section, October 21, 2013, 08:30 a.m. to October 22, 2013, 05:00 p.m., Lorien Hotel & Spa, 1600 King Street, Alexandria, VA, 22314 which was published in the **Federal Register** on September 26, 2013, 78 FR 59362.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on December 2, 2013 at 08:30 a.m. and end on December 6, 2013 at 05:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25486 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cellular and Molecular Immunology—B Study Section, October 17, 2013, 08:30 a.m. to October 18, 2013, 05:00 p.m., Avenue Hotel Chicago, 160 E. Huron Street, Chicago, IL 60611 which was published in the **Federal Register** on September 23, 2013, 78 FR 58324.

The meeting will be held at the Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814. The meeting will start on December 5, 2013 at 08:30 a.m. and end on December 6, 2013 at 05:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25513 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 1, 2013, 12:00 a.m. to October 1, 2013, 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on September 3, 2013, 78 FR 54260.

The meeting will be held on November 26, 2013, from 12:00 p.m. to 3:30 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 24, 2013.

Michelle Trout,

Program Analyst. Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25506 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, IMM–K81, October 24, 2013, 4:30 p.m. to October 24, 2013, 6:00 p.m., Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC, 20037 which was published in the **Federal Register** on October 1, 2013, 78 FR Pgs. 60297–60299.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892. The meeting will start on November 13, 2013 at 8:00 a.m. and will end on November 14, 2013 at 8:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25558 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 24, 2013, 08:00 a.m. to October 25, 2013, 05:00 p.m., Embassy Suites DC Convention Center, 900 10 Street NW., Washington, DC, 20001, which was published in the **Federal Register** on October 01, 2013, 78 FR 60298.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on November 21, 2013 at 08:00 a.m. and end on November 22, 2013 at 06:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25473 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Environmental Health Sciences Special Emphasis Panel, October 10, 2013, 12:30 p.m. to October 10, 2013, 5:00 p.m., NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709 which was published in the **Federal Register** on September 16, 2013, 78 FR 56902.

This meeting, originally scheduled for October 10, 2013, will be held on November 14, 2013 from 1 p.m. to 4 p.m. The meeting is closed to the public.

Dated: October 22, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25465 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Oral, Dental and Craniofacial Sciences Study Section, October 16, 2013, 08:00 a.m. to October 17, 2013, 05:00 p.m., Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on September 17, 2013, 78 FR Pgs. 57168–57169.

The meeting will start on November 19, 2013 at 9:00 a.m. and will end on November 20, 2013 at 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25488 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular Sciences.

Date: November 7–8, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Baltimore, 2 North Charles Street, Baltimore, MD 21201.

Contact Person: Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301–435–1743, *margaret.chandler@nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Basic and Integrative Bioengineering.

Date: November 7, 2013.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle NW., Washington, DC 20037.

Contact Person: David R. Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, *filpuladr@mail.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Brain Disorders, Language, Communication and Related Neurosciences.

Date: November 7–8, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: W Hotel San Diego, W San Diego, 421 W B Street, San Diego, CA 92101.

Contact Person: Vilen A. Movsesyan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040M, MSC 7806, Bethesda, MD 20892, 301–402–7278, *movsesyanv@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: AIDS and Related Research Integrated Review Group; HIV/AIDS Vaccines Study Section.

Date: November 7, 2013.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott Buckhead, 3300 Lenox Road, Atlanta, GA 30326.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Reproductive Health and Pregnancy.

Date: November 7, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *gary.hunnicutt@nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Hematology.

Date: November 7–8, 2013.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bukhtiar H Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301–806–7314, *shahb@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–12–140: Role of the Microflora in the Etiology of Gastro-Intestinal Cancer.

Date: November 7, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Peter J Perrin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, (301) 435–0682, *perrinp@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR10–169: Academic Industrial Partnership.

Date: November 7, 2013.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, *mohsenim@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR10–169: Academic Industrial Partnership.

Date: November 7, 2013.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Behrouz Shabestari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7854, Bethesda, MD 20892, (301) 435–2409, *shabestb@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomedical Sensing, Measurement and Instrumentation.

Date: November 8, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

This meeting notice is being published less than 15 days in advance of the meeting due to the Government shutdown of October 2013.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25481 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 11, 2013, 01:30 p.m. to October 11, 2013, 04:30 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 23, 2013, 78 FR 58324.

The meeting will be held on December 2, 2013 from 03:00 p.m. to 06:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25483 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, ZRG1 F07–K (20), October 24, 2013, 08:00 a.m. to October 24, 2013, 04:30 p.m., Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW, Washington, DC, 20037 which was published in the **Federal Register** on October 1, 2013, 78 FR Pgs. 60297–60299.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892. The meeting will start on November 13, 2013 at 8:00 a.m. and will end on November 14, 2013 at 8:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25557 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Eye Institute Special Emphasis Panel, October 21, 2013, 08:00 a.m. to October 23, 2013, 12:00 p.m., National Institutes of Health, 5635 Fishers Lane, Bethesda, MD, 20892 which was published in the **Federal Register** on September 16, 2013, 78 FR 56905.

Due to the Government Shutdown of October 2013, the meeting has been

rescheduled to November 5, 2013, 08:00 a.m. to November 6, 2013, 10:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

Melanie Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25478 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 22, 2013, 11:00 a.m. to October 22, 2013, 01:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on October 01, 2013, 78 FR 60295.

The meeting will be held on November 19, 2013. The time and location remain the same. The meeting is closed to the public.

Dated: October 24, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25504 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section, October 15, 2013, 8:00 a.m. to October 16, 2013, 6:00 p.m., Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC, 20015 which was published in the **Federal Register** on September 16, 2013, 78 FR Pgs. 56904–56905.

The meeting will be held at The Palomar Hotel, 2121 P. Street, Washington, DC 20037. The meeting will start on November 11, 2013 at 8:00 a.m. and will end on November 11, 2013 at 7:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25554 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 21, 2013, 08:00 a.m. to October 21, 2013, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 26, 2013, 78 FR 59362.

The meeting will be held on November 22, 2013. The meeting time and location will remain the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25493 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Social Sciences and Population Studies A Study Section, October 3, 2013, 8:30 a.m. to October 4, 2013, 12:00 p.m., Renaissance, Washington, DC Hotel, 999 Ninth Street NW., Washington, DC 20001 which was published in the **Federal Register** on September 5, 2013, 78 FR Pgs. 54664–54665.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892. The meeting will start on December 17, 2013 at 9:00 a.m. and end on December 17, 2013 at 7:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25560 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; ''Immune Mechanisms of Virus Control (U19).''

Date: November 13–14, 2013.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Zhuqing Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–9523, *zhuqing.li@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25476 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 18, 2013, 1:00 p.m. to 2:00 p.m., The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854 which was published in the **Federal**

Register on September 24, 2013, 78 FR Pgs. 58547–58548.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The meeting will start on October 31, 2013 at 11:00 a.m. and will end at 12:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25480 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cancer Biomarkers Study Section, October 18, 2013, 08:00 a.m. to October 18, 2013, 06:00 p.m., Houston JW Marriott, 5150 Westheimer Road, Houston, TX 77056 which was published in the **Federal Register** on September 24, 2013, 78 FR Pgs. 58547–58548.

The meeting will start on December 16, 2013 at 8:00 a.m. and end on December 16, 2013 at 6:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25490 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Eye Council, October 17, 2013, 8:30 a.m. to October 17, 2013, 5:00 p.m., NIH, Neuroscience Building, 6001 Executive Boulevard, Conference Room D, Rockville, MD 20852 which was published in the **Federal Register** on September 11, 2013, 78 FR 55751.

Due to the Government Shutdown of October 2013, the meeting has been rescheduled to October 28, 2013, 2:00 p.m. to 3:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

Melanie Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25479 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, October 3, 2013, 8:30 a.m. to 5:00 p.m., National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892, which was published in the **Federal Register** on June 21, 2013, 78 FR 37557.

The meeting notice is amended to change the date from October 3, 2013, to November 4–6, 2013. The time and location remains the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25469 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 22, 2013, 11:30 a.m. to October 22, 2013, 02:30 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 01, 2013, 78 FR 60295.

The meeting will be held on November 12, 2013. The meeting time and location remain the same. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25500 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, October 15, 2013, 01:00 p.m. to October 15, 2013, 02:30 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD, 20892 which was published in the **Federal Register** on August 13, 2013, 78 FR 50428.

The meeting will be held on November 4, 2014 from 2:00 p.m. until 4:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25466 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Chemo/Dietary Prevention Study Section, October 10, 2013, 08:00 a.m. to October 10, 2013, 07:00 p.m., Holiday Inn San Francisco Fisherman's Wharf, 1300 Columbus Avenue, San Francisco, CA 94133 which was published in the **Federal Register** on September 12, 2013, 78 FR Pg. 56239.

The meeting will be held at Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The meeting will start on December 9, 2013 at 8:00 a.m. and end on December 9, 2013 at 7:00 p.m. The meeting is closed to the public.

Dated: October 24, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25559 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 4, 2013, 12:00 p.m. to October 4, 2013, 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the Federal Register on September 10, 2013, 78 FR 55269.

The meeting will be held on November 26, 2013, from 1:00 p.m. to 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: October 24, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25505 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Tumor Microenvironment Study Section, October 21, 2013, 08:00 a.m. to October 22, 2013, 05:00 p.m., Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015 which was published in the **Federal Register** on September 26, 2013, 78 FR 59361.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, on November 5, 2013, starting at 08:00 a.m. and ending at 07:00 p.m. The meeting is closed to the public.

Dated: October 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–25491 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Organization, Functions, and Delegations of Authority

Part N, National Institutes of Health (NIH), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 77 FR 1941, January 12, 2012, and redesignated from Part HN as Part N at 60 FR 56605, November 9, 1995), is amended as set forth below to reflect a functional statement amendment for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD).

Section N–T, Organization and Functions, under the heading *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) (NT, formerly HNT), is revised as follows:

(1) Provides leadership and formulates research goals and long-term plans to accomplish the Institute's mission of child health; maternal health; problems of human development, with special reference to intellectual and developmental disabilities; family structure and the dynamics of human population; the reproductive process; and medical rehabilitation; (2) conducts, fosters, and supports biomedical and behavioral research through research grants, research contracts, and research performed in its own laboratories; (3) supports training in fundamental sciences and clinical disciplines through individual and institutional research training awards; (4) promotes the application of research findings to clinical practice; (5) cooperates in government-wide efforts to improve health and provides consultation to Federal agencies and non-Federal groups in the development of programs to improve health; (6) coordinates and integrates research efforts with service-oriented health agencies; and (7) disseminates information related to research findings to practitioners and the general public for improving health.

Delegations of Authority Statement: All delegations and redelegations of authority to officers and employees of NIH that were in effect immediately prior to the effective date of this reorganization and are consistent with this reorganization shall continue in effect, pending further redelegation.

Dated: September 30, 2013.

Francis S. Collins,

Director.

[FR Doc. 2013–25432 Filed 10–28–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Voluntary Customer Satisfaction Surveys To Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0197)—Extension

Executive Order 12862 directs agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and Web sites. Many of these services are focused on information

dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/ respondent	Hours/ response	Total hours
Focus groups	250	1	2.50	625
Self-administered, mail, telephone and e-mail surveys	89,750	1	.250	22,438
Total	90,000			23,063

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received by December 30, 2013.

Summer King,

Statistician.

[FR Doc. 2013–25563 Filed 10–28–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of November 20, 2013 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Adminstrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

Community	Community map repository address
City and County of Denver, Colorado Docket No.: FEMA–B–1266	
City and County of Denver	Department of Public Works, 201 West Colfax Avenue, Denver, CO 80202.
Lander County, Nevada (All Jurisdictions) Docket No.: FEMA–B–1265	
Unincorporated Areas of Lander County	Lander County Planning Department, 825 North Second Street, Battle Mountain, NV 89820.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: September 16, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–25522 Filed 10–28–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4148–DR; Docket ID FEMA–2013–0001]

New Mexico; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New Mexico (FEMA–4148–DR), dated September 30, 2013, and related determinations.

DATES: *Effective Date:* September 30, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 30, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of New Mexico resulting from severe storms and flooding during the period of July 23–28, 2013, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of New Mexico.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to Section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Nancy M. Casper, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of New Mexico have been designated as adversely affected by this major disaster:

Bernalillo, Colfax, Luna, Sandoval, and Socorro Counties and the Cochiti, Kewa (Santa Domingo), San Felipe, and Sandia Pueblos for Public Assistance.

All counties and Indian Tribes within the State of New Mexico are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–25620 Filed 10–28–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4149–DR; Docket ID FEMA–2013–0001]

Pennsylvania; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Pennsylvania (FEMA–4149–DR), dated October 1, 2013, and related determinations.

DATES: *Effective Date:* October 1, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 1, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the Commonwealth of Pennsylvania resulting from severe storms, tornadoes, and flooding during the period of June 26 to July 11, 2013, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the Commonwealth of Pennsylvania.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to Section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Donald L. Keldsen, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Pennsylvania have

been designated as adversely affected by this major disaster:

Centre, Clearfield, Clinton, Crawford, Fayette, Huntingdon, Jefferson, Lawrence, Venango, and Wayne Counties for Public Assistance.

All counties within the Commonwealth of Pennsylvania are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–25623 Filed 10–28–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Notice of Maximum Amount of Assistance Under the Individuals and Households Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice of the maximum amount for assistance under the Individuals and Households Program for emergencies and major disasters declared on or after October 1, 2013.

DATES: *Effective Date:* October 1, 2013, and applies to emergencies and major disasters declared on or after October 1, 2013.

FOR FURTHER INFORMATION CONTACT: Michael Grimm, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 212–1000.

SUPPLEMENTARY INFORMATION: Section 408 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act), 42 U.S.C. 5174, prescribes that FEMA must annually adjust the maximum amount for assistance provided under the Individuals and Households Program (IHP). FEMA gives notice that the maximum amount of IHP financial assistance provided to an individual or household under section 408 of the Stafford Act with respect to any single emergency or major disaster is $32,400. The increase in award amount as stated above is for any single emergency or major disaster declared on or after October 1, 2013. In addition, in accordance with 44 CFR 61.17(c), this adjustment includes the maximum amount of available coverage under any Group Flood Insurance Policy (GFIP) issued for those disasters.

FEMA bases the adjustment on an increase in the Consumer Price Index for All Urban Consumers of 1.5 percent for the 12-month period, which ended in August 2013. The Bureau of Labor Statistics of the U.S. Department of Labor released the information on September 17, 2013.

Catalog of Federal Domestic Assistance No. 97.048, Federal Disaster Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–25626 Filed 10–28–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Vessel Entrance or Clearance Statement

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Vessel Entrance or Clearance Statement (CBP Form 1300). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Written comments should be received on or before December 30, 2013, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Vessel Entrance or Clearance Statement.

OMB Number: 1651–0019.

Form Number: CBP Form 1300.

Abstract: CBP Form 1300, *Vessel Entrance or Clearance Statement,* is used to collect essential commercial vessel data at time of formal entrance and clearance in U.S. ports. The form allows the master to attest to the truthfulness of all CBP forms associated with the manifest package, and collects information about the vessel, cargo, purpose of entrance, certificate numbers, and expiration for various certificates. It also serves as a record of fees and tonnage tax payments in order to prevent overpayments. CBP Form 1300 was developed through agreement

by the United Nations Intergovernmental Maritime Consultative Organization (IMCO) in conjunction with the United States and various other countries. The form was developed as a single form to replace the numerous other forms used by various countries for the entrance and clearance of vessels. CBP Form 1300 is authorized by 19 U.S.C. 1431, 1433, and 1434, and provided for by 19 CFR 4.7–4.9. This form is accessible at *http://forms.cbp.gov/pdf/CBP_Form_1300.pdf*

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information being collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 12,000.

Estimated Number of Responses per Respondent: 22.

Estimated Total Annual Responses: 264,000.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 132,000

Dated: October 23, 2013.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2013–25366 Filed 10–28–13; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5740–N–01]

60-Day Notice of Proposed Information Collection: HUD Multifamily Rental Project Closing Documents Renewal of Currently Approved Collection

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described in this notice. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on this proposed collection of information. The purpose of this notice is to allow for 60 days of public comment on HUD's proposed renewal of its currently approved collection.

DATES: Comments Due Date: December 30, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov,* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents to be submitted to OMB may be found at: *http://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/mfh/mfhclosingdocuments.* Please note that HUD will not consider any redline/strikeout comparison documents submitted by commenters, as it is far too inefficient for the Department to consolidate and consider redline/strikeout versions of each of the documents from numerous interested parties, based on HUD's past experience in seeking public comments on the FHA multifamily closing documents. HUD will only consider proposed changes to the documents listed below that are submitted in narrative and/or bulleted form, accompanied by a detailed explanation and rationale for each requested change. Commenters may include in their narrative or bullet points the relevant excerpt(s) from the document(s) with redlines/strikeouts, accompanied with a detailed explanation and rationale for the changes.

A. Overview of Information Collection

Title of Information Collection: Multifamily Rental Project Closing Documents.

OMB Approval Number: 2502–0598.

Type of Request: Extension of currently approved collection (with proposed HUD-initiated technical and substantive modifications based on information and experiences of HUD staff working with the documents since 2011) and two proposed new forms, as further discussed in this notice.

Form Number: Please see below.

Description of the need for the information and proposed use: These are closing documents (Closing Documents) used in Federal Housing Administration (FHA) multifamily rental projects. The documents included in the proposed collection of information, including where applicable redline/strikeout versions showing proposed changes to documents currently in use, have been posted on HUD's Web site at: *http://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/mfh/mfhclosingdocuments.*

Estimated Burden: Please see following table.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost	Total annual cost
HUD–91710M	600	1	600	0.5	300	$26	$700
HUD–91712M	600	1	600	0.5	300	26	7,800
HUD–92023M	1250	1	1250	1	1250	26	32,500
HUD–92070M	60	1	60	0.5	30	26	780
HUD–92223M	600	1	600	0.5	300	26	7,800
HUD–92412M	175	1	175	0.5	87.50	26	2,275
HUD–92414M	1250	1	1250	0.5	625	26	16,250
HUD–92450M	175	1	175	0.5	87.50	26	2,275
HUD–92452A–M	175	1	175	0.5	87.50	26	2,275
HUD–92452M	175	1	175	0.5	87.50	26	2,275
HUD–92455M	1075	1	1075	1	1075	26	27,950
HUD–92456M	175	1	175	0.5	87.50	26	2,275
HUD–91073M	1250	1	1250	0.5	625	26	16,250

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hours per response	Annual burden hours	Hourly cost	Total annual cost
HUD–92464M	1250	1	1250	1	1250	46	57,500
HUD–92476.1M	1075	1	1075	0.5	537.50	26	13,975
HUD–92476a-M	175	1	175	0.5	87.50	26	2,275
HUD–92477M	175	1	175	0.5	87.50	26	2,275
HUD–92478M	1250	1	1250	0.5	625	26	16,250
HUD–92479M	175	1	175	0.5	87.50	26	2,275
HUD–91725M	1250	1	1250	1	1250	125	156,250
HUD–91725M–CERT	1250	1	1250	1	1250	46	57,500
HUD–91725M–INST	0	0	0	0	0	0	0
HUD–92434M	175	1	175	1	175	26	4,550
HUD–92441M–SUPP	175	1	175	.75	131.25	26	3,412.50
HUD–92441M	175	1	175	.75	131.25	26	3,412.50
HUD–92442M	175	1	175	1	175	58	10,150
HUD–92466M	1250	1	1250	1	1250	58	72,500
HUD–92554M	175	1	175	0.5	87.50	26	2,275
HUD–94000M	1250	1	1250	0.75	937.5	26	24,375
HUD–94001M	1250	1	1250	1	1250	26	32,500
HUD–93305M	1250	1	1250	0.5	625	26	16,200
HUD–92476M	20	1	20	0.5	10	26	200
HUD–92420M	600	1	600	0.5	300	26	7,800
HUD–92408M	1250	1	600	2	2500	103	257,500
HUD–91070M	1250	1	1250	0.5	625	36	22,500
HUD–91071M	20	1	20	0.5	10	26	260
Totals			23,175		18,325		894,550.00

The hourly rate is an estimate based on an average annual salary of 62,000 for developers and mortgagees.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in this notice on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected or any content of the Closing Documents.

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

(5) With respect to the Construction Contract (HUD–92442M) and the HUD Amendment to AIA Document B108 (HUD–92408–M) (''Owner-Architect Agreement''), are there states with attorney fee shifting statutes that favor contractors and/or architects, such that contractors and/or architects are awarded attorney's fees when they prevail against owners in litigation, but owners who prevail are not similarly awarded attorney's fees unless there is an explicit provision for such awards in the construction contract or owner-architect agreement? If so, does this create an imbalance between the parties that HUD should address in these form documents? Further, irrespective of whether such state fee shifting statutes exist, should the Construction Contract (HUD–92442M) and the HUD Amendment to AIA Document B108 (HUD–92408–M) be revised to include a provision allowing attorney fees to the prevailing party in litigation?

(6) *Whether the new form, Consolidated Certifications—Borrower (HUD–91070M),* improves efficiency by consolidating all the certifications the borrower is required to make in a single form.

(7) *Whether the new form, Escrow Agreement for Off-site Facilities (HUD–91071M),* effectively streamlines, updates and standardizes an outdated and difficult to locate form used in certain situations when there is required work to be performed away from the HUD project site by combining HUD's requirements for the escrow for off-site work with the more modern approach taken in HUD's other escrow forms used in FHA-insured multifamily rental closings.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 23, 2013.

Laura M. Marin,

Associate General Deputy Assistant Secretary for Housing-Associate Deputy Federal Housing Commissioner.

[FR Doc. 2013–25574 Filed 10–28–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[Docket No. ONRR–2012–0003; DS63600000 DR2PS0000.PX8000 134D0102R2]

U.S. Extractive Industries Transparency Initiative Multi-Stakeholder Group (USEITI MSG) Advisory Committee

AGENCY: Policy, Management and Budget, Interior.

ACTION: Meeting.

SUMMARY: This notice announces the rescheduling of the U.S. Extractive Industries Transparency Initiative (USEITI) public outreach sessions that were cancelled due to the Federal Government lapse in appropriations. This notice also serves to extend the public's opportunity to comment on the draft USEITI Candidacy Application.

DATES: The online webinar that had been scheduled for October 2, 2013 will now take place November 4, 2013, from 1:00–3:00 p.m. Eastern Time. View the presentation via WebEx at *http://bit.ly/ZQ9aQP* and dial into a moderated conference line at 888–456–0321 (Passcode: USEITI).

The public outreach session scheduled for October, 10, 2013 is rescheduled for November 14, 2013, and will occur in-person from 4:00 p.m. to 7:00 p.m. Eastern Time at the Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, 2nd Floor, Pittsburgh, Pennsylvania 15220. Members of the public may attend in person.

The deadline to submit public comments on the draft USEITI Candidacy Application is extended to November 18, 2013. Comments may be provided in writing or in person at the public outreach sessions and public webinar, or online at *www.doi.gov/eiti*.

FOR FURTHER INFORMATION CONTACT: Rosita Compton Christian, USEITI Secretariat; 1849 C Street NW., MS–4211, Washington, DC 20240. You may also contact the USEITI Secretariat via email at *useiti@ios.doi.gov*, by phone at 202–208–0272, or by fax at 202–513–0682.

SUPPLEMENTARY INFORMATION: The U.S. Department of the Interior established the USEITI Advisory Committee (Committee) on July 26, 2012, to serve as the initial USEITI multi-stakeholder group. More information about the Committee, including its charter, can be found at *www.doi.gov/eiti/faca*.

If you require special assistance (such as an interpreter for the hearing impaired), please notify Interior staff in advance of the meetings at 202–208–0272 or via email at *useiti@ios.doi.gov*.

Anyone wishing to provide comments during the public comment period must submit written statements by November 18, 2013to *useiti@ios.doi.gov* or to the attention of the USEITI Secretariat, U.S. Department of the Interior, 1849 C St, NW MS–4211, Washington, DC 20240. In addition, individuals or groups wishing to make comments in person or via the online webinar may do so during the designated time on the agenda, as time permits.

For more information on USEITI, visit *www.doi.gov/eiti*.

Dated: October 23, 2013.

Amy Holley,

Chief of Staff—Policy, Management and Budget.

[FR Doc. 2013–25462 Filed 10–28–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2013–0003; OMB Number 1014–0006; 134E1700D2 EEEE500000 ET1SF0000.DAQ000]

Information Collection Activities: Sulphur Operations; Submitted for Office of Management and Budget (OMB) Review; Comment Request

ACTION: 30-day Notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), we are notifying the public that we have submitted to OMB an information collection request (ICR) to renew approval of the paperwork requirements in the regulations under Subpart P, *Sulphur Operations.* This notice also provides the public a second opportunity to comment on the paperwork burden of these regulatory requirements.

DATES: You must submit comments by November 29, 2013.

ADDRESSES: Submit comments by either fax (202) 395–5806 or email (OIRA_Submission@omb.eop.gov) directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior (1014–0006). Please provide a copy of your comments to BSEE by any of the means below.

- *Electronically:* go to *http://www.regulations.gov.* In the Search box, enter BSEE–2013–0003 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- *Email nicole.mason@bsee.govcheryl.blundon@boemre.gov,* fax (703) 787–1546, or mail or hand-carry comments to: Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; Attention: Nicole Mason; 381 Elden Street, HE3313; Herndon, Virginia 20170–4817. Please reference 1014–0006 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Nicole Mason, Regulations and Standards Branch, (703) 787–1605, to request additional information about this ICR. To see a copy of the entire ICR submitted to OMB, go to *http://www.reginfo.gov* (select Information Collection Review, Currently Under Review).

SUPPLEMENTARY INFORMATION:

Title: 30 CFR 250, Subpart P, *Sulphur Operations.*

OMB Control Number: 1014–0006.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations necessary for the administration of the leasing provisions of that Act related to mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease, right-of-way, or a right-of-use and easement. Operations on the OCS must preserve, protect, and develop mineral resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; balance orderly energy resource development with protection of human, marine, and coastal environments; ensure the public a fair and equitable return on the resources of the OCS; and preserve and maintain free enterprise competition.

In addition to the general rulemaking authority of the OCSLA at 43 U.S.C. 1334, section 301(a) of the Federal Oil and Gas Royalty Management Act (FOGRMA), 30 U.S.C. 1751(a), grants authority to the Secretary to prescribe such rules and regulations as are reasonably necessary to carry out FOGRMA's provisions. While the majority of FOGRMA is directed to royalty collection and enforcement, some provisions apply to offshore operations. For example, section 108 of FOGRMA, 30 U.S.C. 1718, grants the Secretary broad authority to inspect lease sites for the purpose of determining whether there is compliance with the mineral leasing laws. Section 109(c)(2) and (d)(1), 30 U.S.C. 1719(c)(2) and (d)(1), impose substantial civil penalties for failure to permit lawful inspections and for knowing or willful preparation or submission of false, inaccurate, or misleading reports, records, or other information. Because the Secretary has delegated some of the authority under FOGRMA to BSEE, 30 U.S.C. 1751 is included as additional authority for these requirements.

Regulations implementing these responsibilities are under 30 CFR part 250. Responses are mandatory and/or required to obtain or retain a benefit. No questions of a sensitive nature are asked. The BSEE will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR 2); 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection;* and 30

CFR part 252, *OCS Oil and Gas Information Program.*

The BSEE uses the information collected to ascertain the condition of drilling sites for the purpose of preventing hazards inherent in sulphur drilling and production operations and to evaluate the adequacy of equipment and/or procedures to be used during the conduct of drilling, well-completion, well-workover, and production operations. The BSEE uses the information to:

- Ascertain that a discovered sulphur deposit can be classified as capable of production in paying quantities.
- Ensure accurate and complete measurement of production to determine the amount of sulphur royalty payments due the United States; and that the sale locations are secure, production has been measured accurately, and appropriate follow-up actions are initiated.
- Ensure the adequacy and safety of firefighting systems; the drilling unit is fit for the intended purpose; and the adequacy of casing for anticipated conditions.
- Review drilling, well-completion, well-workover diagrams and procedures, as well as production operation procedures to ensure the safety of the proposed sulphur drilling, well-completion, well-workover and proposed production operations.
- Monitor environmental data during sulphur operations in offshore areas where such data are not already available to provide a valuable source of information to evaluate the performance of drilling rigs under various weather and ocean conditions. This information is necessary to make reasonable determinations regarding safety of operations and environmental protection.

Frequency: Submissions are on occasion and generally vary by section.

Description of Respondents: Potential respondents comprise Federal OCS sulphur lessees.

Estimated Reporting and Recordkeeping Hour Burden: The estimated annual hour burden for this information collection is a total of 903 hours. The following chart details the individual components and estimated hour burdens. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

Citation 30 CFR 250 subpart P	Reporting and recordkeeping requirement	Hour burden	Average number of annual reponses	Annual burden hours
	Submittals/Notifications			
1600; 1617	Submit exploration or development and production plan, under 30 CFR 550, Subpart B.	Burden covered under (1010–0151)		0
1605(b)(2), (3)	Make drilling units available for inspection; submit and/or resubmit data and information on fitness of drilling unit.	4	1 submission	4
1605(d)	Submit results of additional surveys and soil borings upon request.	1	1 submission	1
1605(f)	Submit application for installation of fixed drilling platforms or structures.	Burden covered under (1014–0011)		0
1608(a), (c)	Submit well casing and cementing plan or modification.	5	1 plan	5
1617; 1622(b)	Submit form BSEE–0123 (Application for Permit to Drill), and all supporting documentation.	Burden covered under (1014–0018)		0
1618; 1619(b); 1622(a), (c)	Submit form BSEE–0124 (Application for Permit to Modify), and all supporting documentation.	Burden covered under (1014–0018)		0
1619(b); 1622(c)	Submit form BSEE–0125 (End of Operations Report); and all supporting documentation.	Burden covered under (1014–0018)		0
1619(c), (d), (e)	Submit copies of records, logs, reports, charts, etc., upon request.	1	8 submissions	8
1628(b), (d)	Submit application for design and installation features of sulphur production facilities and fuel gas safety system; certify new installation conforms to approved design.	4	1 application	4
1630(a)(6)	Notify BSEE of pre-production test and inspection of safety system and commencement of production.	0.5	2 notifications	1
1633(b)	Submit application for method of production measurement.	2	1 application	2
Subtotal			15 responses	25
	Requests			
1603(a)	Request determination whether sulphur deposit can produce in paying quantities.	1	1 request	1
1605(e)(5)	Request copy of directional survey (by holder of adjoining lease).	1	1 request	1
1607	Request establishment, amendment, or cancellation of field rules for drilling, well-completion, or well-workover.	8	2 requests	16

Citation 30 CFR 250 subpart P	Reporting and recordkeeping requirement	Hour burden	Average number of annual reponses	Annual burden hours
1610(d)(7), (8)	Request exception to ram-type blowout preventer (BOP) system components rated working pressure.	1	1 request	1
1611(b); 1625(b)	Request exception to water-rated working pressure to test ram-type and annular BOPs and choke manifold.	1	1 request	1
1611(f); 1625(f)	Request exception to recording pressure conditions during BOP tests on pressure charts; certify by representative.	1	1 request	1
1612	Request exception to § 250.462 requirements for well-control drills.	1	1 request	1
1615	Request exception to blind-shear ram or pipe rams and inside BOP to secure wells.	1	1 request	1
1629(b)(3)	Request approval of firefighting systems; post firefighting system diagram.	4	1 request	4
1608(b), (c); 1629(b)(3); 1600–1634.	General departure and/or alternative compliance requests not specifically covered elsewhere in Subpart P.	2	1 request	2
Subtotal			11 responses	29
	Record/Retain			
1604(f)	Check traveling-block safety device for proper operation weekly and after each drill-line slipping; enter results in log.	0.25	1 lessee × 52 wks × 2 rigs = 104.	26
1605(c)	Report oceanographic, meteorological, and drilling unit performance data upon request.	1	1 report	1
1609(a)	Pressure test casing; record time, conditions of testing, and test results in log.	2	1 lease × 60 tests/records = 60.	120
1611(d)(3); 1625(d)(3)	Record in driller's report the date, time, and reason for postponing pressure testings.	0.17	1 lessee × 6 recordings = 6.	1
1611(f), (g); 1625(f), (g)	Conduct tests, actuations, inspections, maintenance, and crew drills of BOP systems at least weekly; record results in driller's report; certify by representative; retain records for 2 years following completion of drilling activity.	6	1 lessee × 52 weeks = 52	312
1613(d)	Pressure test diverter sealing element/valves weekly; actuate diverter sealing element/valves/control system every 24 hours; test diverter line for flow every 24 hours; record test times and results in driller's report.	2	1 lessee (daily/weekly during drilling) × 2 rigs × 52 weeks = 104.	208
1616(c)	Retain training records for lessee and drilling contractor personnel.	Burden covered under 1014–0008		0
1619(a); 1623(c)	Retain records for each well and all well operations for 2 years; calculate well-control fluid volume and post near operators' station.	12	1 lessee	12
1621	Conduct safety meetings prior to well-completion or well-workover operations; record date and time.	1	1 lessee × 50 meetings/records = 50.	50
1628(b), (d)	Maintain information on approved design and installation features for the life of the facility.	1	1 lessee	1
1629(b)(1)(ii)	Retain pressure-recording charts used to determine operating pressure ranges for 2 years.	12	1 lessee	12
1630(b)	Maintain records for each safety device installed for 2 years; make available for review.	1	1 lessee	1
1631	Conduct safety device training prior to production operations and periodically thereafter; record date and time.	1	1 lessee × 52 train/records × 2 rigs = 104.	104
1634(b)	Report evidence of mishandling of produced sulphur or tampering or falsifying any measurement of production.	1	1 report	1
Subtotal			486 responses	849
Total Burden			512 responses	903 Hours

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified no non-hour cost burdens associated with the collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.)* provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a

collection of information, you are not obligated to respond.

Comments: Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3501, *et seq.*) requires each agency ''. . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .'' Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

To comply with the public consultation process, on July 16, 2013, we published a **Federal Register** notice (78 FR 42538) announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day comment period. Also, 30 CFR 250.199 explains that BSEE will accept comments at any time on the information collection requirements and burdens of our 30 CFR part 250 regulations. We display the OMB control number and provide the address to which they should send comments. We received two comments in response to the **Federal Register** notice; however, neither was germane to this information collection. These are not new regulatory requirements and only an estimate of minimal burden for a potential respondent.

Public Availability of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

BSSE Information Collection Clearance Officer: Cheryl Blundon (703) 787–1607.

Dated: October 22, 2013.

Robert W. Middleton,

Deputy Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2013–25433 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2013–N217: FXES11130600000D2–123–FF06E00000]

Endangered and Threatened Wildlife and Plants; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following application to conduct certain activities with endangered or threatened species. With some exceptions, the Endangered Species Act of 1973, as amended (Act), prohibits activities with endangered and threatened species unless a Federal permit allows such activity. The Act requires that we invite public comment before issuing these permits.

DATES: To ensure consideration, please send your written comments by November 29, 2013.

ADDRESSES: You may submit comments or requests for copies or more information by any of the following methods. Alternatively, you may use one of the following methods to request hard copies or a CD–ROM of the documents. Please specify the permit you are interested in by number (e.g., Permit No. TE–XXXXXX).

- *Email: permitsR6ES@fws.gov.* Please refer to the respective permit number (e.g., Permit No. TE–XXXXXX) in the subject line of the message.
- *U.S. Mail:* Ecological Services, U.S. Fish and Wildlife Service, P.O. Box 25486–DFC, Denver, CO 80225.
- *In-Person Drop-Off, Viewing, or Pickup:* Call (303) 236–4212 to make an appointment during regular business hours at 134 Union Blvd., Suite 645, Lakewood, CO 80228.

FOR FURTHER INFORMATION CONTACT: Kathy Konishi, Permit Coordinator, Ecological Services, (303) 236–4212 (phone); *permitsR6ES@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Background

The Act (16 U.S.C. 1531 *et seq.*) prohibits activities with endangered and threatened species unless a Federal permit allows such activity. Along with our implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR 17, the Act provides for permits and requires that we invite public comment before issuing these permits.

A permit granted by us under section 10(a)(1)(A) of the Act authorizes the permittee to conduct activities with U.S. endangered or threatened species for scientific purposes, enhancement of propagation or survival, or interstate commerce (the latter only in the event that it facilitates scientific purposes or enhancement of propagation or survival). Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, and Federal agencies and the public to comment on the following application. Documents and other information the applicant has submitted with this application is available for review, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552).

Permit Application Number: TE046795

Applicant: Power Engineers, 3940 Glenbrook Drive, Hailey, ID 83333.

The applicant requests a permit to conduct presence/absence surveys in the States of Nebraska and Kansas through trap (take) and release of the American burying beetle (*Nicrophorus americanus*) for the purpose of enhancing the species' survival.

National Environmental Policy Act

In compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), we have made an initial determination that the proposed activities in this permit are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement (516 DM 6 Appendix 1, 1.4C(1)).

Public Availability of Comments

All comments and materials we receive in response to this request will be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section of this notice.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*).

Dated: October 23, 2013.

Michael G. Thabault,

Assistant Regional Director, Mountain-Prairie Region.

[FR Doc. 2013–25538 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[14X LLIDB00100 LF1000000.HT0000 LXSS024D0000 241A]

Resource Advisory Council to the Boise District, Public Meeting

AGENCY: Bureau of Land Management, U.S. Department of the Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Boise District Resource Advisory Council (RAC), will hold a meeting as indicated below.

DATES: The meeting will be held November 19, 2013, at the Boise District Office, located at 3948 S. Development Avenue, Boise, Idaho, beginning at 9:00 a.m. and adjourning at 2:00 p.m. Members of the public are invited to attend. A public comment period will be held.

FOR FURTHER INFORMATION CONTACT: Marsha Buchanan, Supervisory Administrative Specialist and RAC Coordinator, BLM Boise District, 3948 Development Ave., Boise, ID 83705, Telephone (208) 384–3364.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in southwestern Idaho. A report on 2013 wildland fire activity within Boise District and the region will be provided as well as an update on the Paradigm Project. Council members will discuss priority projects for the coming year based on BLM-Idaho priorities. The RAC members will be briefed on ongoing fuels projects. Agenda items and location may change due to changing circumstances. The public may present written or oral comments to members of the Council. At each full RAC meeting, time is provided in the agenda for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance should contact the BLM Coordinator as provided above. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

Dated: October 22, 2013.

Meagan M. Conry,

Associate District Manager.

[FR Doc. 2013–25540 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLID9570000.LL14200000.BJ0000]

Idaho: Filing of Plats of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of surveys.

SUMMARY: The Bureau of Land Management (BLM) has officially filed the plats of survey of the lands described below in the BLM Idaho State Office, Boise, Idaho, effective 9:00 a.m., on the dates specified.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho, 83709–1657.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Land Management to meet their administrative needs. The lands surveyed are:

The plat representing the dependent resurvey of portions of the north and east boundaries and the subdivisional lines, and the subdivision of sections 1 and 12, T. 11 S., R. 37 E., of the Boise Meridian, Idaho, Group Number 1363, was accepted July 9, 2013.

The plat representing the dependent resurvey of portions of the north boundary and subdivisional lines, and the subdivision of sections 6, 7, 8, and 9, T. 11 S., R. 38 E., of the Boise Meridian, Idaho, Group Number 1361, was accepted July 9, 2013.

The plat representing the dependent resurvey of portions of the east boundary and subdivisional lines, and the subdivision of sections 13, 17, 20, 21, 24, 27, 28, and 29, T. 8 N., R. 39 E., of the Boise Meridian, Idaho, Group Number 1351, was accepted July 9, 2013.

The plat representing the dependent resurvey of portions of the north boundary and subdivisional lines, and the subdivision of section 5, and a metes-and-bounds survey in section 5, T. 7 N., R. 23 E., of the Boise Meridian, Idaho, Group Number 1381, was accepted August 26, 2013.

The plat representing the dependent resurvey of portions of the Boise Base Line (south boundary), west boundary, and subdivisional lines, and the subdivision of section 31, T. 1 N., R. 12 E., of the Boise Meridian, Idaho, Group Number 1360, was accepted August 30, 2013.

The plat representing the dependent resurvey of portions of the west boundary, subdivisional lines, and the original 1911 meanders of the Salmon River in section 7, and the subdivision of section 7, the survey of the 2012 meanders of the Salmon River in section 7, and the survey of certain 2012 partition lines in section 7, T. 12 N., R. 19 E., Boise Meridian, Idaho, Group Number 1382, was accepted September 4, 2013.

The plat representing the dependent resurvey of portions of the south boundary and subdivisional lines, and the subdivision of sections 27, 29, and 32, T. 15 N., R. 27 E., Boise Meridian, Idaho, Group Number 1391, was accepted September 5, 2013.

This survey was executed at the request of the Bureau of Indian Affairs to meet their administrative needs. The lands surveyed are:

The plat representing the dependent resurvey of portions of the Boise Meridian (east boundary), south boundary, subdivisional lines, and subdivision of sections 15, 30, and 31, and the further subdivision of sections 15, 30, and 31, T. 35 N., R. 1 W., Boise Meridian, Idaho, Group Number 1352, was accepted September 30, 2013.

This survey was executed at the request of the U.S.D.A. Forest Service to meet their administrative needs. The lands surveyed are:

The supplemental plat was prepared to show amended lottings in sections 2, 3, 10, and 11, T. 28 N., R. 3 E., Boise Meridian, Idaho, Group Number 1402, was accepted August 27, 2013.

Dated: October 18, 2013.

Stanley G. French,

Chief Cadastral Surveyor for Idaho.

[FR Doc. 2013–25523 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L1430000–EU0000]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on November 29, 2013.

DATES: Protests of the survey must be filed before November 29, 2013 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Blaise Lodermeier, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5128 or (406) 896–5009, *bloderme@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the BLM Butte Field Office, and was necessary to determine federal interest lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 10 N., R. 4 W.

The plat, in one sheet, representing the dependent resurvey of a portion of the Boulder Guide Meridian and the survey of a certain lot within Section 36, Township 10 North, Range 4 West, Principal Meridian, Montana, was accepted October 17, 2013.

We will place a copy of the plat, in one sheet, and related field notes we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in one sheet, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in one sheet, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

James D. Claflin,

Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2013–25611 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L14200000–BJ0000]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on November 29, 2013.

DATES: Protests of the survey must be filed before November 29, 2013 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Blaise Lodermeier, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5128 or (406) 896–5009, *bloderme@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the BLM Malta Field Office, and was necessary to determine federal interest lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 25 N., R. 25 E.

The plat, in two sheets, representing the dependent resurvey of a portion of the subdivisional lines and Block 7 of the Zortman Townsite, Township 25 North, Range 25 East, Principal Meridian, Montana, was accepted October 17, 2013.

We will place a copy of the plat, in two sheets, in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in two sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in two sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

James D. Claflin,

Chief Cadastral Surveyor, Division of Resources.

[FR Doc. 2013–25609 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVL02000.L14300000.ET0000; N–56170; 13–08807; MO#4500051113]

Notice of Proposed Withdrawal Extension, Sacramento Pass Recreation Area; Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary of the Interior for Policy, Management and Budget proposes to extend the duration of Public Land Order (PLO) No. 7060 for an additional 20-year term. PLO No. 7060 withdrew 464.93 acres of public land from settlement, sale, location, or entry under the general land laws, including the United States mining laws, but not from leasing under the mineral leasing laws, to protect the Sacramento Pass Recreation Area (SPRA) in White Pine County, Nevada. This notice gives the public an opportunity to comment on the proposed extension and to request a public meeting.

DATES: For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, objections, or request a public meeting in connection with the proposed withdrawal extension may do so in writing until January 27, 2014.

ADDRESSES: Comments and meeting requests should be sent to the District Manager, Bureau of Land Management (BLM), Ely District Office, HC33 Box 33500, 702 North Industrial Way, Ely, Nevada 89301.

FOR FURTHER INFORMATION CONTACT: Elena Montenegro-Long, BLM, Schell Field Office at 775–289–1800, or email *emontenegro@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to reach the BLM. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM has filed an application to extend the withdrawal established by PLO No. 7060 (59 FR 28790 (1994)), for an additional 20-year term. PLO No. 7060 will expire on June 2, 2014, unless extended. PLO No. 7060 is incorporated herein by reference. The land withdrawn by PLO No. 7060 is located about 50 miles east of Ely, Nevada, along State Highway 50. The purpose of the withdrawal extension is to continue to protect a developed campground consisting of picnic facilities, camping areas, vaulted toilets, walking trails, and trailhead access for dispersed recreation opportunities such as hiking, horseback riding, and low-impact camping.

The use of a right-of-way, interagency agreement, or cooperative agreement would not provide adequate protection for the capital improvement investment that the BLM has made in the SPRA.

No additional water rights would be needed to fulfill the purpose of the requested withdrawal extension.

There are no suitable alternative sites since the land described contains the developed campground and improvements of interest for protection.

All persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal extension may present their views in writing to the BLM Ely District Office at the address in the **ADDRESSES** section. Comments, including names and street addresses of respondents, will be available for public review at the BLM Ely District Office, during regular business hours, 7:30 a.m. to 4:30 p.m. Monday through Friday, except Federal holidays.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal extension. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal extension must submit a written request to the District Manager, BLM Ely District Office at the address in the **ADDRESSES** section, within 90 days from the date of publication of this notice. If the authorized officer determines that public meeting will be held, a notice of the date, time, and place will be published in the **Federal Register** and local newspapers and also posted on the BLM Web site at: *http://www.blm.gov/nv/st/en/fo/ely_field_office.html* at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR 2310.4.

Marci L. Todd,

Nevada Associate State Director.

[FR Doc. 2013–25374 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKR–GAAR–14160; PPAKAKROR4] [PPMPRLE1Y.LS0000]

Gates of the Arctic National Park Subsistence Resource Commission Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: As required by the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16), the National Park Service (NPS) is hereby giving notice that the Gates of the Arctic National Park Subsistence Resource Commission (SRC) will hold a meeting to develop and continue work on NPS subsistence program recommendations and other related subsistence management issues. The NPS SRC program is authorized under Title VIII, Section 808 of the Alaska National Interest Lands Conservation Act, Public Law 96–487.

DATES: The Gates of the Arctic National Park SRC will meet from 9:00 a.m. to 5:00 p.m. or until business is completed on Tuesday, November 5, 2013 to Wednesday, November 6, 2013.

ADDRESSES: The SRC will meet at the Gates of the Arctic National Park and Preserve office located at 4175 Geist in Fairbanks, Alaska. For more detailed information regarding this meeting, contact Designated Federal Official Greg Dudgeon, Superintendent, at (907) 457–5752; or Clarence Summers, Subsistence Manager, at (907) 644–3603. If you are interested in applying for SRC membership, contact the Superintendent or visit the park Web site at: *http://www.nps.gov.gaar/contacts.htm.*

SRC Proposed Meeting Agenda

The proposed meeting agenda for each meeting includes the following:

1. Call to Order—Confirm Quorum
2. Welcome and Introduction
3. Review and Adoption of Agenda
4. Approval of Minutes
5. Welcome by Local Community
6. Superintendent's Welcome and Review of the Commission Purpose
7. Commission Membership Status
8. SRC Chair and Members' Reports
9. Superintendent's Report
10. Old Business
11. New Business
12. Federal Subsistence Board Update
13. Alaska Boards of Fish and Game Update
14. National Park Service Reports
    a. Ranger Update
    b. Resource Management Update
    c. Subsistence Manager's Report
15. Public and Other Agency Comments
16. Work Session
17. Set Tentative Date and Location for Next SRC Meeting
18. Adjourn Meeting

SRC meeting locations and dates may change based on inclement weather or exceptional circumstances. If the meeting date and location are changed, the Superintendent will issue a press release and use local newspapers and radio stations to announce the meeting.

SUPPLEMENTARY INFORMATION: This meeting is open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. The meeting will be recorded and meeting minutes will be available upon request from the Park Superintendent for public inspection approximately six weeks after the meeting. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: October 24, 2013.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2013–25634 Filed 10–25–13; 11:15 am]

BILLING CODE 4312–EF–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX066A000 67F 134S180110; S2D2S SS08011000 SX066A00 33F 13xs501520]

Notice of Proposed Information Collection; Request for Comments

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed approval for the collection of information for the State Processes for Designating Areas Unsuitable for Surface Coal Mining Operations. This collection request has been forwarded to the Office of Management and Budget (OMB) for review and approval. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collections but may respond after 30 days. Therefore, public comments should be submitted to OMB by November 29, 2013, in order to be assured of consideration.

ADDRESSES: Comments may be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov,* or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0030 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: The OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted a request to OMB to renew its approval of the collection of information contained in: 30 CFR Part 764—State Processes for Designating Areas Unsuitable for Surface Coal Mining Operations. OSM is requesting a 3-year term of approval for each information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection is 1029–0030, and is displayed in 30 CFR 764.10.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on July 10, 2013 (78 FR 41421). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR Part 764—State Processes for Designating Areas Unsuitable for Surface Coal Mining Operations Areas designated by Act of Congress.

OMB Control Number: 1029–0030.

Summary: This part implements the requirement of section 522 of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Public Law 95–87, which provides authority for citizens to petition States to designate lands unsuitable for surface coal mining operations, or to terminate such designation. The regulatory authority uses the information to identify, locate, compare and evaluate the area requested to be designated as unsuitable, or terminate the designation, for surface coal mining operations.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Individuals or groups that petition the States, and the State regulatory authorities that must process the petitions.

Total Annual Respondents: 4 petitions and 4 regulatory authorities.

Total Annual Burden Hours: 1,000 hours for individuals or groups, and 4,000 for State regulatory authorities.

Total Annual Non-wage Costs: $400.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burdens on respondents, such as use of automated means of collections of the information, to the addresses listed under **ADDRESSES**. Please refer to OMB control number 1029–0030 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: October 22, 2013.

Andrew F. DeVito,

Chief, Division of Regulatory Support.

[FR Doc. 2013–25578 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1205 (Final)]

Silica Bricks and Shapes From China; Revised Schedule for the Subject Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: *Effective Date:* October 23, 2013.

FOR FURTHER INFORMATION CONTACT: Cynthia Trainor (202–205–3354), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On June 20, 2013, the Commission established a

schedule for the conduct of the subject investigation (78 FR 45968, July 30, 2013). The Commission did not operate between October 1, 2013 and October 16, 2013 because of a lack of appropriations. On October 21, 2013 the Commission issued a notice stating that statutory deadlines would be tolled by this disruption in its operations. The Commission, therefore, is revising its schedule to conform to the revised statutory deadlines.

The Commission's new schedule for the review is as follows: Requests to appear at the hearing must be filed with the Secretary to the Commission not later than November 13, 2013; the prehearing conference will be held at the U.S. International Trade Commission Building at 9:30 a.m. on November 15, 2013; the prehearing staff report will be placed in the nonpublic record on November 7, 2013; the deadline for filing prehearing briefs is November 14, 2013; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on November 21, 2013; the deadline for filing posthearing briefs is November 27, 2013; the Commission will make its final release of information on December 5, 2013; and final party comments are due on December 9, 2013.

For further information concerning this investigation see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: October 24, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–25576 Filed 10–28–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–832]

Certain Ink Application Devices and Components Thereof and Methods of Using the Same Commission Issuance of a Limited Exclusion Order Against Infringing Products of Respondents Found in Default; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has issued a limited exclusion order against infringing products of respondents T-Tech Tattoo Device Inc. of Ontario, Canada (''T-Tech''), Yiwu Beyond Tattoo Equipments Co., Ltd. of Yiwu City, China (''Yiwu''), and Guangzhou Pengcheng Cosmetology Firm of Guangzhou, China (''Guangzhou Pengcheng''). The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on March 6, 2012, based on a complaint filed by MT.Derm GmbH of Berlin, Germany and Nouveau Cosmetique USA Inc. of Orlando, Florida (collectively ''Complainants'') alleging violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), as amended (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain ink application devices and components thereof and methods of using the same by reason of infringement of certain claims of U.S. Patent Nos. 6,345,553 (''the '553 patent'') and 6,505,530 (''the '530 patent''). 77 FR 13351, Mar. 6, 2012. The Commission's Notice of Investigation (''NOI'') named T-Tech, Yiwu, and Guangzhou Pengcheng as respondents. The complaint was served on all named respondents on March 1, 2012. The Office of Unfair Import Investigations was named as a party to the investigation.

On April 16, 2012, Complainants filed a motion seeking a determination that respondents T-Tech, Yiwu, and Guangzhou be found in default based on their failure to respond to the Complaint and Notice of Investigation. On May 1, 2012, the ALJ issued Order No. 5, ordering the respondents to show cause by close of business on May 16, 2012, why they should not be found in default. No response was filed, and on May 31, 2012, the ALJ issued an initial determination (''ID'') (Order No. 7), granting the motion for default pursuant to section 210.16(a)(1) of the Commission's Rules of Practice and Procedure (19 CFR 210.16(a)(1)). On June 6, 2012, T-Tech submitted correspondence to the Commission stating that it had not received any prior communication from the Commission and arguing that the ID finding it in default should be reviewed. On June 13, 2012, the IA filed a petition for review of Order No. 7 as to the finding of default against T-Tech. On June 29, 2012, the Commission determined not to review the portion of Order No. 7 finding Yiwu and Guanzhou Pengcheng in default pursuant to section 210.16 of the Commission's Rules of Practice and Procedure (19 CFR 210.16), but reversed the finding of default against T-Tech. Notice (June 29, 2012).

On March 20, 2013, Complainants filed a motion for summary determination of violation of section 337 against T-Tech. On April 17, 2013, Complainants also filed a motion for an ID finding T-Tech in default pursuant to Commission Rule 210.17(e). On April 19, 2013, the ALJ issued Order No. 32, ordering T-Tech to show cause as to why it should not be found in default for failing to comply with deadlines set forth in the procedural schedule. On April 25, 2013, T-Tech filed a response to Order No. 32. On April 29, 2013, the IA filed a response in support of Complainants' motion requesting that T-Tech be found in default. On July 17, 2013, the ALJ issued an ID (Order No. 35), granting-in-part Complainants' motion for summary determination of violation against T-Tech or, in the alternative, granting Complainants' motion for an ID finding T-Tech in default pursuant to section 210.17 of the Commission's Rules of Practice and Procedure (19 CFR 210.17). On August 16, 2013, the Commission determined not to review the portion of the ID finding T-Tech in default. 78 FR 52212–13, Aug. 22, 2013. The Commission found the portion of Order No. 35 granting summary determination of violation moot. *Id.* The Commission also requested briefing from the parties and the public on the issues of remedy, the public interest, and bonding. *Id.*

Complainants and the Commission investigative attorney (''IA'') submitted

briefing responsive to the Commission's request on August 30, 2013. Each proposed a limited exclusion order directed to the accused products of respondents Yiwu, Guangzhou Pengcheng, and T-Tech. Complainants stated that they do not seek entry of cease and desist orders against any of the defaulting respondents. The IA recommended allowing entry by all of the defaulting respondents under a bond of 100 percent of the entered value during the period of Presidential review. Complainants requested a bond of 100 percent against respondent T-Tech, but argued that respondents Yiwu and Guangzhou Pengcheng not be allowed to import any of their infringing products during the period of Presidential review because they were found in default under section 337(g)(1). In the alternative, Complainants requested that the Commission set a bond of 100 percent of the entered value against respondents Yiwu and Guangzhou Pengcheng. On September 6, 2013, Complainants and the IA submitted reply submissions.

The Commission finds that the statutory requirements of section 337(g) (19 U.S.C. 1337(g)) is met with respect to respondents Yiwu and Guangzhou Pengcheng. Accordingly, pursuant to section 337(g)(1) (19 U.S.C. 1337(g)(1)) and Commission rule 210.16(c) (19 CFR 210.16(c)), the Commission presumes the facts alleged in the complaint to be true and finds that Yiwu and Guangzhou Pengcheng are in violation of section 337. The Commission further finds that T-Tech is in violation of section 337 pursuant to section 210.17 of the Commission's Rules of Practice and Procedure (19 CFR 210.17), which states that a failure to participate in an investigation may provide a basis for a finding of violation of section 337 under section 337(d)(1) (19 U.S.C. 1337(d)(1)).

The Commission has determined that the appropriate form of relief in this investigation is a limited exclusion order prohibiting the unlicensed entry of certain ink application devices and components thereof that are manufactured abroad by or on behalf of, or imported by or on behalf of, respondents Yiwu and T-Tech by reason of infringement of one or more of claims 1–3, 7, 8, 19, and 20 of the '530 patent. The Commission has also determined to issue a limited exclusion order prohibiting the unlicensed entry of certain ink application devices and components thereof that are manufactured abroad by or on behalf of, or imported by or on behalf of, respondent Guangzhou Pengcheng by reason of infringement of one or more of 1–3, 7–12 and 16–20 of the '530 patent and claims 1–4, 10, 12–14, 21–23, and 26–28 of the '553 patent. The Commission has further determined that the public interest factors enumerated in section 337(g)(1) (19 U.S.C. 1337(g)(1)) and section 337(d)(1) (19 U.S.C. 1337(d)(1)) do not preclude issuance of the limited exclusion order. Finally, the Commission has determined that the bond for importation during the period of Presidential review shall be in the amount of 100 percent of the entered value of the imported subject articles of all defaulting respondents. The Commission's order was delivered to the President and the United States Trade Representative on the day of its issuance.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

Dated: October 23, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–25425 Filed 10–28–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–13–025]

Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 1, 2013 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none
2. Minutes
3. Ratification List
4. Vote in Inv. Nos. 701–TA–502 and 731–TA–1127 and 1128 (Preliminary)(Steel Concrete Reinforcing Bar from Mexico and Turkey). The Commission is currently scheduled to complete and file its determinations on or before November 6, 2013; Commissioners' opinions will be issued on November 14, 2013.
5. Outstanding action jackets: none

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: October 25, 2013

By order of the Commission.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2013–25722 Filed 10–25–13; 4:15 pm]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Appointment of Individuals To Serve as Members of Performance Review Board

AGENCY: United States International Trade Commission.

ACTION: Appointment of Individuals to Serve as Members of Performance Review Board.

SUMMARY: The Chairman of the U.S. International Trade Commission has appointed the following individuals to serve on the Commission's Performance Review Board (PRB):

Chair of the PRB: Commissioner David S. Johanson
Vice-Chair of the PRB: Commissioner Dean A. Pinkert
Member—Dominic L. Bianchi
Member—Catherine DeFilippo
Member— William E. Dobryzkowski
Member —Robert B. Koopman
Member—Karen Laney
Member—Andrew Martin
Member—Margaret D. MacDonald
Member—Stephen A. McLaughlin
Member—Lyn M Schlitt

DATES: *Effective Date:* October 24, 2013.

FOR FURTHER INFORMATION CONTACT: Patricia Connelly, Director of Human Resources, U.S. International Trade Commission (202) 205–2651.

Authority: This notice is published in the **Federal Register** pursuant to the requirement of 5 U.S.C. 4314(c)(4).

Hearing impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on (202) 205–1810.

Issued: October 24, 2013.

By order of the Chairman.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–25567 Filed 10–28–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Meeting of the CJIS Advisory Policy Board

AGENCY: Federal Bureau of Investigation (FBI), DOJ.

ACTION: Meeting notice.

SUMMARY: The purpose of this notice is to announce the meeting of the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS) Advisory Policy Board (APB). The CJIS APB is a federal advisory committee established pursuant to the Federal Advisory Committee Act (FACA). This meeting announcement is being published as required by Section 10 of the FACA.

The FBI CJIS APB is responsible for reviewing policy issues and appropriate technical and operational issues related to the programs administered by the FBI's CJIS Division, and thereafter, making appropriate recommendations to the FBI Director. The programs administered by the CJIS Division are the Integrated Automated Fingerprint Identification System/Next Generation Identification, Interstate Identification Index, Law Enforcement Online, National Crime Information Center, National Instant Criminal Background Check System, National Incident-Based Reporting System, National Data Exchange, and Uniform Crime Reporting.

This meeting is open to the public. All attendees will be required to sign-in at the meeting registration desk. Registrations will be accepted on a space available basis. Interested persons whose registrations have been accepted may be permitted to participate in the discussions at the discretion of the meeting chairman and with approval of the Designated Federal Officer (DFO). Any member of the public may file a written statement with the Board. Written comments shall be focused on the APB's current issues under discussion and may not be repetitive of previously submitted written statements. Written comments should be provided to Mr. R. Scott Trent, DFO, at least seven (7) days in advance of the meeting so that the comments may be made available to the APB for their consideration prior to the meeting.

Anyone requiring special accommodations should notify Mr. Trent at least seven (7) days in advance of the meeting.

DATES AND TIMES: The APB will meet in open session from 8:30 a.m. until 5 p.m., on December 4–5, 2013.

ADDRESSES: The meeting will take place at Sheraton Atlanta Hotel, 165 Courtland Street NE., Atlanta, Georgia 30303, telephone (404) 659–6500.

FOR FURTHER INFORMATION CONTACT: Inquiries may be addressed to Ms. Jillana L. Plybon; Management and Program Assistant; CJIS Training and Advisory Process Unit, Resources Management Section; FBI CJIS Division, Module C2, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306–0149; telephone (304) 625–5424, facsimile (304) 625–5090.

Dated: September 23, 2013.

R. Scott Trent,

CJIS Designated Federal Officer, Criminal Justice Information Services Division, Federal Bureau of Investigation.

[FR Doc. 2013–25562 Filed 10–28–13; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Claim for Reimbursement of Benefit Payments and Claims Expense Under the War Hazards Compensation Act

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, ''Claim for Reimbursement of Benefit Payments and Claims Expense under the War Hazards Compensation Act,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before November 29, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201306-1240-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Information Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210, email: DOL_PRA_PUBLIC@dol.gov.

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The OWCP is responsible for administering the War Hazards Compensation Act (WHCA) (42 U.S.C. 1701 *et seq.*). WHCA section 1704(a) provides that an insurance carrier or self-insured who has paid workers' compensation benefits to or on account of any person for a war-risk hazard may seek reimbursement for benefits paid (plus expenses) out of the Federal Employees' Compensation Fund. *See also* 5 U.S.C. 8147.

Insurance carriers and the self-insured file a Claim for Reimbursement of Benefit Payments and Claims Expense under the War Hazards Compensation Act, Form CA–278, to request reimbursement. Regulations implementing the WHCA permit the OWCP to collect the information needed to consider an insurance carrier's or self-insured's reimbursement request. *See* 20 CFR 61.101 and 61.104. This ICR has been classified as a revision, because the OWCP has revised Form CA–278 to include an accommodation statement informing claimants with mental or physical limitations to contact the OWCP, Division of Federal Employees' Compensation if they need further assistance with the claims process.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240–0006. The current approval is scheduled to expire on October 31, 2013; however, it should be noted that existing information

collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 5, 2013 (78 FR 40514).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0006. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Claim for Reimbursement of Benefit Payments and Claims Expense under the War Hazards Compensation Act.

OMB Control Number: 1240–0006.

Affected Public: Private Sector–businesses or other for-profits.

Total Estimated Number of Respondents: 7.

Total Estimated Number of Responses: 393.

Total Estimated Annual Burden Hours: 197.

Total Estimated Annual Other Costs Burden: $1,407.

Dated: October 23, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–25510 Filed 10–28–13; 8:45 am]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Coal Mine Rescue Teams: Arrangements for Emergency Medical Assistance and Transportation for Injured Persons—Agreements, Reporting Requirements, and Posting Requirements

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, ''Coal Mine Rescue Teams: Arrangements for Emergency Medical Assistance and Transportation for Injured Persons—Agreements, Reporting Requirements, and Posting Requirements,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before November 29, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201304-1219-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–MSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov*. Commenters are encouraged, but not required, to send a courtesy copy of any comments to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Information Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210, email: *DOL_PRA_PUBLIC@dol.gov*.

FOR FURTHER INFORMATION: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR covers the following requirements for a coal mine: reporting to the MSHA how the mine will comply with mine rescue team requirements; reporting to the MSHA alternative mine rescue capability for a small and remote mine; providing an annual certification to the MSHA that each mine rescue team designated to provide mine rescue coverage meets applicable requirements; maintaining a record of mine rescue equipment testing, medical physical examinations of mine rescue team members, and mine rescue team training; posting a copy of the mine rescue notification plan and providing a written copy to a designated mine worker representative; and posting at appropriate places of an underground or surface mine the names, titles, addresses, and telephone numbers of all persons or services currently available under medical assistance and transportation arrangements. Coal mine operators, supervisors, and employees, as well as State and Federal mine inspectors use the records to provide assurance that each mine operator and mine rescue team is prepared for a mine emergency. Records also show that mine rescue team equipment has been examined and tested and is in good working order. Training records show that mine rescue team members and the responsible persons at the mine are competent to respond to a mine emergency involving a fire, an explosion, or a gas or water inundation.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1219–0144.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on October 31, 2013. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. It should also be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension

while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 14, 2013 (78 FR 35974).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1219–0114. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–MSHA.

Title of Collection: Coal Mine Rescue Teams: Arrangements for Emergency Medical Assistance and Transportation for Injured Persons—Agreements, Reporting Requirements, and Posting Requirements.

OMB Control Number: 1219–0144.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 477.

Total Estimated Number of Responses: 21,379.

Total Estimated Annual Burden Hours: 3,345.

Total Estimated Annual Other Costs Burden: $786,928.

Dated: October 22, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–25395 Filed 10–28–13; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course To Ventilate Working Sections and Areas Where Mechanized Mining Equipment Is Being Installed or Removed

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, ''Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course to Ventilate Working Sections and Areas Where Mechanized Mining Equipment is Being Installed or Removed,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before November 29, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201305-1219-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–MSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov*. Commenters are encouraged, but not required, to send a courtesy copy of any comments to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Information Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210, email: *DOL_PRA_PUBLIC@dol.gov*.

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: Regulations 30 CFR 75.315 make it mandatory for a mine operator electing to use belt air to ventilate a working section or area where mechanized equipment is being installed or removed to maintain records used by coal mine supervisors, miners, and Federal and State mine inspectors to show required examinations and tests were conducted. These records give insight into hazardous conditions that have been or may be encountered. Inspection records help in making decisions that ultimately affect the safety and health of miners working in belt air mines. Federal Mine Safety and Health Act of 1977 section 103(h) (30 U.S.C. 813(h)) authorizes the MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1219–0138.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on October 31, 2013. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. It should also be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 14, 2013 (78 FR 35975).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should

mention OMB Control Number 1219–0138. The OMB is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–MSHA.

Title of Collection: Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course to Ventilate Working Sections and Areas Where Mechanized Mining Equipment is Being Installed or Removed.

OMB Control Number: 1219–0138.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 21.

Total Estimated Number of Responses: 251.

Total Estimated Annual Burden Hours: 4,245.

Total Estimated Annual Other Costs Burden: $40,664.

Dated: October 22, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–25393 Filed 10–28–13; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Energy Employees Occupational Illness Compensation Program Act Forms

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, ''Energy Employees Occupational Illness Compensation Program Act Forms,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before November 29, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201304-1240-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov*. Commenters are encouraged, but not required, to send a courtesy copy of any comments to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Information Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210, email: *DOL_PRA_PUBLIC@dol.gov*.

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov*.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The OWCP is the primary agency responsible for administering the Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA) (42 U.S.C. 7384 *et seq.*). The EEOICPA provides for timely payment of compensation to covered employees who sustained either occupational or otherwise covered illnesses incurred in the performance of duty for the Department of Energy (DOE) and certain of its contractors and subcontractors and, where applicable, survivors of such employees. The EEOICPA sets forth eligibility criteria for claimants for compensation under EEOICPA parts B and E and outlines the various elements of compensation payable from the Energy Employees Occupational Illness Compensation Fund.

Regulations 20 CFR 30.100, –.101, –.102, –.103, –.111, –.112, –.113, –.114, –.206, –.207, –.212, –.213, –.214, –.215, –.221, –.222, –.226, –.231, –.232, –.415, –.416, –.417, –.505, –.620, –.806, –.905, and –.907 implementing the EEOICPA contain information collection requirements covered by this ICR. The OWCP also uses this ICR to obtain PRA authorization to implement the information collection requirement found at 42 U.S.C. 7385s–11.

The OWCP uses forms covered by this ICR to determine a claimant's eligibility for EEOICPA compensation and responses are required to obtain or retain benefits. The information collections in this ICR collect demographic, factual, and medical information needed to determine entitlement to EEOICPA benefits. Before the OWCP can pay benefits, the case file must contain medical and employment evidence showing the claimant's eligibility. The various collections covered by this ICR and the purpose of each are listed below:

Form EE–1—A living current or former employee completes the form to file a claim under parts B and/or E. The form requests information about the illness or illnesses being claimed and information about tort suits, settlements, or awards in litigation; State workers' compensation benefits; and fraud convictions that affect entitlement. This form is also available in Spanish. (20 CFR 30.100, –.103, –.505, and –.620.)

Form EE–2—The survivor of a deceased employee uses the form to file a claim under parts B and/or E. The form requests information regarding both the survivor and the deceased employee. The form also requests information about illnesses, tort suits, settlements, or awards in litigation; State workers' compensation benefits; and fraud convictions that affect entitlement. This form is also available in Spanish. (20 CFR 30.101, –.103, –.505, and –.620.)

Form EE–3—The form gathers information about the employee's work history. This form is also available in Spanish. (20 CFR 30.103, –.111, –.113, –.114, –.206, –.212, –.214, –.221, and –.231.)

Form EE–4—The employee or survivor uses the form to support the claimed employment history by affidavit. This form is also available in Spanish. (20 CFR 30.103, –.111, –.113, –.114, –.206, –.212, –.214, –.221, and –.231.)

Form EE–5A—A claimant must provide supplemental employment evidence to substantiate periods of

unverified employment. There is no standard form or format for the submission of this information. For purposes of identification only, this requirement has been designated Form EE–5A. (20 CFR 30.112.)

Form EE–5B—A current or former DOE contractor provides information to substantiate periods of unverified employment. There is no standard form or format for the submission of the information. For purposes of identification only, this requirement has been designated Form EE–5B. (20 CFR 30.106.)

Form EE–7—The OWCP uses this form to inform an employee, survivor, or physician of the medical evidence needed to establish a diagnosis of an occupational illness under part B or a covered illness under part E. This form is also available in Spanish. (20 CFR 30.103, –.207, –.215, –.222, –.232(a) and (b), –.415, –.416, and –.417.)

Form EE–7A—A claimant is required to provide information about when an injury, illness, or disability is sustained because of an occupational illness under part B or a covered illness under part E. There is no standard form or format for the submission of this medical information. For purposes of identification only, this requirement has been designated Form EE–7A. (20 CFR 30.207, –.215, –.222, –.226, and –.232(c).)

Form EE–8—The OWCP sends this letter with enclosure EN–8 to a claimant to obtain information about an employee's smoking history when lung cancer due to radiation is claimed. Department of Health and Human Services (HHS) guidelines require the OWCP to ask for information regarding the employee's smoking history before the OWCP can determine the probability of causation for radiogenic lung cancer. (20 CFR 30.213.)

Form EE–9—The OWCP sends this letter with enclosure EN–9 to a claimant to obtain information concerning the race or ethnicity of the employee when radiogenic skin cancer is claimed. HHS guidelines require the OWCP to ask for this particular information regarding the employee's race/ethnicity before the OWCP can determine the probability of causation for radiogenic skin cancer. (20 CFR 30.213.)

Form EE–10—A covered part E employee who has received an award for wage-loss and/or impairment due to a covered illness uses this form to provide information needed to support a claim for an additional award for a subsequent calendar year of wage-loss and/or any additional impairment. (20 CFR 30.102, –.103, and –.505.)

Form EE–11A—The OWCP sends this letter about impairment benefits under part E with enclosure EN–11A to a claimant to obtain medical evidence needed to support an initial award for permanent impairment due to an accepted covered illness. (20 CFR 30.905 and –.907.)

Form EE–11B—The OWCP sends this letter with enclosure EE–11B to a part E claimant to obtain the factual and medical evidence necessary to support an initial award for wage-loss benefits due to an accepted covered illness. (20 CFR 30.806.)

Form EE–12—The OWCP sends this letter with enclosure EN–12 to a covered part B or E employee receiving medical benefits to collect updated information about settlements or awards in litigation and State workers' compensation benefits that affect continuing entitlement. (20 CFR 30.100 and –.505.)

Form EE–13—The OWCP sends this letter with enclosure EN–13 to a State workers' compensation authority to identify covered part E employees receiving medical benefits who have also been awarded State workers' compensation for their covered illnesses. (42 USC 7385s–11.)

Form EE–16—The OWCP sends this letter with enclosure EN–16 to a claimant to verify/obtain updated information about tort suits, settlements, or awards in litigation; State workers' compensation benefits; and fraud convictions that affect entitlement immediately prior to issuance of a recommended decision on the claim. (20 CFR 30.505 and –.620.)

Form EE–20—The OWCP sends this letter with enclosure EN–20 to a claimant to obtain financial information necessary to pay approved claims under part B or E. (20 CFR 30.505 and –.620.)

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

The DOL obtains OMB approval for this information collection under Control Number 1240–0002. This ICR has been classified as a revision, because—in accordance with Department of the Treasury guidance—Form EE–20 has been changed to delete the option to request payment by paper check. The current approval is scheduled to expire on October 31, 2013; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New information collection requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 5, 2013 (78 FR 40513).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0002. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Energy Employees Occupational Illness Compensation Program Act Forms.

OMB Control Number: 1240–0002.

Affected Public: Individuals or Households; State, Local, and Tribal Governments; and Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 65,013.

Total Estimated Number of Responses: 66,020.

Total Estimated Annual Burden Hours: 23,190.

Total Estimated Annual Other Costs Burden: $28,089.

Dated: October 23, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–25392 Filed 10–28–13; 8:45 am]

BILLING CODE 4510–CR–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATE: 9:30 a.m., Tuesday, November 5, 2013

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTERS TO BE CONSIDERED:

8462A *Highway Accident Report*—Highway-Railroad Grade Crossing Collision, South Garfield Street, Midland, Texas, November 15, 2012 (HWY–13–MH–003)

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314–6305 or by email at *Rochelle.Hall@ntsb.gov* by Friday, November 1, 2013.

The public may view the meeting via a live or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *www.ntsb.gov*.

Schedule updates including weather-related cancellations are also available at *www.ntsb.gov*.

FOR MORE INFORMATION CONTACT: Candi Bing, (202) 314–6403 or by email at *bingc@ntsb.gov*.

FOR MEDIA INFORMATION CONTACT: Peter Knudson, (202) 314–6100 or by email at *peter.knudson@ntsb.gov*.

Dated: Friday, October 25, 2013.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2013–25732 Filed 10–25–13; 4:15 pm]

BILLING CODE 7533–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0233]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from September 19, 2013, to October 2, 2013. The last biweekly notice was published on October 1, 2013 (78 FR 60321). Due to the Federal Government shutdown, there was no biweekly publication on October 15, 2013.

ADDRESSES: You may submit comment by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0233. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: 3WFN, 06–44M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2013–0233 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0233.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. Documents may be viewed in ADAMS by performing a search on the document date and docket number.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2013–0233 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in section 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR Part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov*, or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html*. System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic

Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html*, by email to *MSHD.Resource@nrc.gov*, or by a toll-free call at 1–866 672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/*, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1)(i)-(iii).

For further details with respect to this license amendment application, see the application for amendment which is available for public inspection at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*.

Dairyland Power Cooperative, Docket Nos. 50–409 and 72–046, La Crosse Boiling Water Reactor (LACBWR), La Crosse County, Wisconsin

Date of amendment request: August 6, 2013.

Description of amendment request: The proposed amendment would change the LACBWR Emergency Plan. Dairyland Power Cooperative (DPC) proposes removal of the various emergency actions related to the former spent fuel pool, the transfer of responsibility for implementing the Emergency Plan to the Security Shift Supervisors at the Independent Spent Fuel Storage Installation (ISFSI), a revised emergency plan organization, removal of the fire brigade, and abandonment of the Control Room consistent with the current state of decommissioning.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

DPC has in effect an NRC-approved E-Plan. There are no longer credible events that would result in doses to the public beyond

the owner controlled area boundary that would exceed the EPA PAGs. LACBWR was shutdown 25 years ago. Emergency Planning Zones beyond the owner controlled area and the associated protective actions are no longer required. No headquarters personnel, personnel involved in off-site dose projections, or personnel with special qualifications are required to augment the LACBWR Emergency Response Organization. The credible events for the ISFSI remain unchanged. The indications of damage to a loaded cask confinement boundary have been revised to be twice the technical specification limit for contact dose. This change is consistent with industry practices previously approved by the NRC for other ISFSIs to be able to distinguish that a degraded condition exists.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

DPC has in effect an NRC-approved E-Plan. There are no longer credible events that would result in doses to the public beyond the owner controlled area boundary that would exceed the EPA PAGs. LACBWR was shutdown 25 years ago. Emergency Planning Zones beyond the owner controlled area and the associated protective actions are no longer required. No headquarters personnel, personnel involved in off-site dose projections, or personnel with special qualifications are required to augment the LACBWR Emergency Response Organization. The advanced state of decommissioning is reflected in the updated and revised ODCM [Offsite Dose Calculation Manual] which shows that there are no longer any events at the former plant that could exceed the EPA PAGs for dose to a member of the public.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

Margin of safety is related to the ability of the fission product barriers (fuel cladding, reactor coolant system, and primary containment) to perform their design functions during and following postulated accidents. DPC has in effect an NRC-approved E-Plan. There are no longer credible events that would result in doses to the public beyond the owner controlled area boundary that would exceed the EPA PAGs. LACBWR was shutdown 25 years ago. Emergency Planning Zones beyond the owner controlled area and the associated protective actions are no longer required. No headquarters personnel, personnel involved in offsite dose projections, or personnel with special qualifications are required to augment the LACBWR Emergency Response Organization. The advanced state of decommissioning is reflected in the updated and revised ODCM which shows that there are no longer any events at the former plant that could exceed the EPA PAGs for dose to a member of the public.

Therefore, the proposed change does not involve a significant reduction in margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Mr. Thomas Zaremba, Wheeler, Van Sickle and Anderson, Suite 801, 25 West Main Street, Madison, WI 53703–3398.

NRC Branch Chief: Bruce Watson.

Energy Northwest, Docket No. 50–397, Columbia Generating Station, Benton County, Washington

Date of amendment request: July 25, 2013.

Description of amendment request: The proposed amendment would change the Technical Specification (TS) 3.7.4, ''Control Room Air Conditioning (AC) System,'' requirements by revising the Required Action and associated Completion Time for two inoperable control room air conditioning subsystems. The proposed changes are consistent with NRC-approved TS Task Force (TSTF) change traveler TSTF–477, Revision 3. The availability of this TS improvement was published in the **Federal Register** on March 26, 2007 (72 FR 14143), as part of the consolidated line item improvement process (CLIIP).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), Energy Northwest affirmed the applicability of the proposed no significant hazards consideration (NSHC) determination published in the **Federal Register** as part of the CLlIP (71 FR 75774; December 18, 2006), which is presented below:

Criterion 1—The Proposed Change Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated

The proposed change is described in Technical Specification Task Force (TSTF) Standard TS Change Traveler TSTF–477 adds an action statement for two inoperable control room subsystems.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed). The proposed changes add an action statement for two inoperable control room subsystems. The equipment qualification temperature of the control room equipment is not affected. Future changes to the Bases or licensee-controlled document will be evaluated pursuant to the requirements of 10 CFR 50.59, ''Changes, test and experiments,'' to ensure that such changes do not result in more than a minimal increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. The proposed changes do not adversely affect the ability of structures, systems and components (SSCs) to perform their intended safety function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological consequences of any accident previously evaluated. Further, the proposed changes do not increase the types and the amounts of radioactive effluent that may be released, nor significantly increase individual or cumulative occupation/public radiation exposures.

Therefore, the changes do not involve a significant increase in the probability or consequences of any accident previously evaluated.

Criterion 2—The Proposed Change Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated

The proposed changes add an action statement for two inoperable control room subsystems. The changes do not involve a physical altering of the plant (i.e., no new or different type of equipment will be installed) or a change in methods governing normal plant operation. The requirements in the TS continue to require maintaining the control room temperature within the design limits.

Therefore, the changes do not create the possibility of a new or different kind of accident from any previously evaluated.

Criterion 3—The Proposed Change Does Not Involve a Significant Reduction in the Margin of Safety

The proposed changes add an action statement for two inoperable control room subsystems. Instituting the proposed changes will continue to maintain the control room temperature within design limits. Changes to the Bases or license controlled document are performed in accordance with 10 CFR 50.59. This approach provides an effective level of regulatory control and ensures that the control room temperature will be maintained within design limits.

The proposed changes maintain sufficient controls to preserve the current margins of safety.

Based upon the reasoning above, the NRC staff concludes that the amendment request involves no significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William A. Horin, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006–3817.

NRC Branch Chief: Michael T. Markley.

Exelon Generation Company, LLC., Docket No. 50–461, Clinton Power Station, Unit 1, DeWitt County, Illinois; Exelon Generation Company, LLC., Docket Nos. 50–237 and 50–249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois; Exelon Generation Company, LLC., Docket Nos. 50–373 and 50–374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois; Exelon Generation Company, LLC., Docket Nos. 50–352 and 50–353, Limerick Generating Station, Unit 1 and 2, Montgomery County, Pennsylvania; Exelon Generation Company, LLC., et al., Docket No. 50–219, Oyster Creek Nuclear Generating Station, Ocean County, New Jersey; Exelon Generation Company, LLC., and PSEG Nuclear LLC., Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania; Exelon Generation Company, LLC., Docket Nos. 50–254 and 50–265, Quad Cities Nuclear Power Station, Units 1 and 2, Rock Island County, Illinois

Date of amendment request: August 2, 2013.

Description of amendment request: The proposed amendment would modify the technical specification definition of ''Shutdown Margin'' (SDM) to require calculation of the SDM at a reactor moderator temperature of 68 °F or a higher temperature that represents the most reactive state throughout the operating cycle. This change is needed to address new Boiling Water Reactor fuel designs that may be more reactive at shutdown temperatures above 68°F.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

EGC [Exelon Generation Company, LLC] has evaluated whether or not a significant hazards consideration is involved with the proposed amendments by focusing on the three standards set forth in 10 CFR 50.92, ''Issuance of amendment,'' as discussed below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the definition of SDM. SDM is not an initiator of any accident previously evaluated. Accordingly, the proposed change to the definition of SDM has no effect on the probability of any accident previously evaluated. SDM is an assumption in the analysis of some previously evaluated accidents and inadequate SDM could lead to an increase in consequences of those accidents. However, the proposed change revises the SDM definition to ensure that the correct SDM is determined for all fuel types at all times during the fuel cycle. As a result, the proposed change does not adversely affect the consequences of any accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change revises the definition of SDM. The change does not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed) or a change in the methods governing normal plant operations. The change does not alter assumptions made in the safety analysis regarding SDM.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change revises the definition of SDM. The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change ensures that the SDM assumed in determining safety limits, limiting safety system settings or limiting conditions for operation is correct for all BWR fuel types at all times during the fuel cycle.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, EGC concludes that the proposed change presents no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of ''no significant hazards consideration'' is justified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Attorney for licensee: Mr. Bradley Fewell, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.

NRC Branch Chief: Travis L. Tate.

NextEra Energy Point Beach, LLC., Docket Nos. 50–266 and 50–301, Point Beach Nuclear Plant, Units 1 and 2, Town of Two Creeks, Manitowac County, Wisconsin

Date of amendment request: June 4, 2013.

Description of amendment request: The license amendment request proposes to revise the technical specifications (TS) to allow the use of Optimized ZIRLO™ fuel rod cladding material. The proposed change would revise TS 5.3.1 to add Optimized ZIRLO™ to the approved fuel rod cladding materials and TS 6.9.1.7 to add Westinghouse Electric Company LLC topical report WCAP–12610–P–A & CENPD–404–P–A, Addendum 1–A, ''Optimized ZIRLO™,'' to the analytical methods used to determine the core operating limits.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change would allow the use of Optimized ZIRLO™ clad nuclear fuel in the reactors. The NRC approved topical report WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, ''Optimized ZIRLO™,'' prepared by Westinghouse Electric Company LLC (Westinghouse), which addresses Optimized ZIRLO™ and demonstrates that Optimized ZIRLO™ has essentially the same properties as currently licensed ZIRLO®. The fuel cladding itself is not an accident initiator and does not affect accident probability. Use of Optimized ZIRLO™ fuel cladding will continue to meet all 10 CFR 50.46 acceptance criteria and, therefore, will not increase the consequences of an accident.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Use of Optimized ZIRLO™ clad fuel will not result in changes in the operation or configuration of the facility. Topical Report WCAP–12610–P–A and CENPD–404–P–A, Addendum 1–A, ''Optimized ZIRLO™,'' demonstrated that the material properties of Optimized ZIRLO™ are similar to those of standard ZIRLO®. Therefore, Optimized ZIRLO™ fuel rod cladding will perform similarly to the cladding fabricated from standard ZIRLO®, thus precluding the possibility of the fuel becoming an accident initiator and causing a new or different type of accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in the margin of safety?

Response: No.

The proposed change will not involve a significant reduction in the margin of safety because it has been demonstrated that the material properties of the Optimized ZIRLO™ are not significantly different from those of standard ZIRLO®. Optimized ZIRLO™ is expected to perform similarly to standard ZIRLO® for all normal operating and accident scenarios, including both loss of coolant accident (LOCA) and non-LOCA

scenarios. For LOCA scenarios, the slight difference in Optimized ZIRLO™ material properties relative to standard ZIRLO™ could have some impact on the overall accident scenario. However, all acceptance criteria of 10 CFR 50.46 are satisfied, therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William Blair, Senior Attorney, NextEra Energy Point Beach, LLC, P.O. Box 14000, Juno Beach, Florida 33408–0420.

NRC Branch Chief: Robert D. Carlson.

South Carolina Electric and Gas, Docket Nos. 52–027 and 52–028, Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, Fairfield County, South Carolina

Date of amendments request: February 7, 2013, and revised on July 19, 2013.

Description of amendment request: The proposed change would amend Combined License Nos. NPF–93 and NPF–94 for VCSNS Units 2 and 3 by departing from the plant-specific Design Control Document (DCD) Tier 1 (and corresponding Combined License Appendix C information) and Tier 2 material by reconciling various valve descriptions and definitions in Tier 1 and Tier 2. This is being done to promote consistency within the Updated Final Safety Analysis Report (UFSAR).

Because, this proposed change requires a departure from Tier 1 information in the Westinghouse Advanced Passive 1000 DCD, the licensee also requested an exemption from the requirements of the Generic DCD Tier 1 in accordance with 10 CFR 52.63(b)(1).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes do not result in any physical changes to the plant, and therefore do not change any safety-related design requirement, qualification requirement or function. The proposed changes do not involve any accident initiating event or component failure, thus, the probabilities of the accidents previously evaluated are not affected. The proposed changes do not affect the radioactive material releases used in the accident analyses, thus, the radiological releases in the accident analyses are not affected.

Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not result in any physical changes to the plant, and therefore do not adversely affect any structure, system or component. No safety-related equipment qualification or design function is affected. The proposed changes do not introduce a new failure mode or create a new fault or sequence of events that could result in a radioactive material release.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed changes do not result in any physical changes to the plant, and therefore do not change valve performance, including containment isolation. No safety acceptance criterion would be exceeded or challenged. No safety-related function would be affected. Valve qualification would not be affected. The proposed changes do not affect compliance with existing design codes and regulatory criteria and do not affect any safety analysis.

Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 111 Pennsylvania Avenue NW., Washington, DC 20004–2514.

NRC Branch Chief: Lawrence J. Burkhart.

STP Nuclear Operating Company, Docket Nos. 50–498 and 50–499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: July 23, 2013.

Description of amendment request: The amendment would revise the South Texas Project (STP), Units 1 and 2, Fire Protection Program (FPP) (incorporated in to the Updated Final Safety Analysis Report by reference) related to the alternate shutdown capability in accordance with license condition 2.E of the Facility Operating Licenses. Specifically, STP Nuclear Operating Company (STPNOC) proposes to credit the following manual operator actions in the control room prior to evacuation due to a fire for meeting the alternate shutdown capability, in addition to manually tripping the reactor that is currently credited in the STP, Units 1 and 2, FPP licensing basis:

- Initiate main steam line isolation
- Closing the pressurizer power-operated relief valves block valves
- Securing all reactor coolant pumps
- Closing feedwater isolation valves
- Securing the startup feedwater pump
- Isolating reactor coolant system (RCS) letdown
- Securing the centrifugal charging pumps

In addition, STPNOC proposes to credit the automatic trip of the main turbine upon the initiation of a manual reactor trip for meeting the alternate shutdown capability. A thermal-hydraulic analysis demonstrates that these operations will ensure that the RCS process variables remain within those values predicted for a loss of normal alternating current (a-c) power, as required by Section III.L.1 of 10 CFR part 50, appendix R.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change credits operations in the control room prior to evacuation in the event of a fire in order to meet safe shutdown performance criteria. The design function of structures, systems and components (SSC) are not impacted by the proposed change. The proposed change will not initiate an event. The proposed change does not alter or prevent the ability of SSCs from performing their intended function to mitigate the consequences of an initiating event. The proposed change does not increase the probability of occurrence of a fire or any other accident previously evaluated.

The proposed operations are feasible and reliable and demonstrate that the unit can be safely [shut down] in the event of a fire with no significant increase in consequences.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of

accident from any accident previously evaluated?

Response: No.

The proposed change credits operations in the control room prior to evacuation in the event of a fire in order to meet safe shutdown performance criteria. The proposed change does not install or remove any plant equipment. The proposed change does not alter the design, physical configuration, or mode of operation of any plant structure, system or component. Therefore, the proposed change does not introduce any new failure mechanisms or malfunctions that can initiate an accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change credits operations in the control room prior to evacuation in the event of a fire in order to meet safe shutdown performance criteria. The proposed change has no effect on the availability, operability, or performance of safety-related systems and components. The proposed change does not alter the design, configuration, operation, or function of any plant structure, system or component. The ability of any structure, system or component to perform its designated safety function is unaffected by the proposed change.

Thermal-hydraulic analyses demonstrate that the proposed operations to be performed in the control room will ensure that the reactor coolant system process variables remain within those values predicted for a loss of normal a-c power, as required by section III.L of 10 CFR part 50, appendix R. After control of the plant is achieved by the alternative shutdown system, the plant can be safely transitioned to cold shutdown conditions. A single fire-induced spurious actuation will not negate the proposed operations.

Considerable fire protection defense-in-depth features exist such that it is unlikely that a fire in the control room would result in evacuation. In the remote likelihood that control room evacuation is required and none of the proposed operator actions other than the manual reactor trip and automatic turbine trip are performed prior to arrival at the alternative shutdown stations, analyses confirm that adequate core cooling is maintained so that fuel cladding integrity is not challenged. The capability to achieve and maintain safe shutdown is maintained.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Attorney for licensee: A. H. Gutterman, Esq., Morgan, Lewis & Bockius, 1111 Pennsylvania Avenue NW., Washington, DC 20004.

NRC Branch Chief: Michael T. Markley.

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant (WBN), Unit 1, Rhea County, Tennessee

Date of amendment request: August 1, 2013.

Description of amendment request: The proposed amendment would modify Technical Specification (TS) Limiting Condition for Operation (LCO) for the Alternating Current Sources Operating in LCO 3.8.1, provide additional time to restore an inoperable offsite circuit, modify Surveillance Requirement 3.8.1.8, and modify the current licensing basis, as described in the Updated Final Safety Analysis Report (UFSAR), for the available maintenance feeder for the Common Station Service Transformers (CSSTs) A and B. The proposed license amendment request credits upgrades made to CSST A and B to provide two new sources of preferred Class 1 E power supply feeds in addition to the two normal Class 1 E power supply feeds. The TS change is needed to support dual unit operations without requiring a dual unit shutdown during maintenance on either preferred power CSST C or D. This proposed request also achieves licensing basis commonality for the current Operating WBN Unit 1 license with respect to those approved elements of the WBN Unit 2 application as docketed in NUREG–0847, Supplements 22 and 24.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequence of an accident previously evaluated?

Response: No.

The proposed changes described in this TS amendment request, do not alter the safety functions of the WBN Offsite Power system. Design calculations document that CSSTs A and B have adequate capacity to supply all connected loads including one train of shutdown boards in all allowable alignments and meet the separation requirements for offsite power sources. The consequences of an accident are not changed when using CSST A or B to power the shutdown boards because these CSSTs are rated to carry all required loads for any design basis accidents. The failure of a CSST is not considered to be an initiator of a plant accident and therefore the probability or consequences of accidents or events previously evaluated, as described in the UFSAR, is not changed.

Therefore, this proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

As stated above, malfunctions of the CSSTs are not considered to be an initiator for plant accidents and the modifications to the offsite power system do not create a new or different kind of accident. The purpose of the offsite power system is to provide a source of power to the safety related equipment required to mitigate a design basis accident. CSSTs A and B have been physically upgraded and proven by design calculation to meet all required GDC [General Design Criterion] 17 requirements for separation and voltage stability. Using CSSTs A and B as alternate sources of shutdown power does not negatively affect the offsite power systems ability to meet its design function.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

CSSTs A and B have adequate design margin to meet all possible loading scenarios as long as both CSSTs A and B are operational prior to one being used as a source of offsite power. This requirement is added to the control room drawings, plant design criteria and the UFSAR in order to ensure acceptable margin is always available prior to CSSTs A or B being used as a source of offsite power.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11A, Knoxville, Tennessee 37902.

NRC Acting Branch Chief: Douglas A. Broaddus.

Virginia Electric and Power Company, Docket No. 50–339, North Anna Power Station, Unit 2, Louisa County, Virginia

Date of amendment request: September 10, 2013.

Description of amendment request: The proposed license amendment (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13260A256) requests the changes to the Technical Specification (TS) 3.8.1, ''AC Sources-Operating.'' TS 3.8.1 contains Surveillance Requirement (SR) 3.8.1.8, which requires verification of the

capability to manually transfer Unit 1, 4.16 kV ESF bus AC power sources from the normal offsite circuit to the alternate required offsite circuit and this surveillance is only applicable to Unit 1. Dominion is developing a plant modification to install an alternate offsite power feed to each of the two 4.16 kV ESF buses for Unit 2, such that it will be similar to the Unit 1 design. Therefore, the proposed change would delete Note 1 to SR 3.8.1.8 to remove the limitation that excludes Unit 2 and will be consistent with the verification currently performed for Unit 1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The previously evaluated accident that could be affected is a complete loss of offsite power (LOOP). Analyses have been performed to confirm that power distribution system voltages and currents with both of the new Unit 2 alternate normal to emergency bus ties in service are adequate during a unit trip scenario. The conditions under which the Unit 2 manual transfer capability is verified are the same as Unit 1. The verification test may only be performed under conditions that will not challenge steady state operation or challenge the safety of the unit. Therefore, the Unit 2 verification test (manual transfer between Unit 2 normal offsite circuit and alternate required offsite circuit) will not significantly increase the probability of a LOOP.

Should a LOOP occur, the consequences are unaffected by availability of offsite power (normal offsite circuit and alternate required offsite circuit). Therefore, the Unit 2 verification test (normal offsite circuit and alternate required offsite circuit) will not affect the consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The purpose of the surveillance test is to verify the capability to manually transfer AC power sources from the normal offsite circuit to the alternate required offsite circuit.

The only effect of the change is to permit the new Unit 2 required offsite circuits to be tested in the same manner and frequency as the corresponding Unit 1 circuits. Since the Unit 2 circuits are similar to the Unit 1 circuits, and the Unit 1 test is a required TS Surveillance to demonstrate operability of the alternate offsite circuits, permitting the Unit 2 circuits to undergo the same surveillance test will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change enables SR testing of the new Unit 2 alternate offsite AC circuits to verify the capability to manually transfer AC power sources from the normal offsite circuit to the alternate required offsite circuit as is performed in Unit 1.

The margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident situation and the ability of the ECCS to provide adequate core cooling. These barriers include the fuel cladding, the reactor coolant system, and the containment system. The proposed change does not directly affect these barriers, nor does it involve any adverse impact on the Class 1E circuits or SSCs supplied by Class 1E power. In fact, it enhances the ability to power the required ECCS equipment during accident conditions.

Therefore, the proposed change will not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

NRC Branch Chief: Robert Pascarelli.

Virginia Electric and Power Company, Docket Nos. 50–280 and 50–281, Surry Power Station, Units 1 and 2, Surry County, Virginia

Date of amendment request: August 12, 2013.

Description of amendment request: The proposed amendments revise Surry Power Station, Units 1 and 2, Technical Specification (TS) 4.4.B, ''Containment Leakage Rate Testing Requirements,'' by replacing the reference to Regulatory Guide (RG) 1.163 with a reference to Nuclear Energy Institute (NEI) topical report NEI 94–01, Revision 3–A, as the implementation document used to develop the Surry performance-based leakage testing program in accordance with Option B of 10 CFR part 50, appendix J.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment involves changes to the Surry Containment Leakage Rate Testing Program. The proposed amendment does not involve a physical change to the plant or a change in the manner in which the plant is operated or controlled. The primary containment function is to provide an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment for postulated accidents. As such, the containment itself and the testing requirements to periodically demonstrate the integrity of the containment do not involve any accident precursors or initiators. Therefore, the probability of occurrence of an accident previously evaluated is not significantly increased by the proposed amendment.

The proposed amendment adopts the NRC-accepted guidelines of NEI 94–01, Revision 3–A, for development of the Surry Power Station Units 1 and 2 performance-based containment testing program. Implementation of these guidelines continues to provide adequate assurance that during design basis accidents, the primary containment and its components will limit leakage rates to less than the values assumed in the plant safety analyses. The potential consequences of extending the ILRT interval to 15 years have been evaluated by analyzing the resulting changes in risk. The increase in risk in terms of person-rem per year within 50 miles resulting from design basis accidents was estimated to be acceptably small and determined to be within the guidelines published in, RG 1.174. Additionally, the proposed change maintains defense-in-depth by preserving a reasonable balance among prevention of core damage, prevention of containment failure, and consequence mitigation. Dominion has determined that the increase in Conditional Containment Failure Probability due to the proposed change would be very small. Therefore, it is concluded that the proposed amendment does not significantly increase the consequences of an accident previously evaluated.

Based on the above discussion, it is concluded that the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed amendment adopts the NRC-accepted guidelines of NEI 94–01, Revision 3–A, for the development of the Surry performance-based leakage testing program and establishes a 15-year interval for the performance of the containment ILRT. The containment and the testing requirements to periodically demonstrate the integrity of the containment exist to ensure the plant's ability to mitigate the consequences of an accident and do not involve any accident precursors or initiators. The proposed change does not involve a physical change to the plant (i.e., no new or different type of equipment will be installed) and does not

change the manner in which the plant is operated or controlled.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed amendment adopts the NRC-accepted guidelines of NEI 94–01, Revision 3–A, for the development of the Surry performance-based leakage testing program and establishes a 15-year interval for the performance of the containment ILRT. This amendment does not alter the manner in which safety limits, limiting safety system setpoints, or limiting conditions for operation are determined. The specific requirements and conditions of the Containment Leakage Rate Testing Program, as defined in the TS, ensure that the degree of primary containment structural integrity and leak-tightness that is considered in the plant's safety analysis is maintained. The overall containment leakage rate limit specified by the TS is maintained, and the Type A, Type B, and Type C containment leakage tests will be performed at the frequencies established in accordance with the NRC-accepted guidelines of NEI 94–01, Revision 3–A. Containment inspections performed in accordance with other plant programs serve to provide a high degree of assurance that the containment will not degrade in a manner that is not detectable by an ILRT. A risk assessment using the current Surry PRA model concluded that extending the ILRT test interval from ten years to 15 years results in a very small change to the Surry risk profile.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

Based on the above, Dominion concludes that the proposed amendment presents no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of ''no significant hazards consideration'' is justified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for Licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resource Services, Inc., 120 Tredegar St., RS–2, Richmond, VA 23219.

NRC Branch Chief: Robert J. Pascarelli.

Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the NRC's Public Document Room (PDR), located at One White Flint North, Room O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through the Agencywide Documents Access and Management System (ADAMS) in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737 or by email to *pdr.resource@nrc.gov*.

Duke Energy Carolinas, LLC., Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: September 25, 2012, as supplemented by letters dated June 12, and August 8, 2013.

Brief description of amendments: The amendments revise selected atmospheric relative concentration values (χ/Q) for use in Control Room radiological dose analysis that were withdrawn during McGuire's request for full scope implementation of the Alternate Source Term (AST). The licensee withdrew the release points due to the source-to-receptor distances being less than 10 meters and needing to be addressed on a case-by-case basis. McGuire received NRC's approval for full scope implementation of AST on March 31, 2009 (ADAMS Accession No. ML090890627). The purpose of this amendment is for the NRC to review and approve the licensee's withdrawn χ/Q values on a case-by-case basis. The licensee will make the necessary changes to the updated final safety analysis report (UFSAR) in accordance with 10 CFR 50.71(e).

Date of issuance: September 23, 2013.

Effective date: These license amendments are effective as of its date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 271 and 251.

Renewed Facility Operating License Nos. NPF–9 and NPF–17: Amendments revised the licenses and UFSAR.

Date of initial notice in **Federal Register**: February 5, 2013 (78 FR 8199). The supplements dated June 12, and August 8, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 23, 2013.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., System Energy Resources, Inc., South Mississippi Electric Power Association, and Entergy Mississippi, Inc., Docket No. 50–416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of application for amendment: September 9, 2011, as supplemented by letters dated September 8, and November 23, 2010; March 9, April 21, May 3, and November 21, 2011; April 18, October 1, and October 22, 2012; and July 2, September 5, and September 16, 2013. The letters dated September 8, and November 23, 2010, and March 9, April 21, and May 3, 2011, are incorporated by reference in the September 2, 2011, license amendment request (LAR) as allowed by 10 CFR 50.32, ''Elimination of replication.''

Brief description of amendment: The amendment approves: 1) additional requirements for the spent fuel and new fuel storage racks in TS 4.3.1,

''Criticality''; 2) a revision to the current Nuclear Criticality Safety Analysis, which is described in the GGNS Updated Final Safety Analysis Report Sections 9.1.1, ''New Fuel Storage,'' and 9.1.2, ''Spent Fuel Storage,'' to reflect changes resulting from the extended power uprate; and 3) deletion of the spent fuel pool loading criteria Operating License condition.

Date of issuance: September 25, 2013.

Effective date: As of the date of issuance and shall be implemented within 120 days of issuance.

Amendment No: 195.

Facility Operating License No. NPF–29: The amendment revised the Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register***: January 24, 2012 (77 FR 3511). The supplemental letters dated September 8, and November 23, 2010; March 9, April 21, May 3, and November 21, 2011; April 18, October 1, and October 22, 2012; and July 2, September 5, and September 16, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 25, 2013.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., System Energy Resources, Inc., South Mississippi Electric Power Association, and Entergy Mississippi, Inc., Docket No. 50–416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of application for amendment: September 14, 2012, as supplemented by letters dated December 17, 2012, and July 29, 2013.

Brief description of amendment: The amendment changed the methodology in the Grand Gulf Nuclear Station Updated Final Safety Analysis Report (USFAR) for postulating single passive failures of the Standby Service Water (SSW) system following a loss-of-coolant accident (LOCA). The revised methodology considers a limited size piping break in the SSW system during the first 24 hours following a LOCA, and consider only pump and valve seal leakage after more than 24 hours. The licensee will include the revised information in the UFSAR in the next periodic update in accordance with 10 CFR 50.71(e).

Date of issuance: September 25, 2013.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment No: 196.

Facility Operating License No. NPF–29: The amendment revised the Facility Operating License and the UFSAR.

Date of initial notice in ***Federal Register***: February 5, 2013 (78 FR 8199). The supplemental letter dated July 29, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 25, 2013.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket No. 50–315, Donald C. Cook Nuclear Plant, Unit 1, Berrien County, Michigan

Date of amendment request: October 7, 2013, as supplemented by letters dated October 8, and October 9, 2013.

Description of amendment request: The amendment revised Technical Specification (TS) 3.6.9, ''Distributed Ignition System (DIS),'' to allow Train B of the DIS to be considered operable with two inoperable ignitors. The existing TS defines train operability as having no more than one ignitor inoperable. The amendment also allows one of five specific primary containment regions to have zero ignitors operable. The existing TS requires that at least one ignitor be operable in each region. The proposed TS revision is applicable until the fall 2014 refueling outage, or until the unit enters a mode that allows replacement of the affected ignitors without exposing personnel to significant radiation and safety hazards.

Date of issuance: October 9, 2013.

Effective date: As of the date of issuance, to be implemented within 1 day.

Amendment No.: 321.

Renewed Facility Operating License No. DPR–58: Amendment revises the Technical Specifications and License.

Public comments requested as to proposed no significant hazards consideration (NSHC):

No.

The Commission's related evaluation of the amendment, finding of emergency circumstances, state consultation, and final NSHC determination are contained in a safety evaluation dated October 9, 2013.

Attorney for licensee: Robert B. Haemer, Senior Nuclear Counsel, One Cook Place, Bridgman, MI 49106.

NRC Branch Chief: Robert D. Carlson.

Luminant Generation Company LLC., Docket Nos. 50–445, and 50–446, Comanche Peak Nuclear Power Plant, Units 1 and 2, Somervell County, Texas

Date of amendment request: December 19, 2012, as supplemented by letter dated May 16, 2013.

Brief description of amendments: The amendments revised Technical Specification (TS) 3.8.1, ''AC [Alternating Current] Sources—Operating,'' to revise the Completion Time (CT) for Required Action A.3, ''Restore required offsite circuit to OPERABLE status,'' on a one-time basis from 72 hours to 14 days for Comanche Peak Nuclear Power Plant, Units 1 and 2. The CT extension from 72 hours to 14 days will be used twice while completing the plant modification to install alternate startup transformer (ST) XST1A and will expire on March 31, 2014. After completion of this modification, if ST XST1 should require maintenance or if failure occurs, the alternate ST XST1A can be aligned to the Class 1E buses well within the current CT of 72 hours. Installation of alternate ST will result in improved plant design and will improve the long-term reliability of the 138 kiloVolt offsite circuit ST.

Date of issuance: September 18, 2013.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: Unit 1—160; Unit 2—160.

Facility Operating License Nos. NPF–87 and NPF–89: The amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register***: March 4, 2013 (78 FR 14131). The supplemental letter dated May 16, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 18, 2013.

No significant hazards consideration comments received: No.

National Institute of Standards and Technology (NIST), Docket No. 50–184, Center for Neutron Research (NBSR), Montgomery County, Maryland

Date of amendment request: July 12, 2012, as supplemented on May 14, 2013.

Brief description of amendment: The proposed amendments would revise NIST NBSR's Technical Specifications, Sections 3.7, 4.7, and 6.8, pertaining to the environmental monitoring requirements and records retention which clarifies environmental sampling procedure and record retention processes.

Date of issuance: September 24, 2013.

Effective date: As of the date of issuance.

Amendment No.: 9.

Facility Operating License No. TR–5: Amendment revised the Renewed Facility Operating License and Technical Specifications.

Date of initial notice in ***Federal Register***: June 25, 2013 (78 FR 38083). The supplemental letter dated May 14, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 24, 2013.

No significant hazards consideration comments received: No.

NextEra Energy Duane Arnold, LLC., Docket No. 50–331, Duane Arnold Energy Center, Linn County, Iowa

Date of application for amendment: November 13, 2012.

Brief description of amendment: The amendment revises the DAEC renewed facility operating license condition (RFOLC) C.12 to: (1) Clarify that the updated final safety analysis report (UFSAR) supplement had been supplemented by Appendix A of NUREG–1955, ''Safety Evaluation Report Related to the License Renewal of Duane Arnold Energy Center,'' dated November 2010, as supplemented by letter from the licensee to the NRC dated November 23, 2010,'' (2) replace ''future activities to be completed prior to and/or during'' with ''programs to be implemented and activities to be completed before,'' (3) included the requirement to implement new programs and enhancements to existing programs no later than February 21, 2014, (4) include the requirement to complete activities no later than February 21, 2014, and (5) include the requirement to notify the NRC within 30 days of having completed the activities.

Date of issuance: October 7, 2013.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment No.: 287.

Renewed Facility Operating License No. DPR–49: The amendment changes recordkeeping, reporting, or administrative procedures or requirements and changes the format of the license or otherwise makes editorial, corrective or other minor revisions.

Date of initial notice in ***Federal Register***: April 16, 2013 (78 FR 22571). The supplemental information dated May 28, 2013, and October 1st, 2013, contained clarifying information, did not change the scope of the November 13, 2012, application on the initial no significant hazards consideration determination, and does not expand the scope of the original **Federal Register** notice.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 7, 2013.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Docket Nos. 52–025 and 52–026, Vogtle Electric Generating Plant, Units 3 and 4, Fairfield County, South Carolina

Date of amendment request: February 24, 2012.

Brief description of amendment: The amendment authorizes the licensee to revise Appendix B, ''Technical Specifications'' of Combined Licenses NPF–91 and NPF–92 in order to improve operator usability by more closely aligning with the form and content of Technical Specifications Task Force (TSTF) Writer's Guide for Plant-Specific Improved Technical Specifications, TSTF–GG–05–01, Revision 1, and with NUREG–1431, Standard Technical Specifications—Westinghouse Plants as updated by NRC approved generic changes.

Date of issuance: September 9, 2013.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: Unit 3–13, and Unit 4–13.

Facility Combined Licenses Nos. NPF–91 and NPF–92: Amendment revised the Facility Combined Licenses and Appendix B to the combined License.

Date of initial notice in **Federal Register***:* May 29, 2012 (77 FR 31662).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 9, 2013.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia and Southern Nuclear Operating Company, Inc., Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendment request: January 23, 2013, as supplemented July 17, 2013.

Brief description of amendments: The amendments revised the following Technical Specifications: 3.4.17, ''Steam Generator (SG) Tube Integrity,'' 5.5.9, ''Steam Generator (SG) Program,'' and 5.6.10, ''Steam Generator Tube Inspection Report.'' These changes summarize and clarify the purpose of the TSs in accordance with TS Task Force Traveler 510, ''Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection.''

Date of issuance: September 26, 2013.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment Nos.: 171, 153, 192, and 188.

Facility Operating License Nos. NPF–68, NPF–81, NPF–2 and NPF–8 : Amendments revised the Facility Operating Licenses and the Technical Specifications.

Date of initial notice in ***Federal Register****:* May 14, 2013 (78 FR 28254). The supplemental letter dated July 17, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposal no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 26, 2013.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendment request: August 15, 2012, as supplemented by letters dated March 14, and June 14, 2013.

Brief description of amendment request: The amendments revised the Technical Specifications associated

with the Low Temperature Overpressure System and the Pressure and Temperature Limits Report for Joseph M. Farley Nuclear Plant, Units 1 and 2.

Date of issuance: October 2, 2013.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment Nos.: 193 and 189.

Renewed Facility Operating License Nos. NPF–2 and NPF–8: Amendments revised the Facility Operating Licenses and the Technical Specifications.

*Date of initial notice in **Federal Register**:* October 2, 2012 (77 FR 60153). The supplements dated March 14, and June 14, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 2, 2013.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Inc., Docket Nos. 50–424 and 50–425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: September 1, 2011, as supplemented on February 10, April 30, December 18, 2012, February 27, June 14, August 7, August 30, 2013.

Brief description of amendments: The amendments revise Technical Specifications (TSs) 3.7.9 by changing the criteria for nuclear service cooling water tower three- and four-fan operation and provides a 7-day Completion Time for one-fan/spray cell being inoperable under certain conditions.

Date of issuance: September 18, 2013.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment Nos.: 170 and 152.

Facility Operating License Nos. NPF–68 and NPF–81: Amendments revised the licenses and the TSs.

*Date of initial notice in **Federal Register**:* November 1, 2011 (76 FR 67489). The supplemental letters dated February 10, April 30, December 18, 2012, February 27, June 14, August 7, August 30, 2013, provided additional information clarifying the license amendment request, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 18, 2013.

No significant hazards consideration comments received: No.

Virginia Electric and Power Company, Docket Nos. 50–338 and 50–339, North Anna Power Station, Units 1 and 2, Louisa County, Virginia and Docket Nos. 50–280 and 50–281, Surry Power Station, Units 1 and 2, Surry County, Virginia

Date of application for amendment: September 27, 2012.

Brief description of amendment: The amendments authorize the addition of a 15-minute threshold for reactor coolant system leaks, based on NRC's Regulatory Issue Summary (RIS) 2003–18, Supplement 2, ''Use of NEI 99–01, Methodology for Development of Emergency Action Levels, Revision 4, Dated January 2003,'' dated December 12, 2005.

Date of issuance: September 25, 2013.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment Nos.: 270, 252, 280, and 280.

Renewed Facility Operating License Nos. NPF–4 and NPF–7, DPR–32 and DPR–37: Amendments changed the licenses.

*Date of initial notice in **Federal Register**:* December 11, 2012 (77 FR 73691), and August 1, 2013 (78 FR 46616).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 25, 2013.

No significant hazards consideration comments received: No.

Virginia Electric and Power Company, et al., Docket Nos. 50–280 and 50–281, Surry Power Station, Units 1 and 2, Surry County, Virginia

Date of application for amendments: September 26, 2012.

Brief description of amendments: These amendments revise the Technical Specifications to use a temporary 30″ seismic, non-missile protected jumper for providing service water to the component cooling heat exchangers (CCHX) while the licensee cleans, inspects, repairs (if necessary), and recoats (if necessary) the existing CCHX service water supply piping. The licensee will use the temporary jumper for up to 35 days during each of the next two Unit 1 refueling outages, which the licensee has scheduled to perform in 2013 and 2015.

Date of issuance: September 20, 2013.

Effective date: As of the date of issuance and shall be implemented within 30 days.

Amendment Nos.: 279 and 279.

Renewed Facility Operating License Nos. DPR–32 and DPR–37: Amendments change the licenses and the Technical Specifications.

*Date of initial notice in **Federal Register**:* The supplements dated June 4, and September 3, 2013, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 20, 2013.

No significant hazards consideration comments received: No

ZionSolutions, LLC, Docket Nos. 50–295 and 50–304, Zion Nuclear Power Station, Units 1 and 2, Lake County, Illinois

Date of application for amendment: May 31, 2012, and October 25, 2012, as supplemented by letters dated December 20, 2012, January 17, 2013, February 21, 2013, April 4, 2013, and May 16, 2013.

Brief description of amendment: The amendments approve the upgraded Fuel Handling Building crane.

Date of issuance: September 19, 2013.

Effective date: As of the date of issuance and shall be implemented immediately.

Amendment Nos.: 186 and 173.

Facility Operating License Nos. DPR–39 and DPR–48: These amendments are effective on the date of issuance and shall be implemented prior to the start of operations to transfer spent fuel to the Zion Independent Spent Fuel Storage Installation

*Date of initial notice in **Federal Register**:* August 7, 2012 (77 FR 47123). The October 25, 2012, December 20, 2012, January 17, 2013, February 21, 2013, April 4, 2013, and May 16, 2013, submittals provided clarifying information that did not change the scope of the original request.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated September 19, 2013.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 21st day of October 2013.

For the Nuclear Regulatory Commission.

John D. Monninger,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2013–25394 Filed 10–28–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0138; Docket No. 040–08903, License No. SUA–1471]

License Amendment Request for Homestake Mining Company of California, Grants Reclamation Project, Cibola County, New Mexico

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to request a hearing and to petition for leave to intervene.

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) has received, by letter dated September 23, 2013, a request to amend Homestake Mining Company of California's (HMC's or Licensee's) license to change the background monitoring location used to measure radon-222 concentrations in air.

DATES: A request for a hearing or petition for leave to intervene must be filed by December 30, 2013.

ADDRESSES: Please refer to Docket ID NRC–2013–0138 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0138. Address questions about NRC dockets to Carol Gallagher; telephone: 301–287–3422; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS Accession Number for each document referenced is provided the first time the document is referenced. The license amendment request is available in ADAMS under Package Accession No. ML13281A790.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: John Buckley, Office of Federal and State Materials and Environmental Management Programs, telephone: 301–415–6607; email: *john.buckley@nrc.gov,* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC has received, by letter dated September 23, 2013, a request to amend Homestake Mining Company of California's (HMC's or Licensee's) license to change the background monitoring location used to measure radon-222 concentrations in air. Specifically, HMC is requesting to amend Table 1—Environmental Monitoring Program Excluding Groundwater Monitoring, referenced in License Condition 10 (LC10) to reflect the replacement of HMC–16 with HMC–1Off as the background location for radon-22 monitoring. Upon NRC's review and approval, Table 1—Environmental Monitoring Program Excluding Groundwater Monitoring, will be revised by replacing radon monitoring location HMC–16 with new location HMC–1Off. HMC's evaluation of background monitoring locations titled, ''Basis for Selection of a Representative Background Monitoring Location for the Homestake Uranium Mill Site, SUA–1471'' dated September 2013, can be found in ADAMS under Accession No. ML13281A790.

HMC–16 was identified in Table 1 as the background radon-222 monitoring location in HMC's license amendment request dated September 2, 1993 (ADAMS Accession No. ML13274A418). Amendment No. 16, incorporating Table 1, was approved on September 23, 1993. Additional documents related to the license amendment application can be found in ADAMS under Docket No. 04008903.

An NRC administrative completeness review found the application acceptable for a technical review (ADAMS Accession No. ML13274A290). Prior to approving the amendment request, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations. The NRC's findings will be documented in a safety evaluation report.

II. Opportunity To Request a Hearing; Petition for Leave to Intervene

Within 60 days after the date of publication of this **Federal Register** notice, any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene with respect to the license amendment request. Requirements for hearing requests and petitions for leave to intervene are found in 10 CFR 2.309, ''Hearing requests, petitions to intervene, requirements for standing, and contentions.'' Interested persons should consult 10 CFR 2.309, which is available at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852 (or call the PDR at 1–800–397–4209 or 301–415–4737). The NRC's regulations are also accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

Any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition must provide the name, address, and telephone number of the petitioner and specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order that may be entered in the proceeding on the petitioner's interest.

A petition for leave to intervene must also include a specification of the contentions that the petitioner seeks to have litigated in the hearing. For each contention, the petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings that the NRC must make to support the granting of a license amendment in response to the

application. The petition must also include a concise statement of the alleged facts or expert opinions which support the position of the petitioner and on which the petitioner intends to rely at the hearing, together with references to the specific sources and documents on which the petitioner intends to rely. Finally, the petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for amendment that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application for amendment fails to contain information on a relevant matter as required by law, the identification of each failure, and the supporting reasons for the petitioner's belief. Each contention must be one that, if proven, would entitle the petitioner to relief.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC's regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1)(i)–(iii).

A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by December 30, 2013. The petition must be filed in accordance with the filing instructions in section III of this document, and should meet the requirements for petitions for leave to intervene set forth in this section. A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may also have the opportunity to participate in a hearing as a nonparty under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by December 30, 2013.

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counselor representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC's guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital led

certificate before a hearing request/petition for leave to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals/contact-us-eie.html* by email to *MSHOResource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8:00 a.m. and 8:00 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/EHD/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Dated at Rockville, Maryland, this 17th day of October 2013.

For the Nuclear Regulatory Commission.

Andrew Persinko,

Deputy Director, Decommissioning and Uranium Recovery Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2013–25422 Filed 10–28–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2013–0001]

Sunshine Act Meeting Notice

DATES: Weeks of October 28, November 4, 11, 18, 25, December 2, 2013.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of October 28, 2013

Thursday, October 31, 2013

10:00 a.m. NRC All Employees Meeting (Public Meeting), Marriott Bethesda North Hotel, 5701 Marinelli Road, Rockville, MD 20852.

Week of November 4, 2013—Tentative

There are no meetings scheduled for the week of November 4, 2013.

Week of November 11, 2013—Tentative

There are no meetings scheduled for the week of November 11, 2013.

Week of November 18, 2013—Tentative

Thursday, November 21, 2013

9:00 a.m. Briefing on Spent Fuel Pool Safety and Consideration of Expedited Transfer to Dry Casks (Public Meeting) (Contact: Kevin Witt, 301–415–2145)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of November 25, 2013—Tentative

There are no meetings scheduled for the week of November 25, 2013.

Week of December 2, 2013—Tentative

There are no meetings scheduled for the week of December 2, 2013.

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The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—301–415–1292. Contact person for more information: Rochelle Bavol, 301–415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an email to *Darlene.Wright@nrc.gov.*

Dated: October 24, 2013.

Richard J. Laufer,

Technical Coordinator, Office of the Secretary.

[FR Doc. 2013–25735 Filed 10–25–13; 4:15 pm]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549.

Extension:

Form ID; OMB Control No. 3235–0328, SEC File No. 270–291.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Form ID (OMB Control No. 3235–0328; SEC File No. 270–291) is used by

companies and other entities to apply for identification numbers and passwords used in conjunction with the EDGAR electronic filing system. The information provided on Form ID is essential to the security of the EDGAR system. Form ID is a not a public document because it is used solely for the purpose of registering filers on the EDGAR system. Form ID must be filed every time a registrant or other person obtains or changes an identification number. Form ID is filed by individuals, companies or other for-profit organizations that are required to file electronically. We estimate approximately 65,784 registrants file Form ID and it takes approximately an estimated 0.15 hours per response for a total annual burden of 9,868 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov* . Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: October 23, 2013.

Kevin M. O'Neill,

Deputy Director.

[FR Doc. 2013–25447 Filed 10–28–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, October 31, 2013 at 1:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Stein, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting will be:

institution and settlement of injunctive actions;

institution and settlement of administrative proceedings;

adjudicatory matters;

amicus consideration; and

other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: October 24, 2013.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2013–25647 Filed 10–25–13; 12:00 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70747; File No. SR–NASDAQ–2013–133]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Implement Transition to Friday Expiration for Most Options Contracts

October 23, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 11, 2013, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend certain procedural rules to implement the change in the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday. The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/,* at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 21, 2013, the Exchange filed to change the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.[3] This proposed rule change is intended to clarify certain rule changes that were made in the Expiration Date Filing and to amend additional procedural and other rules intended to implement the change in expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.

The Exchange has adopted rules to change the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.[4] The changes to the expiration date apply to all standard expiration

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 70260 (August 26, 2013), 78 FR 53794 (August 30, 2013) (SR–NASDAQ–2013–112)(''Expiration Date Filing''). The changes proposed in the Expiration Date Filing were effective on filing and became operative on September 20, 2013.

[4] *See* Chapter XIV, Index Rules, Section 2(q) (definition of ''expiration date'').

contracts including those in which the rules are silent on the expiration date. Option contracts having non-standard expiration dates (''non-standard expiration contracts'') were unaffected by the proposed rule changes, except that FLEX options having expiration dates later than February 1, 2015 cannot expire on a Saturday unless they are specified by The Options Clearing Corporation (''OCC'') as grandfathered.[5]

The Exchange is making the proposed rule changes to further harmonize its rules in connection with a recently approved rule filing made by OCC which made substantially similar changes.[6] The Exchange believes that the industry must remain consistent in expiration dates, and, thus, is proposing to update its rules to remain consistent with those of OCC. In addition, the Exchange understands that other exchanges have and will be filing similar rules to effect this industry-wide initiative.[7]

In order to provide a smooth transition to the Friday expiration, OCC has begun to move the expiration exercise procedures to Friday for all standard expiration contracts even though the contracts would continue to expire on Saturday.[8] After February 1, 2015, virtually all standard expiration contracts will actually expire on Friday. The only standard expiration contracts that will expire on a Saturday after February 1, 2015 are certain options that were listed prior to the effectiveness of the OCC rule change, and a limited number of options that may be listed prior to necessary systems changes of the options exchanges. The NASDAQ Options Market (''NOM''), along with the other option exchanges, has agreed not to list any additional options with Saturday expiration dates falling after February 1, 2015. NASDAQ understands that the other exchanges are committed to the same listing schedule.[9]

Certain option contracts have already been listed with Saturday expiration dates as distant as January 2016 (which is the furthest out expiration as of the date of this filing). For these contracts, transitioning to a Friday expiration for newly listed option contracts expiring after February 1, 2015 would create a situation under which certain options with open interest would expire on a Saturday while other options with open interest would expire on a Friday in the same expiration month.

Clearing members have expressed a clear preference to not have a mix of options with open interest that expire on different days in a single month.[10] Accordingly, OCC represented in its recently approved filing that it will not issue and clear any new option contracts with a Friday expiration if existing option contracts of the same options class expire on the Saturday following the third Friday of the same month. However, Friday expiration processing will be in effect for these Saturday expiration contracts. As with standard expiration options during the transition period, exercise requests received after Friday expiration processing is complete but before the Saturday contract expiration time will continue to be processed without fines or penalties.

Since the rule changes implementing the change in expiration date apply only to new series of standard expiration contracts opened for trading consistent with the OCC rules and having expiration dates later than February 1, 2015, the Exchange is proposing to amend certain rules relating to the procedures of the Exchange. The proposed changes take into account that, during a transition period, there will be options with open interest having both Friday and Saturday expiration dates.

More specifically, the Exchange is proposing to amend Chapter 1, General Provisions, Section 1(a)(16) to provide that European-style options can be exercised only on the expiration date if such day is a business day or, in the case of option contracts expiring on a day that is not a business day, the last business day prior to expiration.

In addition, the Exchange seeks to amend Chapter III, Business Conduct, Section 12(a)(ii) with respect to certain timing for restrictions on the exercise of option contracts. Specifically, the Exchange proposes to specify that the 10 business day period referenced in Section 12(a)(ii) includes the expiration date for an option contract that expires on a business day. With respect to index options, restrictions on exercise may be in effect until the opening of business on the business day of their expiration or, in the case of an option contract expiring on a day that is not a business day, on the last business day before the expiration date. In addition, the Exchange proposes to amend Section 12(a)(iii)(2) to specify that exercises of expiring American-style, cash-settled index options would not be prohibited on an expiration date that is a business day (i.e., for Friday expirations), or, in the case of an option contract expiring on a non-business day (as is currently the case for Saturday expirations), on the last business day prior to expiration.

The Exchange also proposes to amend Chapter IV, Securities Traded on NOM, Section 6(c) to differentiate between Friday and Saturday expirations. Specifically, the Exchange would specify that, in the event of unusual market conditions, additional series of individual stock options may be added in the discretion of the Exchange until the close of trading on the business day prior to expiration in the case of an option contract expiring on a business day (i.e., Thursday for a Friday expiration), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, until the close of trading on the second business day prior to expiration (i.e., until the close of trading on Thursday for Saturday expirations).

Additionally, the Exchange proposes to amend Chapter V, Regulation of Trading on NOM, Section 6(f)(ii) to add greater specificity regarding the timing surrounding notifications to the Exchange of a Catastrophic Error. Specifically, the Exchange proposes to specify that, for transactions in an expiring options series that take place on an expiration day that is a business day (i.e., for Friday expirations), a party must notify MarketWatch by 5:00 p.m. ET that same day. For transactions in an expiring options series that take place on the business day immediately prior to a non-business expiration day (i.e., for Saturday expirations), a party must notify MarketWatch by 5:00 p.m. ET on such business day (i.e., on Friday).

The Exchange's proposal includes several proposed changes to Chapter VIII, Exercises and Deliveries, Section 1 in order to differentiate between Friday and Saturday expirations. First, the Exchange proposes to specify in Section 1(b) that special procedures apply to the exercise of equity options on the business day of their expiration (i.e., for

[5] Examples of options with non-standard expiration contracts include: Quarterly Equity and Exchange-Traded Fund Shares (''ETFs'') Option Series (Chapter IV, Section 6, Commentary .04), Quarterly Options Series for indexes (Chapter XIV, Section 11(g)), Short Term Option Series (Chapter IV, Section 6, Commentary .07) and Short Term Option Series for indexes (Chapter XIV, Section 11(h)).

[6] *See* Securities Exchange Act Release No. 34–69772 (June 17, 2013), 78 FR 37645(June 21, 2013) (order approving SR–OCC–2013–004).

[7] *See* Securities Exchange Act Release Nos. 70091 (August 1, 2013), 78 FR 48212 (August 7, 2013) (SR–CBOE–2013–073); 69996 (July 17, 2013), 78 FR 44183 (July 23, 2013) (SR–MIAX–2013–32); 70373 (September 11, 2013), 78 FR 57198 (September 17, 2013) (SR–NYSEMKT–2013–73); 70372 (September 11, 2013), 78 FR 57186 (September 17, 2013) (SR–NYSEARCA–2013–88); and 70488 (September 24, 2013), 78 FR 59998 (September 30, 2013) (SR–BOX–2013–45).

[8] *See* note 6 *supra.*

[9] *See* note 7 *supra.*

[10] *Id.*

Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, on the last business day before their expiration. Second, the Exchange proposes to specify in Section 1(c) that, regarding exercise cut-off times, option holders have until 5:30 p.m. ET on the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, on the business day immediately prior to the expiration date. Third, the Exchange proposes to specify in Section 1(h) that the advance notice described therein is applicable if provided by the Exchange on or before 5:30 p.m. ET on the business day (i.e., on Thursday) immediately prior to the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the second business day immediately prior to the expiration date (i.e., Thursday for Saturday expirations). Fourth, the Exchange proposes to amend Section 1(i) at ii. to specify that the reference therein to ''unusual circumstances'' includes, but is not limited to, a significant news announcement concerning the underlying security of an option contract that is scheduled to be released just after the close on the business day the option contract expires (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the business day immediately prior to expiration. Fifth, the Exchange proposes to amend Section 1(l)iii., v., and vii. to correct a cross-reference. Sixth, the proposal seeks to amend Section 1(l)viii.2) to specify that exercises of expiring American-style, cash-settled index option would not be prohibited on an expiration date that is a business day (i.e., for Friday expirations), or, in the case of an option contract expiring on a non-business day (as is currently the case for Saturday expirations), on the last business day prior to expiration.

Additionally, the Exchange proposes to amend Chapter XIV, Index Rules, Section 2(g)–(q) to reorder the defined terms into alphabetical order. In newly renumbered Section 2(h) the definition of ''European-style index option'' is modified to provide that the term European-style index option means an option on an industry or market index that can be exercised only on the expiration date if such day is a business day or, in the case of option contracts expiring on a day that is not a business day, the last business day prior to expiration.

The Exchange also seeks to amend Sections 10 and 11 of Chapter XIV, Index Rules to differentiate between Friday and Saturday expirations. Section 10(a) would be amended to specify that transactions with respect to the MSCI EAFE Index may be effected on NOM until 11:00 a.m. ET on the business day of expiration, or, in the case of an option contract expiring on a day that is not a business day, the business day immediately prior to the last business day before the expiration date.

The proposed rule change to Section 11(a)(5) would provide that the last day of trading for A.M.-settled index options shall be the business day (i.e., on Thursday) immediately prior to the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, the business day immediately prior to the last business day before the expiration date (i.e., Thursday for Saturday expirations). In addition, the current index value at the expiration of an A.M.-settled index option would be determined on the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, on the last business day before its expiration (i.e., Friday). The Exchange also proposes to amend Section 11(a)(5)(i) to refer to Section 10(g) in order to correct a cross-reference. With respect to P.M.-settled index options, the proposal would specify that the last day of trading for P.M.-settled index options would be the business day of expiration, or, in the case of an option contract expiring on a day that is not a business day, on the last business day before its expiration date. Additionally, it is proposed that Section 11(c)(2) would be amended to specify that new series of index option contracts may be added up to, but not on or after, the fourth business day prior to expiration for an option contract expiring on a business day (i.e., up to, but not on or after, the opening of trading on Monday morning for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the fifth business day prior to expiration. The Exchange also proposes to amend Section 11(d) to more generally specify that the reported level of the underlying index that is calculated by the reporting authority for the purposes of determining the current index value at expiration of an A.M.-settled index option may differ from the level of the index that is separately calculated and reported reflecting trading activity subsequent to the opening of trading in any of the underlying securities.

As stated above, the Exchange believes the proposed change will keep the Exchange consistent with the processing at OCC and will enable the Exchange to give effect to the industry-wide initiative. In addition, the Exchange understands that other exchanges have filed similar rules to differentiate between Friday and Saturday expiration dates for standard options on listed classes.[11]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that implementing the change to Friday expiration processing and eventually transitioning to Friday expiration for all monthly expiration contracts would foster cooperation and coordination with persons engaged in facilitating transactions in securities. In particular, the Exchange believes that keeping its rules consistent with those of the industry will protect all participants in the market by eliminating confusion and would facilitate the long-term goal of OCC and its clearing members to move the expiration process for all monthly

[11] *See* note 7 *supra.*

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *Id.*

expiration contracts from Saturday to Friday night. The proposed changes thus allow for a more orderly market by allowing all options markets, including the clearing agencies, to have the same expiration date for standard options and to have clarity around the procedures that apply during the transition period when both Friday and Saturday expirations will exist for standard options.

In addition, the proposed changes will foster cooperation and coordination with persons engaged in regulating clearing, settling, processing information with respect to, and facilitating transactions in securities by aligning a pivotal part of the options processing to be consistent industry wide. If the industry were to differ, investors would suffer from confusion and be more vulnerable to inadvertent violations of different exchange rules. The proposed changes do not permit unfair discrimination between any members because they are applied to all members equally. In the alternative, the Exchange believes that the proposed changes help all members by keeping the Exchange consistent with OCC practices and those of other exchanges.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Specifically, the Exchange does not believe the proposed rule change will impose a burden on intramarket competition because it will be applied to all members equally. In addition, the Exchange does not believe the proposed rule change will impose any burden to intermarket competition because it will be applied industry-wide, apply to all market participants and is designed to allow OCC to streamline the expiration process for all monthly expiration contracts and increase operational efficiencies for OCC and its clearing members.

The proposed rule change is structured to enhance competition because the shift from an expiration date of the Saturday following the third Friday to the third Friday is anticipated to be adopted industry-wide and will apply to multiple listed classes. The proposed changes in turn will allow NOM to continue to compete with other exchanges making similar rule changes. For the reasons above, the Exchange does not believe that the proposed rule change would impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received. The Exchange notes, however, that a favorable comment was submitted to the OCC filing.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6) [16] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2013–133 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2013–133. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NASDAQ–2013–133 and should be submitted on or before November 19, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–25446 Filed 10–28–13; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70745; File No. SR-Phlx-2013–104]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Implement Transition to Friday Expiration for Most Options Contracts

October 23, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the

''Act'') [1] and Rule 19b-4 thereunder,[2] notice is hereby given that on October 11, 2013, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend certain procedural rules to implement the change in the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday. The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/nasdaqomxphlx/phlx,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 21, 2013, the Exchange filed to change the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.[3] This proposed rule change is intended to clarify certain rule changes that were made in the Expiration Date Filing and to amend additional procedural and other rules intended to implement the change in expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.

The Exchange has adopted rules to change the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.[4] The changes to the expiration date apply to all standard expiration contracts including those in which the rules are silent on the expiration date. Option contracts having non-standard expiration dates (''non-standard expiration contracts'') were unaffected by the proposed rule changes, except that FLEX options having expiration dates later than February 1, 2015 cannot expire on a Saturday unless they are specified by The Options Clearing Corporation (''OCC'') as grandfathered.[5]

The Exchange is making the proposed rule changes to further harmonize its rules in connection with a recently approved rule filing made by OCC which made substantially similar changes.[6] The Exchange believes that the industry must remain consistent in expiration dates, and, thus, is proposing to update its rules to remain consistent with those of OCC. In addition, the Exchange understands that other exchanges have and will be filing similar rules to effect this industry-wide initiative.[7]

In order to provide a smooth transition to the Friday expiration, OCC has begun to move the expiration exercise procedures to Friday for all standard expiration contracts even though the contracts would continue to expire on Saturday.[8] After February 1, 2015, virtually all standard expiration contracts will actually expire on Friday. The only standard expiration contracts that will expire on a Saturday after February 1, 2015 are certain options that were listed prior to the effectiveness of the OCC rule change, and a limited number of options that may be listed prior to necessary systems changes of the options exchanges. Phlx, along with the other option exchanges, has agreed not to list any additional options with Saturday expiration dates falling after February 1, 2015. The Exchange understands that the other exchanges are committed to the same listing schedule.[9]

Certain option contracts have already been listed with Saturday expiration dates as distant as January 2016 (which is the furthest out expiration as of the date of this filing). For these contracts, transitioning to a Friday expiration for newly listed option contracts expiring after February 1, 2015 would create a situation under which certain options with open interest would expire on a Saturday while other options with open interest would expire on a Friday in the same expiration month.

Clearing members have expressed a clear preference to not have a mix of options with open interest that expire on different days in a single month.[10] Accordingly, OCC represented in its recently approved filing that it will not issue and clear any new option contracts with a Friday expiration if existing option contracts of the same options class expire on the Saturday following the third Friday of the same month. However, Friday expiration processing will be in effect for these Saturday expiration contracts. As with standard expiration options during the transition period, exercise requests received after Friday expiration processing is complete but before the Saturday contract expiration time will continue to be processed without fines or penalties.

Since the rule changes implementing the change in expiration date apply only to new series of standard expiration contracts opened for trading consistent with the OCC rules and having expiration dates later than February 1, 2015, the Exchange is proposing to amend certain rules relating to the procedures of the Exchange. The proposed changes take into account that, during a transition period, there will be options with open interest

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] *See* Securities Exchange Act Release No. 70258 (August 26, 2013), 78 FR 54340 (August 30, 2013) (SR-Phlx-2013–89) (''Expiration Date Filing''). Certain changes proposed in the Expiration Date Filing became effective on filing and become operative on September 20, 2013. The Exchange filed a proposal to adopt a temporary rule to implement the amended definition of ''expiration date'' in Rule 1000(b)(21) as of September 16, 2013. *See* Securities Exchange Act Release No. 70451 (September 19, 2013), 78 FR 59076 (September 25, 2013) (SR-Phlx-2013–95) (''Temporary Rule Filing'').

[4] *See* Rule 1000(b)(21) (definition of ''expiration date'').

[5] Examples of options with non-standard expiration contracts include: FLEX options (Rule 1079), Quarterly Equity and Exchange-Traded Fund Shares (''ETFs'') Option Series (Rule 1012, Commentary .08), Quarterly Expiring Index Options Series (Rule 1101A(b)(iv)), Quarterly Options Index Series Program (Rule 1101A(b)(v)), Short Term Option Series (Rule 1012, Commentary .11) and Short Term Option Index Series (Rule 1101A(b)(vi)).

[6] *See* Securities Exchange Act Release No. 34–69772 (June 17, 2013), 78 FR 37645 (June 21, 2013) (order approving SR–OCC–2013–004).

[7] *See* Securities Exchange Act Release Nos. 70091 (August 1, 2013), 78 FR 48212 (August 7, 2013) (SR–CBOE–2013–073); 69996 (July 17, 2013), 78 FR 44183 (July 23, 2013) (SR–MIAX–2013–32); 70373 (September 11, 2013), 78 FR 57198 (September 17, 2013) (SR–NYSEMKT–2013–73); 70372 (September 11, 2013), 78 FR 57186 (September 17, 2013) (SR–NYSEARCA–2013–88); and 70488 (September 24, 2013), 78 FR 59998 (September 30, 2013) (SR–BOX–2013–45).

[8] *See* note 6 *supra.*

[9] *See* note 7 *supra.*

[10] *Id.*

having both Friday and Saturday expiration dates.

More specifically, the Exchange seeks to amend Rule 1006 with respect to certain timing for restrictions on the exercise of American style option. Specifically, the Exchange proposes to specify that the 10 business day period referenced in Rule 1006 includes the expiration date for an option contract that expires on a business day. In addition, the proposal would amend Rule 1006A to provide that restrictions may be in effect for index options until the open of business on the business day of expiration, or, in the case of an option contract expiring on a day that is not a business day, the business day prior to the expiration date.

The Exchange also proposes to amend Rule 1012, Series of Options Open for Trading, to differentiate between Friday and Saturday expirations. Specifically, the Exchange proposes to amend Rule 1012(a)(i)(B) to specify that additional series of individual stock options may be added in unusual market conditions until the close of trading on the business day prior to expiration in the case of an option contract expiring on a business day (i.e., Thursday for a Friday expiration), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, until the close of trading on the second business day prior to expiration (i.e., until the close of trading on Thursday for Saturday expirations). The Exchange also seeks to modify Rule 1012(b) to specify that, on a business day of expiration, or, in the case of an option contract expiring on a non-business day, on the business day prior to the expiration date of a series of options, a closing rotation shall commence at 4:00 p.m. in the case of options on stocks or 4:15 p.m. in the case of options on designated Exchange-Traded Fund Shares.

The Exchange's proposal includes several proposed changes to Rules 1042 and 1042A in order to differentiate between the exercise procedures for Friday and Saturday expirations. First, the Exchange proposes to specify in Rule 1042(b) that special procedures apply to the exercise of equity options on the business day of their expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, on the last business day before their expiration. Second, the Exchange proposes to specify in Rule 1042(c) that, regarding exercise cut-off times, option holders have until 5:30 p.m. EST on the business day of their expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, on the business day immediately prior to the expiration date. Third, the Exchange proposes to specify in Rule 1042(h) that the advance notice described therein is applicable if provided by the Exchange on or before 5:30 p.m. EST on the business day (i.e., on Thursday) immediately prior to the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the business day immediately prior to the last business day before the expiration date (i.e., Thursday for Saturday expirations). Fourth, the Exchange proposes to amend Rule 1042, Commentary .03 to specify that the reference therein to ''unusual circumstances'' includes, but is not limited to, a significant news announcement concerning the underlying security of an option contract that is scheduled to be released just after the close on the business day the option contract expires (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the business day immediately prior to expiration. In addition, the Exchange proposes to amend Rule 1042A(b) to make clear when certain procedures do not apply with respect to the exercise of any stock index option series on the business day of expiration, or in the case of an option expiring on a day that is not a business day, the business day prior to the expiration date.

The Exchange also seeks to modify Rule 1047(c) to specify that an Options Exchange Official has the authority to conduct a closing rotation on a business day of expiration, or, in the case of an option contract expiring on a non-business day, on the trading day prior to expiration where the underlying stock or Exchange-Traded Fund Share did not open or was halted, whenever such action is deemed necessary in the interests of maintaining a fair and orderly market and to protect investors. Rule 1047, Commentary .01(c) also would be modified to clarify certain procedures relating to closing rotations that may commence on a business day of expiration, or, in the case of an option contract expiring on a non-business day, on the last trading day prior to expiration with respect to expiring stock option contracts, expiring stock option contracts or options on Exchange-Traded Fund Shares.

Additionally, the Exchange proposes to amend Rule 1092 to add greater specificity regarding the timing surrounding notifications to the Exchange of a Catastrophic Error. Specifically, the Exchange proposes to specify that, for such transactions in an expiring options series that take place on an expiration day that is a business day (i.e., for Friday expirations), a party must notify the Exchange by 5:00 p.m. ET that same day. For such transactions in an options series that take place on the business day immediately prior to an expiration day that is not a business day (i.e., for Saturday expirations), an Exchange member must notify the Exchange's Regulatory staff by 5:00 p.m. ET on such business day (i.e., on Friday).

Additionally, it is proposed that Rule 1101A(b)(i) would be amended to specify that due to unusual market conditions new series of index option contracts may be added up to, but not on or after, the fourth business day prior to expiration for an option contract expiring on a business day (i.e., up to, but not on or after, the opening of trading on Monday morning for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the fifth business day prior to expiration. Similarly, Rule 1002C is proposed to be modified to specify that due to unusual market conditions new series of PHLX FOREX Options may be added consistent with the timing described above for new series of index option contracts. The Exchange also proposes to modify Rule 1101A(c) and Rule 1101A, Commentary .01 to specify the applicable hours for trading for index options series and options on the Full Value MSCI EAFE Index on an expiration date that is a business day or the business day prior to expiration when the expiration date is a non-business day.

The Exchange also seeks to clarify rules governing the closing settlement value of certain option contracts. Rule 1057, as proposed to be amended, would provide that the closing settlement value for U.S. dollar-settled foreign currency options on the currencies listed therein, shall be the Exchange Spot Price at 12:00:00 Eastern Time (noon) on the expiration date, if that expiration date is a business day, or on the business day prior to expiration, when the expiration date is a non-business day, unless the Exchange determines to apply an alternative closing settlement value as a result of

extraordinary circumstances. The proposal would amend Rule 1009A(f)(1) to provide that the exercise settlement value for Alpha Index options will be based upon the opening prices of the individual stock or ETF from the primary listing market on the business day of expiration, or, in the case of an option contract expiring on a day that is not a business day, the business day prior to the expiration date. Under proposed Rule 1006C, the closing settlement value for PHLX FOREX Options and for the FLEX PHLX FOREX Options on the currencies listed in the rule shall be the spot market price at 12:00:00 Eastern Time (noon) on an expiration date that is a business day or on the business day prior to expiration, when the expiration date is a non-business day, unless the Exchange determines to apply an alternative closing settlement value as a result of extraordinary circumstances.

As stated above, the Exchange believes the proposed change will keep the Exchange consistent with the processing at OCC and will enable the Exchange to give effect to the industry-wide initiative. In addition, the Exchange understands that other exchanges have filed similar rules to differentiate between Friday and Saturday expiration dates for standard options on listed classes.[11]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that implementing the change to Friday expiration processing and eventually transitioning to Friday expiration for all monthly expiration contracts would foster cooperation and coordination with persons engaged in facilitating transactions in securities. In particular, the Exchange believes that keeping its rules consistent with those of the industry will protect all participants in the market by eliminating confusion and would facilitate the long-term goal of OCC and its clearing members to move the expiration process for all monthly expiration contracts from Saturday to Friday night. The proposed changes thus allow for a more orderly market by allowing all options markets, including the clearing agencies, to have the same expiration date for standard options and to have clarity around the procedures that apply during the transition period when both Friday and Saturday expirations will exist for standard options.

In addition, the proposed changes will foster cooperation and coordination with persons engaged in regulating clearing, settling, processing information with respect to, and facilitating transactions in securities by aligning a pivotal part of the options processing to be consistent industry wide. If the industry were to differ, investors would suffer from confusion and be more vulnerable to inadvertent violations of different exchange rules. The proposed changes do not permit unfair discrimination between any members because they are applied to all members equally. In the alternative, the Exchange believes that the proposed changes help all members by keeping the Exchange consistent with OCC practices and those of other exchanges.

B. Self-Regulatory Organization's Statement on Burden on Competition

Phlx does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Specifically, the Exchange does not believe the proposed rule change will impose a burden on intramarket competition because it will be applied to all members equally. In addition, the Exchange does not believe the proposed rule change will impose any burden to intermarket competition because it will be applied industry-wide, apply to all market participants and is designed to allow OCC to streamline the expiration process for all monthly expiration contracts and increase operational efficiencies for OCC and its clearing members.

The proposed rule change is structured to enhance competition because the shift from an expiration date of the Saturday following the third Friday to the third Friday is anticipated to be adopted industry-wide and will apply to multiple listed classes. The proposed changes in turn will allow Phlx to continue to compete with other exchanges making similar rule changes. For the reasons above, the Exchange does not believe that the proposed rule change would impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received. The Exchange notes, however, that a favorable comment was submitted to the OCC filing.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[15] and Rule 19b–4(f)(6)[16] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[11] *See* note 7 *supra.*

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *Id.*

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2013–104 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2013–104. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–Phlx–2013–104 and should be submitted on or before November 19, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–25444 Filed 10–28–13; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70746; File No. SR–BX–2013–055]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Implement Transition to Friday Expiration for Most Options Contracts

October 23, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 11, 2013, NASDAQ OMX BX LLC (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend certain procedural rules to implement the change in the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday. The text of the proposed rule change is available at *http://nasdaqomxbx.cchwallstreet.com/,* at the Exchange's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.196–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 21, 2013, the Exchange filed to change the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.[3] This proposed rule change is intended to clarify certain rule changes that were made in the Expiration Date Filing and to amend additional procedural and other rules intended to implement the change in expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.

The Exchange has adopted rules to change the expiration date for most option contracts to the third Friday of the expiration month instead of the Saturday following the third Friday.[4] The changes to the expiration date apply to all standard expiration contracts including those in which the rules are silent on the expiration date. Option contracts having non-standard expiration dates (''non-standard expiration contracts'') were unaffected by the proposed rule changes, except that FLEX options having expiration dates later than February 1, 2015 cannot expire on a Saturday unless they are specified by The Options Clearing Corporation (''OCC'') as grandfathered.[5]

The Exchange is making the proposed rule changes to further harmonize its rules in connection with a recently approved rule filing made by OCC which made substantially similar changes.[6] The Exchange believes that the industry must remain consistent in expiration dates, and, thus, is proposing to update its rules to remain consistent with those of OCC. In addition, the Exchange understands that other exchanges have and will be filing

[3] *See* Securities Exchange Act Release No. 70258 (August 26, 2013), 78 FR 53797 (August 30, 2013) (SR–BX–2013–50) (''Expiration Date Filing''). The changes proposed in the Expiration Date Filing were effective on filing and became operative on September 20, 2013.

[4] *See* Chapter XIV, Index Rules, Section 2(p) (definition of ''expiration date'').

[5] Examples of options with non-standard expiration contracts include: Quarterly Equity and Exchange-Traded Fund Shares (''ETFs'') Option Series (Chapter IV, Section 6, Commentary .04), Quarterly Options Series for indexes (Chapter XIV, Section 11(g)), Short Term Option Series (Chapter IV, Section 6, Commentary .07) and Short Term Option Series for indexes (Chapter XIV, Section 11(h)).

[6] *See* Securities Exchange Act Release No. 34–69772 (June 17, 2013), 78 FR 37645 (June 21, 2013) (order approving SR–OCC–2013–004).

similar rules to effect this industry-wide initiative.[7]

In order to provide a smooth transition to the Friday expiration, OCC has begun to move the expiration exercise procedures to Friday for all standard expiration contracts even though the contracts would continue to expire on Saturday.[8] After February 1, 2015, virtually all standard expiration contracts will actually expire on Friday. The only standard expiration contracts that will expire on a Saturday after February 1, 2015 are certain options that were listed prior to the effectiveness of the OCC rule change, and a limited number of options that may be listed prior to necessary systems changes of the options exchanges. BX, along with the other option exchanges, has agreed not to list any additional options with Saturday expiration dates falling after February 1, 2015. BX understands that the other exchanges are committed to the same listing schedule.[9]

Certain option contracts have already been listed with Saturday expiration dates as distant as January 2016 (which is the furthest out expiration as of the date of this filing). For these contracts, transitioning to a Friday expiration for newly listed option contracts expiring after February 1, 2015 would create a situation under which certain options with open interest would expire on a Saturday while other options with open interest would expire on a Friday in the same expiration month.

Clearing members have expressed a clear preference to not have a mix of options with open interest that expire on different days in a single month.[10] Accordingly, OCC represented in its recently approved filing that it will not issue and clear any new option contracts with a Friday expiration if existing option contracts of the same options class expire on the Saturday following the third Friday of the same month. However, Friday expiration processing will be in effect for these Saturday expiration contracts. As with standard expiration options during the transition period, exercise requests received after Friday expiration processing is complete but before the Saturday contract expiration time will continue to be processed without fines or penalties.

Since the rule changes implementing the change in expiration date apply only to new series of standard expiration contracts opened for trading consistent with the OCC rules and having expiration dates later than February 1, 2015, the Exchange is proposing to amend certain rules relating to the procedures of the Exchange. The proposed changes take into account that, during a transition period, there will be options with open interest having both Friday and Saturday expiration dates.

More specifically, the Exchange is proposing to amend Chapter 1, General Provisions, Section 1(a)(25) to provide that European-style options can be exercised only on the expiration date if such day is a business day or, in the case of option contracts expiring on a day that is not a business day, the last business day prior to expiration.

In addition, the Exchange seeks to amend Chapter III, Business Conduct, Section 12(a)(ii) with respect to certain timing for restrictions on the exercise of option contracts. Specifically, the Exchange proposes to specify that the 10 business day period referenced in Section 12(a)(ii) includes the expiration date for an option contract that expires on a business day. With respect to index options, restrictions on exercise may be in effect until the opening of business on the business day of their expiration or, in the case of an option contract expiring on a day that is not a business day, on the last business day before the expiration date. In addition, Section 12(a)(iii)(2) would be amended to specify that exercises of expiring American-style, cash-settled index options would not be prohibited on an expiration date that is a business day (i.e., for Friday expirations), or, in the case of an option contract expiring on a non-business day (as is currently the case for Saturday expirations), on the last business day prior to expiration.

The Exchange also proposes to amend Chapter IV, Securities Traded on BX Options, Section 6(c) to differentiate between Friday and Saturday expirations. Specifically, the Exchange would specify that additional series of individual stock options may be added in unusual market conditions until the close of trading on the business day prior to expiration in the case of an option contract expiring on a business day (i.e., Thursday for a Friday expiration), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, until the close of trading on the second business day prior to expiration (i.e., until the close of trading on Thursday for Saturday expirations).

Additionally, the Exchange's proposal would change Chapter V, Regulation of Trading on BX Options, Section 6(f)(ii) to add greater specificity regarding the timing surrounding notifications to the Exchange of a Catastrophic Error. Specifically, the Exchange proposes to specify that, for such transactions in an expiring options series that take place on an expiration day that is a business day (i.e., for Friday expirations), a party must notify MarketWatch by 5:00 p.m. ET that same day. For such transactions in an options series that take place on the business day immediately prior to an expiration day that is not a business day (i.e., for Saturday expirations), a party must notify MarketWatch by 5:00 p.m. ET on such business day (i.e., on Friday).

The Exchange's proposal includes several proposed changes to Chapter VIII, Exercises and Deliveries, Section 1 in order to differentiate between Friday and Saturday expirations. First, the Exchange proposes to specify in Section 1(b) that special procedures apply to the exercise of equity options on the business day of their expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, on the last business day before their expiration. Second, the Exchange proposes to specify in Section 1(c) that, regarding exercise cut-off times, option holders have until 5:30 p.m. ET on the business day of their expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, on the business day immediately prior to the expiration date. Third, the Exchange proposes to specify in Section 1(h) that the advance notice described therein is applicable if provided by the Exchange on or before 5:30 p.m. ET on the business day (i.e., on Thursday) immediately prior to the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the business day immediately prior to the last business day before the expiration date (i.e., Thursday for Saturday expirations). Fourth, the Exchange proposes to amend Section 1(i) at ii. to specify that the reference therein to ''unusual circumstances'' includes, but is not limited to, a significant news announcement concerning the underlying security of an option

[7] *See* Securities Exchange Act Release Nos. 70091 (August 1, 2013), 78 FR 48212 (August 7, 2013) (SR–CBOE–2013–073); 69996 (July 17, 2013), 78 FR 44183 (July 23, 2013) (SR–MIAX–2013–32); 70373 (September 11, 2013), 78 FR 57198 (September 17, 2013) (SR–NYSEMKT–2013–73); 70372 (September 11, 2013), 78 FR 57186 (September 17, 2013) (SR–NYSEARCA–2013–88); and 70488 (September 24, 2013), 78 FR 59998 (September 30, 2013) (SR–BOX–2013–45).

[8] *See* note 6 *supra.*

[9] *See* note 7 *supra.*

[10] *Id.*

contract that is scheduled to be released just after the close on the business day the option contract expires (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the business day immediately prior to expiration. Fifth, the Exchange proposes to amend Section 1(l)iii., v., and vii. to correct a cross-reference. Sixth, the proposal also seeks to amend Section 1(l)viii.2) to specify that exercises of expiring American-style, cash-settled index option would not be prohibited on an expiration date that is a business day (i.e., for Friday expirations), or, in the case of an option contract expiring on a non-business day (as is currently the case for Saturday expirations), on the last business day prior to expiration.

Additionally, the Exchange seeks to amend Chapter XIV, Index Rules, Section 2(g)–(p) to reorder the defined terms into alphabetical order. In newly renumbered Section 2(h), the definition of ''European-style index option'' is modified to provide that the term European-style index option means an option on an industry or market index that can be exercised only on the expiration date if such day is a business day or, in the case of option contracts expiring on a day that is not a business day, the last business day prior to expiration.

The Exchange also seeks to amend Section 11 of Chapter XIV, Index Rules to differentiate between Friday and Saturday expirations. The proposed rule change to Section 11(a)(5) would provide that the last day of trading for A.M.-settled index options would be the business day (i.e., on Thursday) immediately prior to the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, the business day immediately prior to the last business day before the expiration date (i.e., Thursday for Saturday expirations). In addition, the current index value at the expiration of an A.M.-settled index option would be determined on the business day of expiration (i.e., for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, on the last business day before its expiration (i.e., Friday). The Exchange also proposes to amend Section 11(a)(5)(i) to refer to Section 10(g) in order to correct a cross-reference. Additionally, it is proposed that Section 11(c)(2) would be amended to specify that new series of index option contracts may be added up to, but not on or after, the fourth business day prior to expiration for an option contract expiring on a business day (i.e., up to, but not on or after, the opening of trading on Monday morning for Friday expirations), or, in the case of an option contract expiring on a day that is not a business day, and as is currently the case for Saturday expirations, the fifth business day prior to expiration. The Exchange also proposes to amend Section 11(d) to more generally specify that the reported level of the underlying index that is calculated by the reporting authority for the purposes of determining the current index value at expiration of an A.M.-settled index option may differ from the level of the index that is separately calculated and reported reflecting trading activity subsequent to the opening of trading in any of the underlying securities.

As stated above, the Exchange believes the proposed changes will keep the Exchange consistent with the processing at OCC and will enable the Exchange to give effect to the industry-wide initiative. In addition, the Exchange understands that other exchanges have filed similar rules to differentiate between Friday and Saturday expiration dates for standard options on listed classes.[11]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that implementing the change to Friday expiration processing and eventually transitioning to Friday expiration for all monthly expiration contracts would foster cooperation and coordination with persons engaged in facilitating transactions in securities. In particular, the Exchange believes that keeping its rules consistent with those of the industry will protect all participants in the market by eliminating confusion and would facilitate the long-term goal of OCC and its clearing members to move the expiration process for all monthly expiration contracts from Saturday to Friday night. The proposed changes thus allow for a more orderly market by allowing all options markets, including the clearing agencies, to have the same expiration date for standard options and to have clarity around the procedures that apply during the transition period when both Friday and Saturday expirations will exist for standard options.

In addition, the proposed changes will foster cooperation and coordination with persons engaged in regulating clearing, settling, processing information with respect to, and facilitating transactions in securities by aligning a pivotal part of the options processing to be consistent industry wide. If the industry were to differ, investors would suffer from confusion and be more vulnerable to inadvertent violations of different exchange rules. The proposed changes do not permit unfair discrimination between any members because they are applied to all members equally. In the alternative, the Exchange believes that the proposed changes help all members by keeping the Exchange consistent with OCC practices and those of other exchanges.

B. Self-Regulatory Organization's Statement on Burden on Competition

BX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Specifically, the Exchange does not believe the proposed rule change will impose a burden on intramarket competition because it will be applied to all members equally. In addition, the Exchange does not believe the proposed rule change will impose any burden to intermarket competition because it will be applied industry-wide, apply to all market participants and is designed to allow OCC to streamline the expiration process for all monthly expiration contracts and increase operational efficiencies for OCC and its clearing members.

The proposed rule change is structured to enhance competition

[11] *See* note 7 *supra.*

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *Id.*

because the shift from an expiration date of the Saturday following the third Friday to the third Friday is anticipated to be adopted industry-wide and will apply to multiple listed classes. The proposed changes in turn will allow BX to continue to compete with other exchanges making similar rule changes. For the reasons above, the Exchange does not believe that the proposed rule change would impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received. The Exchange notes, however, that a favorable comment was submitted to the OCC filing.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6) [16] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2013–055 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2013–055. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–BX–2013–055 and should be submitted on or before November 19, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–25445 Filed 10–28–13; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70744; File No. SR–FINRA–2013–045]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Revise the Series 6 Examination Program

October 23, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''SEA'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 16, 2013, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as ''constituting a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule'' under Section 19(b)(3)(A)(i) of the Act [3] and Rule 19b–4(f)(1) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is filing revisions to the content outline and selection specifications for the Investment Company and Variable Contracts Products Representative (Series 6) examination program.[5] The proposed revisions update the material to reflect changes to the laws, rules and regulations covered by the examination and to incorporate the functions and associated tasks currently performed by an Investment Company and Variable Contracts Products Representative. In addition, FINRA is proposing to make

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(i).

[4] 17 CFR 240.19b–4(f)(1).

[5] FINRA also is proposing corresponding revisions to the Series 6 question bank. Based on instruction from SEC staff, FINRA is submitting this filing for immediate effectiveness pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(1) thereunder, and is not filing the question bank for review. *See* Letter to Alden S. Adkins, Senior Vice President and General Counsel, NASD Regulation, from Belinda Blaine, Associate Director, Division of Market Regulation, SEC, dated July 24, 2000. The question bank is available for SEC review.

changes to the format of the content outline. FINRA is not proposing any textual changes to the By-Laws, Schedules to the By-Laws or Rules of FINRA.

The revised content outline is attached.[6] The Series 6 selection specifications have been submitted to the Commission under separate cover with a request for confidential treatment pursuant to SEA Rule 24b–2.[7]

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Section 15A(g)(3) of the Act[8] authorizes FINRA to prescribe standards of training, experience, and competence for persons associated with FINRA members. In accordance with that provision, FINRA has developed examinations that are designed to establish that persons associated with FINRA members have attained specified levels of competence and knowledge, consistent with applicable registration requirements under FINRA rules. FINRA periodically reviews the content of the examinations to determine whether revisions are necessary or appropriate in view of changes pertaining to the subject matter covered by the examinations.

Pursuant to NASD Rule 1032(b)[9] (Limited Representative—Investment Company and Variable Contracts Products), if a representative's activities are limited solely to redeemable securities of companies registered under the Investment Company Act of 1940 (''Investment Company Act''), securities of closed-end companies registered under the Investment Company Act during the period of original distribution, and variable contracts and insurance premium funding programs and other contracts issued by an insurance company (except contracts that are exempt securities pursuant to Section 3(a)(8) of the Securities Act of 1933), the representative may register and qualify as an Investment Company and Variable Contracts Products Representative instead of registering and qualifying as a General Securities Representative (Series 7) pursuant to NASD Rule 1032(a) (General Securities Representative).[10] The Series 6 examination qualifies an individual to function as an Investment Company and Variable Contracts Products Representative.

In consultation with a committee of industry representatives, FINRA recently undertook a review of the Series 6 examination program. As a result of this review, FINRA is proposing to make revisions to the content outline to reflect changes to the laws, rules and regulations covered by the examination and to incorporate the functions and associated tasks currently performed by an Investment Company and Variable Contracts Products Representative. FINRA also is proposing to make changes to the format of the content outline.

Current Outline

The current content outline is divided into six sections. The following are the six sections and the number of questions associated with each of the sections, denoted Section 1 through Section 6:

1. Securities Markets, Investment Securities and Economic Factors, 8 questions;
2. Securities and Tax Regulation, 23 questions;
3. Marketing, Prospecting and Sales Presentation, 18 questions;
4. Evaluation of Customers, 13 questions;
5. Product Information; Investment Company Securities and Variable Contracts, 26 questions; and
6. Opening and Servicing Customer Accounts, 12 questions.

Each section also includes the applicable laws, rules and regulations associated with that section. The current outline also includes a preface (addressing, among other things, the purpose, administration and scoring of the examination), sample questions and reference materials.

Proposed Revisions

FINRA is proposing to divide the content outline into four major job functions that are performed by an Investment Company and Variable Contracts Products Representative. The following are the four major job functions, denoted Function 1 through Function 4, with the associated number of questions:

Function 1: Regulatory fundamentals and business development, 22 questions;

Function 2: Evaluates customers' financial information, identifies investment objectives, provides information on investment products, and makes suitable recommendations, 47 questions;

Function 3: Opens, maintains, transfers and closes accounts and retains appropriate account records, 21 questions; and

Function 4: Obtains, verifies, and confirms customer purchase and sale instructions, 10 questions.

Each function also includes specific tasks describing activities associated with performing that function. There are four tasks (1.1–1.4) associated with Function 1; four tasks (2.1–2.4) associated with Function 2; three tasks (3.1–3.3) associated with Function 3; and two tasks (4.1–4.2) associated with Function 4.[11] By way of example, one such task (Task 2.1) is to gather customers' financial and non-financial information to identify, analyze, and assess risk tolerance, investment experience and sophistication level.[12] Further, the outline lists the knowledge required to perform each function and associated tasks (*e.g.,* account authorizations and legal documents).[13] In addition, where applicable, the outline lists the laws, rules and regulations a candidate is expected to know to perform each function and associated tasks. These include the applicable FINRA Rules (*e.g.,* FINRA Rule 1250), NASD Rules (*e.g.,* NASD

[6] The Commission notes that the revised content outline is attached to the filing as Exhibit 3a, not to this Notice.

[7] 17 CFR 240.24b–2.

[8] 15 U.S.C. 78*o*–3(g)(3).

[9] The current FINRA rulebook consists of (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE (''Incorporated NYSE Rules'') (together, the NASD Rules and Incorporated NYSE Rules are referred to as the ''Transitional Rulebook''). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE (''Dual Members''). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, *see Information Notice,* March 12, 2008 (Rulebook Consolidation Process).

[10] *See also* Incorporated NYSE Rule 345.15(3) and Incorporated NYSE Rule Interpretation 345.15/02.

[11] *See* Exhibit 3a, Outline Pages 6–18.

[12] *See* Exhibit 3a, Outline Page 10.

[13] *See* Exhibit 3a, Outline Page 15.

Rule 1070) and SEC rules (*e.g.,* SEA Rule 17f-2).[14] FINRA conducted a job analysis study of Investment Company and Variable Contracts Products Representatives, which included the use of a survey, in developing each function and associated tasks and updating the required knowledge set forth in the revised outline. The functions and associated tasks, which appear in the revised outline for the first time, reflect the day-to-day activities of an Investment Company and Variable Contracts Products Representative.

As noted above, FINRA also is proposing to revise the content outline to reflect changes to the laws, rules and regulations covered by the examination. Among other revisions, FINRA is proposing to revise the content outline to reflect the adoption of rules in the consolidated FINRA rulebook (*e.g.,* NASD Rule 2310 (Recommendations to Customers (Suitability)) and NASD Rule 3110 (Books and Records) were adopted as FINRA Rule 2111 (Suitability) and FINRA Rule 4510 Series (Books and Records), respectively).[15]

FINRA is proposing similar changes to the Series 6 selection specifications and question bank.

Finally, FINRA is proposing to make changes to the format of the content outline, including the preface, sample questions and reference materials. Among other changes, FINRA is proposing to: (1) Add a table of contents;[16] (2) provide more details regarding the purpose of the examination;[17] (3) provide more details on the application procedures;[18] (4) provide more details on the development and maintenance of the content outline and examination;[19] (5) explain that the passing scores are established by FINRA staff, in consultation with a committee of industry representatives, using a standard setting procedure and that the scores are an absolute standard independent of the performance of candidates taking the examination;[20] and (6) note that each candidate will receive a score report at the end of the test session, which will indicate a pass or fail status and include a score profile listing the candidate's performance on each major content area covered on the examination.[21]

The number of questions on the Series 6 examination will remain at 100 multiple-choice questions,[22] and candidates will continue to have 135 minutes to complete the examination. Currently, a score of 70 percent is required to pass the examination. The passing score will remain the same.

Availability of Content Outlines

The current Series 6 content outline is available on FINRA's Web site, at www.finra.org/brokerqualifications/exams. The revised Series 6 content outline will replace the current content outline on FINRA's Web site.

FINRA is filing the proposed rule change for immediate effectiveness. FINRA proposes to implement the revised Series 6 examination program on December 16, 2013. FINRA will announce the proposed rule change and the implementation date in a Regulatory Notice.

2. Statutory Basis

FINRA believes that the proposed revisions to the Series 6 examination program are consistent with the provisions of Section 15A(b)(6) of the Act,[23] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, and Section 15A(g)(3) of the Act,[24] which authorizes FINRA to prescribe standards of training, experience, and competence for persons associated with FINRA members. FINRA believes that the proposed revisions will further these purposes by updating the examination program to reflect changes to the laws, rules and regulations covered by the examination and to incorporate the functions and associated tasks currently performed by an Investment Company and Variable Contracts Products Representative.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The updated examination aligns with the functions and associated tasks currently performed by an Investment Company and Variable Contracts Products Representative and tests knowledge of the most current laws, rules, regulations and skills relevant to those functions and associated tasks. As such, the proposed revisions would make the examination more efficient and effective.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[25] and paragraph (f)(1) of Rule 19b–4 thereunder.[26] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2013–045 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2013–045. This file

[14] *See* Exhibit 3a, Outline Pages 6–7.

[15] *See* Rule Conversion Chart, available at *http://www.finra.org/Industry/Regulation/FINRARules/p085560.*

[16] *See* Exhibit 3a, Outline Page 2.

[17] *See* Exhibit 3a, Outline Page 3.

[18] *See* Exhibit 3a, Outline Page 3.

[19] *See* Exhibit 3a, Outline Page 4.

[20] *See* Exhibit 3a, Outline Page 5.

[21] *See* Exhibit 3a, Outline Page 5.

[22] Consistent with FINRA's practice of including ''pre-test'' questions on certain qualification examinations, which is designed to ensure that new examination questions meet acceptable testing standards prior to use for scoring purposes, the examination includes five additional, unidentified pre-test questions that do not contribute towards the candidate's score. Therefore, the examination actually consists of 105 questions, 100 of which are scored. The five pre-test questions are randomly distributed throughout the examination.

[23] 15 U.S.C. 78*o*–3(b)(6).

[24] 15 U.S.C. 78*o*–3(g)(3).

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(1).

number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2013–045 and should be submitted on or before November 19, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–25443 Filed 10–28–13; 8:45 am]

BILLING CODE 8011–01–P

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–70748; File No. SR–Phlx–2013–105]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish for PHLX Orders Managed Data Solution Fees for Non-Display Usage

October 23, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder[2] notice is hereby given that on October 16, 2013, NASDAQ OMX PHLX LLC (''PHLX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

PHLX proposes to establish for PHLX orders (''PHLX Orders'') Managed Data Solution fees for non-display usage (''Non-Display Usage''), and to establish that Managed Data Solutions containing Top of PHLX Options (also known as ''TOPO'') are for non-display usage.

While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on November 1, 2013.

The text of the proposed rule change is available at *http://nasdaqomxphlx.cchwallstreet.com/nasdaqomxphlx/phlx/*, at Phlx's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

PHLX is proposing to create a new data distribution model (a Managed Data Solution for Non-Display Usage) to further the distribution of the PHLX Orders datafeed. PHLX is also proposing to establish that Managed Data Solutions containing Top of PHLX Options are for non-display usage. The proposed Managed Data Solution for non-display usage is similar to data distribution models currently in use and aligns PHLX with other markets in the NASDAQ OMX Group.[3]

The Managed Data Solution proposal offers a delivery method to firms seeking simplified market data administration. The Managed Data Solution for Non-Display Usage may be offered by Distributors externally distributing data to clients and/or client organizations that are using the PHLX Orders information internally for Non-Display Usage. This new pricing and administrative option is in response to industry demand, as well as due to changes in the technology used to distribute market data. As such, rather than substantive changes the proposal reflects current data distribution practices in the industry. Distributors offering Managed Data Solutions for Non-Display Usage continue to be fee liable for the applicable distributor fees for the receipt and distribution of PHLX Orders data.

This Managed Data Solution for Non-Display Usage is a delivery option that will assess a new, innovative fee schedule to Distributors of PHLX Orders that provide data feed solutions such as an Application Programming Interface (API) or similar automated delivery solutions to Recipients for Non-Display Usage with only limited entitlement controls (*e.g.,* usernames and/or passwords) (''Managed Data Recipients''). However, the Distributor must first agree to reformat, redisplay and/or alter the PHLX Orders data prior to retransmission, but not to affect the integrity of the PHLX Orders data and not to render it inaccurate, unfair, uninformative, fictitious, misleading, or discriminatory. A Managed Data Solution for Non-Display Usage is any retransmission data product containing PHLX Orders offered by a Distributor where the Distributor manages and monitors, but does not control, the information. However, the Distributor does maintain contracts with the Managed Data Recipients and is liable for any unauthorized use by the Managed Data Recipients under a Managed Data Solution. The Recipient of a Managed Data Solution may use the information for internal Non-Display purposes only and may not distribute the information outside of their organization.

[3] *See* Securities Exchange Act Release Nos. 70269 (August 27, 2013), 78 FR 54336 (September 3, 2013) (SR–NASDAQ–2013–106) (notice of filing and immediate effectiveness of proposed rule change to establish non-display Managed Data Solution for equities on NASDAQ); and 69182 (March 19, 2013), 78 FR 18378 (March 26, 2013) (SR–Phlx–2013–28) (notice of filing and immediate effectiveness of proposed rule change to establish non-display Managed Data Solution for Phlx equities market PSX). *See also* Securities Exchange Act Release No. 69041 (March 5, 2013), 78 FR 15791 (March 12, 2013) (SR–BX–2013–018) (notice of filing and immediate effectiveness of proposed rule change to establish Managed Data Solution for BX).

Currently, the Exchange does not distinguish between Managed Data Solution Recipients and a recipient of an uncontrolled data product. Some Distributors believe that the Managed Data Solution for Non-Display Usage is a viable alternative to an uncontrolled data product. Some Distributors have even delayed deploying new PHLX Orders offerings, pending the initiation of Managed Data Solutions for Non-Display Usage. Thus, offering a Managed Data Solution fee schedule would not only result in PHLX offering lower fees for existing Managed Data Recipients utilizing a Managed Data Solution, but will allow new Distributors to deliver Managed Data Solutions to new clients, thereby increasing transparency of the market.

PHLX proposes to establish two fees for Distributors that adopt the Managed Data Solution for Non-Display Usage to Distributors, a monthly Managed Data Solution Administration fee of $2,000 and a monthly Subscriber fee of $500.[4] The proposed monthly License fee would be in addition to the monthly Distributor fee of $3,500 (for external usage) currently set forth in Section IX of the PHLX Pricing Schedule, and the $500 monthly Subscriber fee would be assessed for each Subscriber of a Managed Data Solution. PHLX proposes to establish that Managed Data Solution for Top of PHLX is for non-display usage only,[5] as is done on other markets. The Exchange believes that the proposal is in line with current market practice.

2. Statutory Basis

PHLX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[6] in general, and with Section 6(b)(4) of the Act,[7] in particular, in that it provides an equitable allocation of reasonable fees among Subscribers and Recipients of PHLX data. In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers (''BDs'') increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

The Commission concluded that Regulation NMS—by lessening the regulation of the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[8]

By removing ''unnecessary regulatory restrictions'' on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to BDs at all, it follows that the price at which such data is sold should be set by the market as well.

The decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoaliton* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010) (''*NetCoalition I*''), upheld the Commission's reliance upon competitive markets to set reasonable and equitably allocated fees for market data. ''In fact, the legislative history indicates that the Congress intended that the market system 'evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed' and that the SEC wield its regulatory power 'in those situations where competition may not be sufficient,' such as in the creation of a 'consolidated transactional reporting system.' *NetCoaltion I,* at 535 (quoting H.R. Rep. No. 94–229, at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 321, 323). The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' ''[9]

The court in *NetCoalition I,* while upholding the Commission's conclusion that competitive forces may be relied upon to establish the fairness of prices, nevertheless concluded that the record *in that case* did not adequately support the Commission's conclusions as to the competitive nature of the market for NYSE Arca's data product at issue in that case. As explained below in PHLX's Statement on Burden on Competition, however, PHLX believes that there is substantial evidence of competition in the marketplace for data that was not in the record in the *NetCoalition I* case, and that the Commission is entitled to rely upon such evidence in concluding that the fees established in this filing are the product of competition, and therefore in accordance with the relevant statutory standards.[10] Moreover, PHLX further notes that the product at issue in this filing—PHLX Orders Managed Data Solution fees—is quite different from the NYSE Arca depth-of-book data product at issue in *NetCoalition I.* Accordingly, any findings of the court with respect to that product may not be relevant to the product at issue in this filing.

B. Self-Regulatory Organization's Statement on Burden on Competition

PHLX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. PHLX's ability to price its PHLX Orders Managed Data Solution fees is constrained by (1) competition between exchanges and other trading platforms that compete with each other in a variety of dimensions; (2) the existence of inexpensive real-time consolidated data and market-specific data and free delayed consolidated data; and (3) the inherent contestability of the market for this data.

The market for proprietary data products is currently competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data and strict pricing discipline for the proprietary products themselves. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. This proprietary data is produced by each individual exchange, as well as other entities, in a vigorously competitive market.

[4] Without a Managed Data Solution as proposed herein, the current fee for internal distribution that is not a Managed Data Solution but rather an uncontrolled PHLX Orders data product with a distributor fee of $3,000 per month would apply (along with a $40 professional subscriber fee). Per the proposal for the Managed Data Solution, on the other hand, the managed data recipient fee for non-display internal use of PHLX Orders managed data would be $500 per subscriber, thereby providing a reduced cost option where the data is for non-distribution only.

[5] The Exchange believes that most firms currently use TOPO in non-display format.

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[9] *NetCoalition I,* at 535.

[10] It should also be noted that Section 916 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act'') has amended paragraph (A) of Section 19(b)(3) of the Act, 15 U.S.C. 78s(b)(3), to make it clear that all exchange fees, including fees for market data, may be filed by exchanges on an immediately effective basis.

Transaction execution and proprietary data products are complementary in that market data is both an input and a byproduct of the execution service. In fact, market data and trade execution are a paradigmatic example of joint products with joint costs. The decision whether and on which platform to post an order will depend on the attributes of the platform where the order can be posted, including the execution fees, data quality and price and distribution of its data products. Without trade executions, exchange data products cannot exist. Moreover, data products are valuable to many end users only insofar as they provide information that end users expect will assist them or their customers in making trading decisions.

The costs of producing market data include not only the costs of the data distribution infrastructure, but also the costs of designing, maintaining, and operating the exchange's transaction execution platform and the cost of regulating the exchange to ensure its fair operation and maintain investor confidence. The total return that a trading platform earns reflects the revenues it receives from both products and the joint costs it incurs. Moreover, the operation of the exchange is characterized by high fixed costs and low marginal costs. This cost structure is common in content and content distribution industries such as software, where developing new software typically requires a large initial investment (and continuing large investments to upgrade the software), but once the software is developed, the incremental cost of providing that software to an additional user is typically small, or even zero (*e.g.,* if the software can be downloaded over the internet after being purchased).[11] In PHLX's case, it is costly to build and maintain a trading platform, but the incremental cost of trading each additional share on an existing platform, or distributing an additional instance of data, is very low. Market information and executions are each produced jointly (in the sense that the activities of trading and placing orders are *the* source of the information that is distributed) and are each subject to significant scale economies. In such cases, marginal cost pricing is not feasible because if all sales were priced at the margin, PHLX would be unable to defray its platform costs of providing the joint products.

An exchange's BD customers view the costs of transaction executions and of data as a unified cost of doing business with the exchange. A BD will direct orders to a particular exchange only if the expected revenues from executing trades on the exchange exceed net transaction execution costs and the cost of data that the BD chooses to buy to support its trading decisions (or those of its customers). The choice of data products is, in turn, a product of the value of the products in making profitable trading decisions. If the cost of the product exceeds its expected value, the BD will choose not to buy it. Moreover, as a BD chooses to direct fewer orders to a particular exchange, the value of the product to that BD decreases, for two reasons. First, the product will contain less information, because executions of the BD's trading activity will not be reflected in it. Second, and perhaps more important, the product will be less valuable to that BD because it does not provide information about the venue to which it is directing its orders. Data from the competing venue to which the BD is directing orders will become correspondingly more valuable.

Similarly, in the case of products such as this that are distributed through market data vendors, the vendors provide price discipline for proprietary data products because they control the primary means of access to end users. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end users will not purchase in sufficient numbers. Internet portals, such as Google, impose a discipline by providing only data that will enable them to attract ''eyeballs'' that contribute to their advertising revenue. Retail BDs, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: They can simply refuse to purchase any proprietary data product that fails to provide sufficient value. PHLX and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully. Moreover, PHLX believes that products such as this can enhance order flow to PHLX, thereby encouraging wider participation in the market by investors with access to the Internet or television. Conversely, the value of such products to distributors and investors decreases if order flow falls, because the products contain less content.

Analyzing the cost of market data distribution in isolation from the cost of all of the inputs supporting the creation of market data will inevitably underestimate the cost of the data. Thus, because it is impossible to create data without a fast, technologically robust, and well-regulated execution system, system costs and regulatory costs affect the price of market data. It would be equally misleading, however, to attribute all of the exchange's costs to the market data portion of an exchange's joint product. Rather, all of the exchange's costs are incurred for the unified purposes of attracting order flow, executing and/or routing orders, and generating and selling data about market activity. The total return that an exchange earns reflects the revenues it receives from the joint products and the total costs of the joint products.

Competition among trading platforms can be expected to constrain the aggregate return each platform earns from the sale of its joint products, but different platforms may choose from a range of possible, and equally reasonable, pricing strategies as the means of recovering total costs. For example, some platforms may choose to pay rebates to attract orders, charge relatively low prices for market information (or provide information free of charge) and charge relatively high prices for accessing posted liquidity. Other platforms may choose a strategy of paying lower liquidity rebates to attract orders, setting relatively low prices for accessing posted liquidity and setting relatively high prices for market information. Still others may provide most data free of charge and rely exclusively on transaction fees to recover their costs. Finally, some platforms may incentivize use by providing opportunities for equity ownership, which may allow them to charge lower direct fees for executions and data.

In this environment, there is no economic basis for regulating maximum prices for one of the joint products in an industry in which suppliers face competitive constraints with regard to the joint offering. Such regulation is unnecessary because an ''excessive'' price for one of the joint products will ultimately have to be reflected in lower prices for other products sold by the firm, or otherwise the firm will experience a loss in the volume of its sales that will be adverse to its overall profitability. In other words, an increase

[11] *See* William J. Baumol and Daniel G. Swanson, ''The New Economy and Ubiquitous Competitive Price Discrimination: Identifying Defensible Criteria of Market Power,'' *Antitrust Law Journal,* Vol. 70, No. 3 (2003).

in the price of data will ultimately have to be accompanied by a decrease in the cost of executions, or the volume of both data and executions will fall.

The level of competition and contestability in the market is evident in the numerous alternative venues that compete for order flow, including thirteen SRO markets, as well as internalizing BDs and various forms of alternative trading systems (''ATSs''), including dark pools and electronic communication networks (ECNs''). Each SRO market competes to produce transaction reports via trade executions, and two FINRA-regulated TRFs compete to attract internalized transaction reports. It is common for BDs to further and exploit this competition by sending their order flow and transaction reports to multiple markets, rather than providing them all to a single market. Competitive markets for order flow, executions, and transaction reports provide pricing discipline for the inputs of proprietary data products.

The large number of SROs, TRFs, BDs, and ATSs that currently produce proprietary data or are currently capable of producing it provides further pricing discipline for proprietary data products. Each SRO, TRF, ATS, and BD is currently permitted to produce proprietary data products, and many currently do or have announced plans to do so, including NASDAQ, NYSE, NYSE MKT, NYSE Arca, BATS, and Direct Edge.

Any ATS or BD can combine with any other ATS, BD, or multiple ATSs or BDs to produce joint proprietary data products. Additionally, order routers and market data vendors can facilitate single or multiple BD' production of proprietary data products. The potential sources of proprietary products are virtually limitless.

Market data vendors provide another form of price discipline for proprietary data products because they control the primary means of access to end Subscribers. Vendors impose price restraints based upon their business models. For example, vendors such as Bloomberg and Thomson Reuters that assess a surcharge on data they sell may refuse to offer proprietary products that end Subscribers will not purchase in sufficient numbers. Internet portals, such as Google, impose a discipline by providing only data that will enable them to attract ''eyeballs'' that contribute to their advertising revenue. Retail broker-dealers, such as Schwab and Fidelity, offer their customers proprietary data only if it promotes trading and generates sufficient commission revenue. Although the business models may differ, these vendors' pricing discipline is the same: they can simply refuse to purchase any proprietary data product that fails to provide sufficient value. PHLX and other producers of proprietary data products must understand and respond to these varying business models and pricing disciplines in order to market proprietary data products successfully.

In addition to the competition and price discipline described above, the market for proprietary data products is also highly contestable because market entry is rapid, inexpensive, and profitable. The history of electronic trading is replete with examples of entrants that swiftly grew into some of the largest electronic trading platforms and proprietary data producers: Archipelago, Bloomberg Tradebook, Island, RediBook, Attain, TracECN, BATS Trading and Direct Edge. A proliferation of dark pools and other ATSs operate profitably with fragmentary shares of consolidated market volume.

Regulation NMS, by deregulating the market for proprietary data, has increased the contestability of that market. While BDs have previously published their proprietary data individually, Regulation NMS encourages market data vendors and BDs to produce proprietary products cooperatively in a manner never before possible. Multiple market data vendors already have the capability to aggregate data and disseminate it on a profitable scale, including Bloomberg, and Thomson Reuters.

Competition among platforms has driven PHLX continually to improve its platform data offerings and to cater to customers' data needs. For example, PHLX has developed and maintained multiple delivery mechanisms (IP, multi-cast, and compression) that enable customers to receive data in the form and manner they prefer and at the lowest cost to them. PHLX has created new products like Depth Data, TOPO and TOPO Plus Orders, because offering data in multiple formatting allows PHLX to better fit customer needs. PHLX offers data via multiple extranet providers, thereby helping to reduce network and total cost for its data products. PHLX has developed an online administrative system to provide customers transparency into their datafeed requests and streamline data usage reporting.

Despite these enhancements and a dramatic increase in message traffic, PHLX's fees for market data have remained flat. In fact, as a percent of total Subscriber costs, PHLX data fees have fallen relative to other data usage costs—including bandwidth, programming, and infrastructure—that have risen. The same holds true for execution services; despite numerous enhancements to PHLX's trading platform, absolute and relative trading costs have declined. Platform competition has intensified as new entrants have emerged, constraining prices for both executions and for data.

The vigor of competition for proprietary information is significant and the Exchange believes that this proposal itself clearly evidences such competition. PHLX is offering a new pricing model in order to keep pace with changes in the industry and evolving customer needs. It is entirely optional and is geared towards attracting new customers, as well as retaining existing customers.

The Exchange has witnessed competitors creating new products and innovative pricing in this space over the course of the past year. PHLX continues to see firms challenge its pricing on the basis of the Exchange's explicit fees being higher than the zero-priced fees from other competitors such as BATS. In all cases, firms make decisions on how much and what types of data to consume on the basis of the total cost of interacting with PHLX or other exchanges. Of course, the explicit data fees are but one factor in a total platform analysis. Some competitors have lower transactions fees and higher data fees, and others are vice versa. The market for this proprietary information is highly competitive and continually evolves as products develop and change.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[12] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine

[12] 15 U.S.C. 78s(b)(3)(a)(ii).

whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comment

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2013–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2013–105. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2013–105, and should be submitted on or before November 19, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–25571 Filed 10–28–13; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13781 and #13782]

Colorado Disaster Number CO–00066

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Colorado (FEMA–4145–DR), dated 09/24/2013.

Incident: Severe storms, flooding, landslides, and mudslides.

Incident Period: 09/11/2013 through 09/30/2013.

Effective Date: 10/21/2013.

Physical Loan Application Deadline Date: 11/25/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 06/24/2014.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of COLORADO, dated 09/24/2013, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Arapahoe; Crowley; Denver; Fremont; Gilpin; Lake; Lincoln; Sedgwick.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013–25457 Filed 10–28–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13768 and #13769]

Colorado Disaster Number CO–00065

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 4.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Colorado (FEMA–4145–DR), dated 09/14/2013.

Incident: Severe Storms, Flooding, Landslides, and Mudslides.

Incident Period: 09/11/2013 through 09/30/2013.

Effective Date: 10/21/2013.

Physical Loan Application Deadline Date: 11/14/2013.

EIDL Loan Application Deadline Date: 06/16/2014.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of Colorado, dated 09/14/2013 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Fremont, Morgan.

Contiguous Counties: (Economic Injury Loans Only):

Colorado: Chaffee, Custer, Saguache.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013–25456 Filed 10–28–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

U.S. Small Business Development Center Advisory Board

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal Advisory Committee meetings.

SUMMARY: The SBA is issuing this notice to announce the location, date, time and agenda for the 1st quarter meetings of

the National Small Business Development Center (SBDC) Advisory Board.

DATES: The meetings for the 1st quarter will be held on the following dates: Tuesday, October 29, 2013 at 1:00 p.m. EST; Tuesday, November 19, 2013 at 1:00 p.m. EST; Tuesday, December 17, 2013 at 1:00 p.m. EST.

ADDRESSES: These meetings will be held via conference call.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2), SBA announces the meetings of the National SBDC Advisory Board. This Board provides advice and counsel to the SBA Administrator and Associate Administrator for Small Business Development Centers.

The purpose of these meetings is to discuss following issues pertaining to the SBDC Advisory Board:

—SBA Update
—Annual Meetings
—Board Assignments
—Member Roundtable

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public however advance notice of attendance is requested. Anyone wishing to be a listening participant must contact Monika Cuff by fax or email. Her contact information is Monika Cuff, Program Specialist, 409 Third Street SW., Washington, DC 20416, Phone, 202–205–7310, Fax 202–481–5624, email, *monika.cuff@sba.gov.*

Additionally, if you need accommodations because of a disability or require additional information, please contact Monika Cuff at the information above.

Diana Doukas,

Committee Management Officer.

[FR Doc. 2013–24996 Filed 10–28–13; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 8506]

60-Day Notice of Proposed Information Collection: Form DS–3057, Medical Clearance Update

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to December 30, 2013.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the Internet may use the Federal Docket Management System (FDMS) to comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Public Notice 8506'' in the Search bar. If necessary, use the Narrow by Agency filter option on the Results page.
- *Email: summerssb@state.gov.*
- *Mail:* Department of State, Office of Medical Clearances, SA–15 Room 400, 1800 North Kent St., Rosslyn, VA 22209.
- *Fax:* 703–875–4850.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Susan B. Summers, who may be reached on 703–875–5411 or at *summerssb@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Medical Clearance Update.
- *OMB Control Number:* 1405–0131.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Office of Medical Services—Medical Clearances.
- *Form Number:* DS 3057.
- *Respondents:* Foreign service officers, federal employees, or family members.
- *Estimated Number of Respondents:* 16,280.
- *Estimated Number of Responses:* 16,280.
- *Average Time Per Response:* 30 minutes.
- *Total Estimated Burden Time:* 8,140 hours.
- *Frequency:* As needed.
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection:

Form DS–3057 is designed to collect medical information to provide medical providers with current and adequate information to base decisions on whether a federal employee and family members will have sufficient medical resources at a diplomatic mission abroad to maintain the health and fitness of the individual and family members.

Methodology:

The information collected will be collected through the use of an electronic forms engine or by hand written submission using a pre-printed form.

Dated: October 16, 2013.

Ernest E. Davis,

Director of Medical Clearances, Office of Medical Services, Department of State.

[FR Doc. 2013–25619 Filed 10–28–13; 8:45 am]

BILLING CODE 4710–02–P

STATE JUSTICE INSTITUTE

Grant Guideline, Notice

AGENCY: State Justice Institute.

ACTION: Grant Guideline for FY 2014.

SUMMARY: This Guideline sets forth the administrative, programmatic, and financial requirements attendant to Fiscal Year 2014 State Justice Institute grants, cooperative agreements, and contracts.

DATE: October 29, 2013.

FOR FURTHER INFORMATION CONTACT: Jonathan Mattiello, Executive Director, State Justice Institute, 11951 Freedom Drive, Suite 1020, Reston, VA 20190, 571–313–8843, *jonathan.mattiello@sji.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the State Justice Institute Act of 1984 (42 U.S.C. 10701, et seq.), SJI is authorized to award grants, cooperative agreements, and contracts to state and local courts, nonprofit organizations, and others for the purpose of improving

the quality of justice in the state courts of the United States.

The following Grant Guideline is adopted by the State Justice Institute for FY 2014.

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I. The Mission of the State Justice Institute

SJI was established by State Justice Institute Authorization Act of 1984 (42 U.S.C. 10701 et seq.) to improve the administration of justice in the state courts of the United States. Incorporated in the State of Virginia as a private, nonprofit corporation, SJI is charged, by statute, with the responsibility to:

- Direct a national program of financial assistance designed to assure that each citizen of the United States is provided ready access to a fair and effective system of justice;
- Foster coordination and cooperation with the federal judiciary;
- Promote recognition of the importance of the separation of powers doctrine to an independent judiciary; and
- Encourage education for judges and support personnel of state court systems through national and state organizations.

To accomplish these broad objectives, SJI is authorized to provide funding to state courts, national organizations which support and are supported by state courts, national judicial education organizations, and other organizations that can assist in improving the quality of justice in the state courts. SJI is supervised by a Board of Directors appointed by the President, with the advice and consent of the Senate. The Board is statutorily composed of six judges; a state court administrator; and four members of the public, no more than two of the same political party.

Through the award of grants, contracts, and cooperative agreements, SJI is authorized to perform the following activities:

A. Support technical assistance, demonstrations, special projects, research and training to improve the administration of justice in the state courts;

B. Provide for the preparation, publication, and dissemination of information regarding state judicial systems;

C. Participate in joint projects with federal agencies and other private grantors;

D. Evaluate or provide for the evaluation of programs and projects to determine their impact upon the quality of criminal, civil, and juvenile justice and the extent to which they have contributed to improving the quality of justice in the state courts;

E. Encourage and assist in furthering judicial education; and,

F. Encourage, assist, and serve in a consulting capacity to state and local justice system agencies in the development, maintenance, and coordination of criminal, civil, and juvenile justice programs and services.

II. Eligibility for Award

SJI is authorized by Congress to award grants, cooperative agreements, and contracts to the following entities and types of organizations:

A. *State and local courts and their agencies (42 U.S.C. 10705(b)(1)(A)).*

B. *National nonprofit organizations controlled by, operating in conjunction with, and serving the judicial branches of state governments (42 U.S.C. 10705(b)(1)(B)).*

C. *National nonprofit organizations for the education and training of judges and support personnel of the judicial branch of state governments (42 U.S.C. 10705(b)(1)(C)).* An applicant is considered a national education and training applicant under section 10705(b)(1)(C) if:

1. The principal purpose or activity of the applicant is to provide education and training to state and local judges and court personnel; and

2. The applicant demonstrates a record of substantial experience in the field of judicial education and training.

D. *Other eligible grant recipients (42 U.S.C. 10705(b)(2)(A)–(D)).*

1. Provided that the objectives of the project can be served better, the Institute is also authorized to make awards to:

a. Nonprofit organizations with expertise in judicial administration;

b. Institutions of higher education;

c. Individuals, partnerships, firms, corporations (for-profit organizations must waive their fees); and

d. Private agencies with expertise in judicial administration.

2. SJI may also make awards to state or local agencies and institutions other than courts for services that cannot be adequately provided through nongovernmental arrangements (42 U.S.C. 10705(b)(3)).

E. *Inter-agency Agreements.* SJI may enter into inter-agency agreements with federal agencies (42 U.S.C. 10705(b)(4)) and private funders to support projects consistent with the purposes of the State Justice Institute Act.

SJI is prohibited from awarding grants to federal, tribal, and international courts.

III. Scope of the Program

SJI is offering six types of grants in FY 2014: Project Grants, Technical Assistance (TA) Grants, Curriculum Adaptation and Training (CAT) Grants, Partner Grants, Strategic Initiatives Grants (SIG) Program, and the Education Support Program (ESP).

The SJI Board of Directors has established Priority Investment Areas for grant funding. SJI will allocate significant financial resources through grant-making for these Priority Investment Areas (in no ranking order):

- Language Access and the State Courts—e.g., interpretation service plans, remote interpretation (outside the courtroom), interpreter certification, courtroom services (plain language forms, Web sites, etc.).
- Self-Represented Litigation—e.g., court-operated self-help centers, online services, training.
- Reengineering in Response to Budget Reductions—e.g., the process of court reengineering, regionalization or centralization of services, structural changes, the electronic record.
- Remote Technology—e.g., innovative use of technology to improve the business operations of courts and provide enhanced services outside the courtroom.
- Human Trafficking and the State Courts—e.g., technical assistance/training, trafficking victim identification and assistance.
- Immigration Issues and the State Courts—e.g., impact of federal and state immigration law and policies, juvenile and family issues, technical assistance/training.
- Guardianship, Conservatorship, and Elder Issues—e.g., court visitor programs, electronic reporting, reports, technical assistance/training.

A. Project Grants

Project Grants are intended to support innovative education and training, research and evaluation, demonstration, and technical assistance projects that can improve the administration of justice in state courts locally or nationwide. Project Grants may ordinarily not exceed $300,000. Examples of expenses not covered by Project Grants include the salaries, benefits, or travel of full- or part-time court employees. Grant periods for Project Grants ordinarily may not exceed 36 months.

Applicants for Project Grants will be required to contribute a cash match of not less than 50 percent of the total cost of the proposed project. In other words, grant awards by SJI must be matched at least dollar for dollar by grant applicants. Applicants may contribute the required cash match directly or in cooperation with third parties. Prospective applicants should carefully review Section VI.8. (matching requirements) and Section VI.16.a. (non-supplantation) of the Guideline prior to beginning the application process. Funding from other federal departments or agencies may not be used for cash match. If questions arise, applicants are strongly encouraged to consult SJI.

A temporary reduced cash match process is available for state courts submitting Project Grant applications. The use of this cash match reduction authority is intended to help the state courts in this climate of severe budget reductions. The process requires the state court to formally request a reduced cash match, and that the request be certified by the chief justice of that state. The state court must explain in detail how it is facing budgetary cutbacks that will result in significant reductions in other services, and why it will be unable to undertake the project without a cash match reduction. This must be described in detail in the application and verified by the chief justice of that state. Only state courts may apply for a cash match reduction.

Applicants should examine their projected project costs closely, and if they are unable to cover half the costs of the project, they may apply for a reduction in cash match. Applicants are strongly encouraged to provide as much cash match as possible in their application, as some cash match contribution is still required.

Applicants are also encouraged to provide the percentage of budget reductions in their court(s), and the measures that have been taken by the jurisdiction/state to handle the budget shortfalls. This may include staff reductions, as well as reductions in services and programs. Some cash contribution is still required for Project Grants, and should be reflected in the budget proposal for the project. For example, if the total cost of the proposed project is $100,000, the normal cash match would be $50,000. However, if the applicant is unable to provide $50,000 for the activities, but is able to contribute $25,000, the budget should show the request to SJI totaling $75,000, with the cash match of $25,000.

As set forth in Section I., SJI is authorized to fund projects addressing a broad range of program areas. Funding will not be made available for the ordinary, routine operations of court systems.

B. Technical Assistance (TA) Grants

TA Grants are intended to provide state or local courts, or regional court associations, with sufficient support to obtain expert assistance to diagnose a problem, develop a response to that problem, and implement any needed changes. TA Grants may not exceed $50,000. Examples of expenses not covered by TA Grants include the salaries, benefits, or travel of full- or part-time court employees. Grant periods for TA Grants ordinarily may not exceed 24 months. In calculating project duration, applicants are cautioned to fully consider the time required to issue a request for proposals, negotiate a contract with the selected provider, and execute the project.

Applicants for TA Grants will be required to contribute a *total* match of not less than 50 percent of the grant amount requested, of which 20 percent must be cash. In other words, an applicant seeking a $50,000 TA grant must provide a $25,000 match, of which up to $20,000 can be in-kind and not less than $5,000 must be cash. Funding from other federal departments and agencies may not be used for cash match. TA Grant application procedures can be found in section IV.B.

C. Curriculum Adaptation and Training (CAT) Grants

CAT Grants are intended to: (1) Enable courts and regional or national court associations to modify and adapt model curricula, course modules, or conference programs to meet states' or local jurisdictions' educational needs; train instructors to present portions or all of the curricula; and pilot-test them to determine their appropriateness, quality, and effectiveness, or (2) conduct judicial branch education and training programs, led by either expert or in-house personnel, designed to prepare judges and court personnel for innovations, reforms, and/or new technologies recently adopted by grantee courts. CAT Grants may not exceed $30,000. Examples of expenses not covered by CAT Grants include the salaries, benefits, or travel of full- or part-time court employees. Grant periods for CAT Grants ordinarily may not exceed 12 months.

Applicants for CAT Grants will be required to contribute a match of not less than 50 percent of the grant amount requested, of which 20 percent must be cash. In other words, an applicant seeking a $30,000 CAT grant must provide a $15,000 match, of which up to $12,000 can be in-kind and not less than $3,000 must be cash. Funding from other federal departments and agencies may not be used for cash match. CAT Grant application procedures can be found in section IV.C.

D. Partner Grants

Partner Grants are intended to allow SJI and federal, state, or local agencies or foundations, trusts, or other private entities to combine financial resources in pursuit of common interests. SJI and its financial partners may set any level for Partner Grants, subject to the entire amount of the grant being available at the time of the award. Grant periods for Partner Grants ordinarily may not exceed 36 months.

Partner Grants are subject to the same cash match requirement as Project Grants. In other words, grant awards by SJI must be matched at least dollar-for-dollar. Partner Grants are initiated and coordinated by the funding organizations. More information on Partner Grants can be found in section IV.D.

E. Strategic Initiatives Grants

The Strategic Initiatives Grants (SIG) program provides SJI with the flexibility to address national court issues as they occur, and develop solutions to those problems. This is an innovative approach where SJI uses its expertise and the expertise and knowledge of its grantees to address key issues facing state courts across the United States.

The funding is used for grants or contractual services, and any remaining balance not used for the SIG program will become available for SJI's other grant programs. The program is handled at the discretion of the SJI Board of Directors and staff outside the normal grant application process (i.e., SJI will initiate the project).

F. Education Support Program (ESP) for Judges and Court Managers

The Education Support Program (ESP) is intended to enhance the skills, knowledge, and abilities of state court judges and court managers by enabling them to attend out-of-state, or to enroll in online, educational and training programs sponsored by national and state providers that they could not otherwise attend or take online because of limited state, local, and personal budgets. An ESP award only covers the cost of tuition up to a maximum of $1,000 per award. ESP application procedures can be found in section IV.E.

IV. Grant Applications

A. Project Grants

An application for a Project Grant must include an application form; budget forms (with appropriate documentation); a project abstract and program narrative; a disclosure of lobbying form, when applicable; and certain certifications and assurances (see below). See *www.sji.gov/forms* for Project Grant application forms.

1. Forms

a. Application Form (Form A)

The application form requests basic information regarding the proposed project, the applicant, and the total amount of funding requested from SJI. It also requires the signature of an individual authorized to certify on behalf of the applicant that the information contained in the application is true and complete; that submission of the application has been authorized by the applicant; and that if funding for the proposed project is approved, the applicant will comply with the requirements and conditions of the award, including the assurances set forth in Form D.

b. Certificate of State Approval (Form B)

An application from a state or local court must include a copy of Form B signed by the state's chief justice or state court administrator. The signature denotes that the proposed project has been approved by the state's highest court or the agency or council it has designated. It denotes further that, if applicable, a cash match reduction has been requested, and that if SJI approves funding for the project, the court or the specified designee will receive, administer, and be accountable for the awarded funds.

c. Budget Form (Form C)

Applicants must submit a Form C. In addition, applicants must provide a detailed budget narrative providing an explanation of the basis for the estimates in each budget category (see subsection A.4. below).

If funds from other sources are required to conduct the project, either as match or to support other aspects of the project, the source, current status of the request, and anticipated decision date must be provided.

d. Assurances (Form D)

This form lists the statutory, regulatory, and policy requirements with which recipients of Institute funds must comply.

e. Disclosure of Lobbying Activities (Form E)

Applicants other than units of state or local government are required to disclose whether they, or another entity that is part of the same organization as the applicant, have advocated a position before Congress on any issue, and to identify the specific subjects of their lobbying efforts (see section VI.A.7.).

2. Project Abstract

The abstract should highlight the purposes, goals, methods, and anticipated benefits of the proposed project. It should not exceed 1 single-spaced page.

3. Program Narrative

The program narrative for an application may not exceed 25 double-spaced pages. The pages should be numbered. This page limit does not include the forms, the abstract, the budget narrative, and any appendices containing resumes and letters of cooperation or endorsement. Additional background material should be attached only if it is essential to impart a clear understanding of the proposed project. Numerous and lengthy appendices are strongly discouraged.

The program narrative should address the following topics:

a. Project Objectives

The applicant should include a clear, concise statement of what the proposed project is intended to accomplish. In stating the objectives of the project, applicants should focus on the overall programmatic objective (e.g., to enhance understanding and skills regarding a specific subject, or to determine how a certain procedure affects the court and litigants) rather than on operational objectives.

The applicant must describe how the proposed project addresses one or more Priority Investment Areas. If the project does not address one or more Priority Investment Areas, the applicant must provide an explanation why not.

b. Need for the Project

If the project is to be conducted in any specific location(s), the applicant should discuss the particular needs of the project site(s) to be addressed by the project and why those needs are not being met through the use of existing programs, procedures, services, or other resources.

If the project is not site-specific, the applicant should discuss the problems that the proposed project would address, and why existing programs, procedures, services, or other resources cannot adequately resolve those problems. In addition, the applicant should describe how, if applicable, the project will be sustained in the future through existing resources.

The discussion should include specific references to the relevant literature and to the experience in the field. SJI continues to make all grant reports and most grant products available online through the National Center for State Courts (NCSC) Library and Digital Archive. Applicants are required to conduct a search of the NCSC Library and Digital Archive on the topic areas they are addressing. This search should include SJI-funded grants, and previous projects not supported by SJI. Searches for SJI grant reports and other state court resources begin with the NCSC Library section. Applicants must discuss the results of their research; how they plan to incorporate the previous work into their proposed project; and if the project will differentiate from prior work.

c. Tasks, Methods and Evaluations

(1) Tasks and Methods. The applicant should delineate the tasks to be performed in achieving the project objectives and the methods to be used for accomplishing each task. For example:

(a) *For research and evaluation projects,* the applicant should include the data sources, data collection strategies, variables to be examined, and analytic procedures to be used for conducting the research or evaluation and ensuring the validity and general applicability of the results. For projects involving human subjects, the discussion of methods should address the procedures for obtaining respondents' informed consent, ensuring the respondents' privacy and freedom from risk or harm, and protecting others who are not the subjects of research but would be affected by the research. If the potential exists for risk or harm to human subjects, a discussion should be included that explains the value of the proposed research and the methods to be used to minimize or eliminate such risk.

(b) *For education and training projects,* the applicant should include the adult education techniques to be used in designing and presenting the program, including the teaching/learning objectives of the educational design, the teaching methods to be used, and the opportunities for structured interaction among the participants; how faculty would be recruited, selected, and trained; the proposed number and length of the conferences, courses, seminars, or workshops to be conducted

and the estimated number of persons who would attend them; the materials to be provided and how they would be developed; and the cost to participants.

(c) *For demonstration projects,* the applicant should include the demonstration sites and the reasons they were selected, or if the sites have not been chosen, how they would be identified and their cooperation obtained; and how the program or procedures would be implemented and monitored.

(d) *For technical assistance projects,* the applicant should explain the types of assistance that would be provided; the particular issues and problems for which assistance would be provided; the type of assistance determined; how suitable providers would be selected and briefed; and how reports would be reviewed.

(2) Evaluation. Projects should include an evaluation plan to determine whether the project met its objectives. The evaluation should be designed to provide an objective and independent assessment of the effectiveness or usefulness of the training or services provided; the impact of the procedures, technology, or services tested; or the validity and applicability of the research conducted. The evaluation plan should be appropriate to the type of project proposed.

d. Project Management

The applicant should present a detailed management plan, including the starting and completion date for each task; the time commitments to the project of key staff and their responsibilities regarding each project task; and the procedures that would ensure that all tasks are performed on time, within budget, and at the highest level of quality. In preparing the project time line, Gantt Chart, or schedule, applicants should make certain that all project activities, including publication or reproduction of project products and their initial dissemination, would occur within the proposed project period. The management plan must also provide for the submission of Quarterly Progress and Financial Reports within 30 days after the close of each calendar quarter (i.e., no later than January 30, April 30, July 30, and October 30), per section VI.A.13.

Applicants should be aware that SJI is unlikely to approve a limited extension of the grant period without strong justification. Therefore, the management plan should be as realistic as possible and fully reflect the time commitments of the proposed project staff and consultants.

e. Products

The program narrative in the application should contain a description of the product(s) to be developed (e.g., training curricula and materials, Web sites or other electronic multimedia, articles, guidelines, manuals, reports, handbooks, benchbooks, or books), including when they would be submitted to SJI. The budget should include the cost of producing and disseminating the product to the state chief justice, state court administrator, and other appropriate judges or court personnel. If final products involve electronic formats, the applicant should indicate how the product would be made available to other courts. Discussion of this dissemination process should occur between the grantee and SJI prior to the final selection of the dissemination process to be used.

(1) Dissemination Plan. The application must explain how and to whom the products would be disseminated; describe how they would benefit the state courts, including how they could be used by judges and court personnel; identify development, production, and dissemination costs covered by the project budget; and present the basis on which products and services developed or provided under the grant would be offered to the court community and the public at large (i.e., whether products would be distributed at no cost to recipients, or if costs are involved, the reason for charging recipients and the estimated price of the product) (see section VI.A.11.b.). Ordinarily, applicants should schedule all product preparation and distribution activities within the project period.

Applicants proposing to develop web-based products should provide for sending a notice and description of the document to the appropriate audiences to alert them to the availability of the Web site or electronic product (i.e., a written report with a reference to the Web site).

Three (3) copies of all project products should be submitted to SJI, along with an electronic version in HTML or PDF format. Discussions of final product dissemination should be conducted with SJI prior to the end of the grant period.

(2) Types of Products. The type of product to be prepared depends on the nature of the project. For example, in most instances, the products of a research, evaluation, or demonstration project should include an article summarizing the project findings that is publishable in a journal serving the courts community nationally, an executive summary that would be disseminated to the project's primary audience, or both. Applicants proposing to conduct empirical research or evaluation projects with national import should describe how they would make their data available for secondary analysis after the grant period (see section VI.A.14.a.).

The curricula and other products developed through education and training projects should be designed for use by others and again by the original participants in the course of their duties.

(3) SJI Review. Applicants must submit a final draft of all written grant products to SJI for review and approval at least 30 days before the products are submitted for publication or reproduction. For products in Web site or multimedia format, applicants must provide for SJI review of the product at the treatment, script, rough-cut, and final stages of development, or their equivalents. No grant funds may be obligated for publication or reproduction of a final grant product without the written approval of SJI (see section VI.A.11.f.).

(4) Acknowledgment, Disclaimer, and Logo. Applicants must also include in all project products a prominent acknowledgment that support was received from SJI and a disclaimer paragraph based on the example provided in section VI.A.11.a.2. in the Grant Guideline. The ''SJI'' logo must appear on the front cover of a written product, or in the opening frames of a Web site or other multimedia product, unless SJI approves another placement. The SJI logo can be downloaded from SJI's Web site: *www.sji.gov.*

f. Applicant Status

An applicant that is not a state or local court and has not received a grant from SJI within the past three years should indicate whether it is either a national non-profit organization controlled by, operating in conjunction with, and serving the judicial branches of state governments, or a national non-profit organization for the education and training of state court judges and support personnel (see section II). If the applicant is a non-judicial unit of federal, state, or local government, it must explain whether the proposed services could be adequately provided by non-governmental entities.

g. Staff Capability

The applicant should include a summary of the training and experience of the key staff members and consultants that qualify them for conducting and managing the proposed project. Resumes of identified staff

should be attached to the application. If one or more key staff members and consultants are not known at the time of the application, a description of the criteria that would be used to select persons for these positions should be included. The applicant also should identify the person who would be responsible for managing and reporting on the financial aspects of the proposed project.

h. Organizational Capacity

Applicants that have not received a grant from SJI within the past three years should include a statement describing their capacity to administer grant funds, including the financial systems used to monitor project expenditures (and income, if any), and a summary of their past experience in administering grants, as well as any resources or capabilities that they have that would particularly assist in the successful completion of the project.

Unless requested otherwise, an applicant that has received a grant from SJI within the past three years should describe only the changes in its organizational capacity, tax status, or financial capability that may affect its capacity to administer a grant.

If the applicant is a non-profit organization (other than a university), it must also provide documentation of its 501(c) tax-exempt status as determined by the Internal Revenue Service and a copy of a current certified audit report. For purposes of this requirement, ''current'' means no earlier than two years prior to the present calendar year.

If a current audit report is not available, SJI will require the organization to complete a financial capability questionnaire, which must be signed by a certified public accountant. Other applicants may be required to provide a current audit report, a financial capability questionnaire, or both, if specifically requested to do so by the Institute.

i. Statement of Lobbying Activities

Non-governmental applicants must submit SJI's Disclosure of Lobbying Activities Form E, which documents whether they, or another entity that is a part of the same organization as the applicant, have advocated a position before Congress on any issue, and identifies the specific subjects of their lobbying efforts.

j. Letters of Cooperation or Support

If the cooperation of courts, organizations, agencies, or individuals other than the applicant is required to conduct the project, the applicant should attach written assurances of cooperation and availability to the application, or send them under separate cover. Letters of general support for a project are also encouraged.

4. Budget Narrative

In addition to Project Grant applications, the following section also applies to Technical Assistance and Curriculum Adaptation and Training grant applications.

The budget narrative should provide the basis for the computation of all project-related costs. When the proposed project would be partially supported by grants from other funding sources, applicants should make clear what costs would be covered by those other grants. Additional background information or schedules may be attached if they are essential to obtaining a clear understanding of the proposed budget. Numerous and lengthy appendices are strongly discouraged.

The budget narrative should cover the costs of all components of the project and clearly identify costs attributable to the project evaluation.

a. Justification of Personnel Compensation

The applicant should set forth the percentages of time to be devoted by the individuals who would staff the proposed project, the annual salary of each of those persons, and the number of work days per year used for calculating the percentages of time or daily rates of those individuals. The applicant should explain any deviations from current rates or established written organizational policies. No grant funds or cash match may be used to pay the salary and related costs for a current or new employee of a court or other unit of government because such funds would constitute a supplantation of state or local funds in violation of 42 U.S.C. 10706(d)(1); this includes new employees hired specifically for the project. The salary and any related costs for a current or new employee of a court or other unit of government may only be accepted as in-kind match.

b. Fringe Benefit Computation

For non-governmental entities, the applicant should provide a description of the fringe benefits provided to employees. If percentages are used, the authority for such use should be presented, as well as a description of the elements included in the determination of the percentage rate.

c. Consultant/Contractual Services and Honoraria

The applicant should describe the tasks each consultant would perform, the estimated total amount to be paid to each consultant, the basis for compensation rates (e.g., the number of days multiplied by the daily consultant rates), and the method for selection. Rates for consultant services must be set in accordance with section VII.I.2.c. Prior written SJI approval is required for any consultant rate in excess of $800 per day; SJI funds may not be used to pay a consultant more than $1,100 per day. Honorarium payments must be justified in the same manner as consultant payments.

d. Travel

Transportation costs and per diem rates must comply with the policies of the applicant organization. If the applicant does not have an established travel policy, then travel rates must be consistent with those established by the federal government. The budget narrative should include an explanation of the rate used, including the components of the per diem rate and the basis for the estimated transportation expenses. The purpose of the travel should also be included in the narrative.

e. Equipment

Grant funds may be used to purchase only the equipment necessary to demonstrate a new technological application in a court or that is otherwise essential to accomplishing the objectives of the project. In other words, grant funds cannot be used strictly for the purpose of purchasing equipment. Equipment purchases to support basic court operations ordinarily will not be approved. The applicant should describe the equipment to be purchased or leased and explain why the acquisition of that equipment is essential to accomplish the project's goals and objectives. The narrative should clearly identify which equipment is to be leased and which is to be purchased. The method of procurement should also be described. Purchases of automated data processing equipment must comply with section VII.I.2.b.

f. Supplies

The applicant should provide a general description of the supplies necessary to accomplish the goals and objectives of the grant. In addition, the applicant should provide the basis for the amount requested for this expenditure category.

g. Construction

Construction expenses are prohibited except for the limited purposes set forth in section VI.A.16.b. Any allowable construction or renovation expense should be described in detail in the budget narrative.

h. Postage

Anticipated postage costs for project-related mailings, including distribution of the final product(s), should be described in the budget narrative. The cost of special mailings, such as for a survey or for announcing a workshop, should be distinguished from routine operational mailing costs. The bases for all postage estimates should be included in the budget narrative.

i. Printing/Photocopying

Anticipated costs for printing or photocopying project documents, reports, and publications should be included in the budget narrative, along with the bases used to calculate these estimates.

j. Indirect Costs

Indirect costs are only applicable to organizations that are not state courts or government agencies. Recoverable indirect costs are limited to no more than 75 percent of a grantee's direct personnel costs, i.e. salaries plus fringe benefits (see section VII.I.4.).

Applicants should describe the indirect cost rates applicable to the grant in detail. If costs often included within an indirect cost rate are charged directly (e.g., a percentage of the time of senior managers to supervise project activities), the applicant should specify that these costs are not included within its approved indirect cost rate. These rates must be established in accordance with section VII.I.4. If the applicant has an indirect cost rate or allocation plan approved by any federal granting agency, a copy of the approved rate agreement must be attached to the application.

5. Submission Requirements

a. Every applicant must submit an original and three copies of the application package consisting of Form A; Form B, if the application is from a state or local court, or a Disclosure of Lobbying Form (Form E), if the applicant is not a unit of state or local government; Form C; the Application Abstract; the Program Narrative; the Budget Narrative; and any necessary appendices.

Letters of application may be submitted at any time. However, applicants are encouraged to review the grant deadlines available on the SJI Web site. Receipt of each application will be acknowledged by letter or email.

b. Applicants submitting more than one application may include material that would be identical in each application in a cover letter. This material will be incorporated by reference into each application and counted against the 25-page limit for the program narrative. A copy of the cover letter should be attached to each copy of the application.

B. Technical Assistance (TA) Grants

1. Application Procedures

Applicants for TA Grants may submit an original and three copies of a detailed letter describing the proposed project, as well as a Form A—State Justice Institute Application; Form B—Certificate of State Approval from the State Supreme Court, or its designated agency; and Form C—Project Budget in Tabular Format (see *www.sji.gov/forms*).

2. Application Format

Although there is no prescribed form for the letter, or a minimum or maximum page limit, letters of application should include the following information:

a. Need for Funding. The applicant must explain the critical need facing the applicant, and the proposed technical assistance that will enable the applicant meet this critical need. The applicant must also explain why state or local resources are not sufficient to fully support the costs of the project. In addition, the applicant should describe how, if applicable, the project will be sustained in the future through existing resources.

The discussion should include specific references to the relevant literature and to the experience in the field. SJI continues to make all grant reports and most grant products available online through the National Center for State Courts (NCSC) Library and Digital Archive. Applicants are required to conduct a search of the NCSC Library and Digital Archive on the topic areas they are addressing. This search should include SJI-funded grants, and previous projects not supported by SJI. Searches for SJI grant reports and other state court resources begin with the NCSC Library section. Applicants must discuss the results of their research; how they plan to incorporate the previous work into their proposed project; and if the project will differentiate from prior work.

b. Project Description. The applicant must describe how the proposed project addressed one or more Priority Investment Areas. If the project does not address one or more Priority Investment Areas, the applicant must provide an explanation why not.

The applicant must describe the tasks the consultant will perform, and how would they be accomplished. In addition, the applicant must identify which organization or individual will be hired to provide the assistance, and how the consultant was selected. If a consultant has not yet been identified, what procedures and criteria would be used to select the consultant (applicants are expected to follow their jurisdictions' normal procedures for procuring consultant services)? What specific tasks would the consultant(s) and court staff undertake? What is the schedule for completion of each required task and the entire project? How would the applicant oversee the project and provide guidance to the consultant, and who at the court or regional court association would be responsible for coordinating all project tasks and submitting quarterly progress and financial status reports?

If the consultant has been identified, the applicant should provide a letter from that individual or organization documenting interest in and availability for the project, as well as the consultant's ability to complete the assignment within the proposed time frame and for the proposed cost. The consultant must agree to submit a detailed written report to the court and SJI upon completion of the technical assistance.

c. Likelihood of Implementation. What steps have been or would be taken to facilitate implementation of the consultant's recommendations upon completion of the technical assistance? For example, if the support or cooperation of specific court officials or committees, other agencies, funding bodies, organizations, or a court other than the applicant would be needed to adopt the changes recommended by the consultant and approved by the court, how would they be involved in the review of the recommendations and development of the implementation plan?

3. Budget and Matching State Contribution

Applicants must follow the same guidelines provided under Section IV.A.4. A completed Form C—Project Budget, Tabular Format and budget narrative must be included with the letter requesting technical assistance.

The budget narrative should provide the basis for all project-related costs, including the basis for determining the estimated consultant costs, if compensation of the consultant is

required (e.g., the number of days per task times the requested daily consultant rate). Applicants should be aware that consultant rates above $800 per day must be approved in advance by SJI, and that no consultant will be paid more than $1,100 per day from SJI funds. In addition, the budget should provide for submission of two copies of the consultant's final report to the SJI.

Recipients of TA Grants do not have to submit an audit report but must maintain appropriate documentation to support expenditures (see section VI.A.3.).

4. Submission Requirements

Letters of application should be submitted according to the grant deadlines provided on the SJI Web site.

If the support or cooperation of agencies, funding bodies, organizations, or courts other than the applicant would be needed in order for the consultant to perform the required tasks, written assurances of such support or cooperation should accompany the application letter. Letters of general support for the project are also encouraged. Support letters may be submitted under separate cover; however, they should be received by the same date as the application.

C. Curriculum Adaptation and Training (CAT) Grants

1. Application Procedures

In lieu of formal applications, applicants should submit an original and three photocopies of a detailed letter as well as a Form A—State Justice Institute Application; Form B—Certificate of State Approval; and Form C—Project Budget, Tabular Format (see *www.sji.gov/forms*).

2. Application Format

Although there is no prescribed format for the letter, or a minimum or maximum page limit, letters of application should include the following information.

a. For adaptation of a curriculum:

(1) Project Description. The applicant must describe how the proposed project addresses one or more Priority Investment Areas. If the project does not address one or more Priority Investment Areas, the applicant must provide an explanation why not. Due to the high costs of travel to attend training events, the innovative use of distance learning is highly encouraged.

The applicant must provide the title of the curriculum that will be adapted, and identify the entity that originally developed the curriculum. The applicant must also address the following questions: Why is this education program needed at the present time? What are the project's goals? What are the learning objectives of the adapted curriculum? What program components would be implemented, and what types of modifications, if any, are anticipated in length, format, learning objectives, teaching methods, or content? Who would be responsible for adapting the model curriculum? Who would the participants be, how many would there be, how would they be recruited, and from where would they come (e.g., from a single local jurisdiction, from across the state, from a multi-state region, from across the nation)?

(2) Need for Funding. The discussion should include specific references to the relevant literature and to the experience in the field. SJI continues to make all grant reports and most grant products available online through the National Center for State Courts (NCSC) Library and Digital Archive. Applicants are required to conduct a search of the NCSC Library and Digital Archive on the topic areas they are addressing. This search should include SJI-funded grants, and previous projects not supported by SJI. Searches for SJI grant reports and other state court resources begin with the NCSC Library section. Applicants must discuss the results of their research; how they plan to incorporate the previous work into their proposed project; and if the project will differentiate from prior work.

The applicant should explain why state or local resources are unable to fully support the modification and presentation of the model curriculum. The applicant should also describe the potential for replicating or integrating the adapted curriculum in the future using state or local funds, once it has been successfully adapted and tested. In addition, the applicant should describe how, if applicable, the project will be sustained in the future through existing resources.

(3) Likelihood of Implementation. The applicant should provide the proposed timeline, including the project start and end dates, the date(s) the judicial branch education program will be presented, and the process that will be used to modify and present the program. The applicant should also identify who will serve as faculty, and how they were selected, in addition to the measures taken to facilitate subsequent presentations of the program. Ordinarily, an independent evaluation of a curriculum adaptation project is not required; however, the results of any evaluation should be included in the final report.

(4) Expressions of Interest by Judges and/or Court Personnel. Does the proposed program have the support of the court system or association leadership, and of judges, court managers, and judicial branch education personnel who are expected to attend? Applicants may demonstrate this by attaching letters of support.

b. For training assistance:

(1) Need for Funding. The applicant must describe how the proposed project addresses one or more Priority Investment Areas. If the project does not address one or more Priority Investment Areas, the applicant must provide an explanation why not.

The discussion should include specific references to the relevant literature and to the experience in the field. SJI continues to make all grant reports and most grant products available online through the National Center for State Courts (NCSC) Library and Digital Archive. Applicants are required to conduct a search of the NCSC Library and Digital Archive on the topic areas they are addressing. This search should include SJI-funded grants, and previous projects not supported by SJI. Searches for SJI grant reports and other state court resources begin with the NCSC Library section. Applicants must discuss the results of their research; how they plan to incorporate the previous work into their proposed project; and if the project will differentiate from prior work.

The applicant should describe the court reform or initiative prompting the need for training. The applicant should also discuss how the proposed training will help the applicant implement planned changes at the court, and why state or local resources are not sufficient to fully support the costs of the required training. In addition, the applicant should describe how, if applicable, the project will be sustained in the future through existing resources.

(2) Project Description. The applicant must identify the tasks the trainer(s) will be expected to perform, which organization or individual will be hired, and, if in-house personnel are not the trainers, how the trainer will be selected. If a trainer has not yet been identified, the applicant must describe the procedures and criteria that will be used to select the trainer. In addition, the applicant should address the following questions: What specific tasks would the trainer and court staff or regional court association members undertake? What presentation methods will be used? What is the schedule for completion of each required task and the entire project? How will the applicant oversee the project and

provide guidance to the trainer, and who at the court or affiliated with the regional court association would be responsible for coordinating all project tasks and submitting quarterly progress and financial status reports?

If the trainer has been identified, the applicant should provide a letter from that individual or organization documenting interest in and availability for the project, as well as the trainer's ability to complete the assignment within the proposed time frame and for the proposed cost.

(3) Likelihood of Implementation. The applicant should explain what steps have been or will be taken to coordinate the implementation of the training. For example, if the support or cooperation of specific court or regional court association officials or committees, other agencies, funding bodies, organizations, or a court other than the applicant will be needed to adopt the reform and initiate the training proposed, how will the applicant secure their involvement in the development and implementation of the training?

3. Budget and Matching State Contribution

Applicants must also follow the same guidelines provided under Section IV.A.4. Applicants should attach a copy of budget Form C and a budget narrative (see subsection A.4. above) that describes the basis for the computation of all project-related costs and the source of the match offered.

4. Submission Requirements

For curriculum adaptation requests, applicants should allow at least 90 days between the Board meeting and the date of the proposed program to allow sufficient time for needed planning. Letters of support for the project are also encouraged. Applicants are encouraged to call SJI to discuss concerns about timing of submissions.

D. Partner Grants

SJI and its funding partners may meld, pick and choose, or waive their application procedures, grant cycles, or grant requirements to expedite the award of jointly-funded grants targeted at emerging or high priority problems confronting state and local courts. SJI may solicit brief proposals from potential grantees to fellow financial partners as a first step. Should SJI be chosen as the lead grant manager, Project Grant application procedures will apply to the proposed Partner Grant.

E. Education Support Program (ESP)

1. Limitations

Applicants may not receive more than one ESP award in a two-year fiscal year period unless the course specifically assumes multi-year participation, such as a certification program or a graduate degree program in judicial studies in which the applicant is currently enrolled (neither exception should be taken as a commitment on the part of the SJI Board of Directors to approve serial ESP awards). If the course assumes multi-year participation, awards will be limited to one per fiscal year. Attendance at annual or mid-year meetings or conferences of a state or national organization does not qualify as an out-of-state educational program for the ESP, even though it may include workshops or other training sessions.

The ESP only covers the cost of tuition up to a maximum of $1,000 per award, per course. Awards will be made for the exact amount requested for tuition. Funds to pay tuition in excess of $1,000, and other cost of attending the program such as travel, lodging, meals, materials, transportation to and from airports (including rental cars) must be obtained from other sources or borne by the ESP award recipient. Applicants are encouraged to check other sources of financial assistance and to combine aid from various sources whenever possible. An ESP award is not transferable to another individual. It may be used only for the course specified in the application unless the applicant's request to attend a different course that meets the eligibility requirements is approved in writing by SJI.

2. Eligibility Requirements

a. Recipients. Because of the limited amount of funding available, only full-time judges of state or local trial and appellate courts; full-time professional, state, or local court personnel with management and supervisory responsibilities; and supervisory and management probation personnel in judicial branch probation offices are eligible for the program. Senior judges, part-time judges, quasi-judicial hearing officers including referees and commissioners, administrative law judges, staff attorneys, law clerks, line staff, law enforcement officers, and other executive branch personnel are not eligible.

b. Courses. An ESP award is only for: (1) A course presented in a state other than the one in which the applicant resides or works, or (2) an online course. The course must be designed to enhance the skills of new or experienced judges and court managers; or be offered by a recognized graduate program for judges or court managers.

Applicants are encouraged not to wait for the decision on an ESP application to register for an educational program they wish to attend. SJI does not submit the names of ESP award recipients to educational organizations, nor provide the funds to the educational organization. ESP funds are provided as reimbursements directly to the recipient.

3. Forms

a. Education Support Program Application—Form ESP–1 (see *www.sji.gov/forms*). The application requests basic information about the applicant and the educational program the applicant would like to attend. It also addresses the applicant's commitment to share the skills and knowledge gained with state and local court colleagues. The application must bear the original signature of the applicant. Faxed or photocopied signatures will not be accepted. Please be sure to indicate whether the state will be providing funds for the course and, if so, how much. SJI will not supplant state funds with these awards.

b. Education Support Program Concurrence—Form ESP–2 Judges and court managers applying for the program must submit the original written concurrence of the chief justice of the state's supreme court (or the chief justice's designee) on Form ESP–2. The signature of the presiding judge of the applicant's court may not be substituted for that of the state's chief justice or the chief justice's designee. The chief justice or state court administrator must notify SJI of the designees within the state for ESP purposes.

4. Submission Requirements

Applications may be submitted at any time but will be reviewed on a quarterly basis. This means ESP awards will be on a ''first-come, first-considered'' basis. The dates for applications to be received by SJI for consideration in FY 2014 are November 1, February 1, May 1, and August 1. These are *not* mailing deadlines. The applications must be received by SJI on or before each of these dates. No exceptions or extensions will be granted. All the required items must be received for an application to be considered. If the Concurrence form or letter of support is sent separately from the application, the postmark date of the last item sent will be used in determining the review date. All applications should be sent by mail or courier (not fax or email).

V. Application Review Procedures

A. Preliminary Inquiries

SJI staff will answer inquiries concerning application procedures.

B. Selection Criteria

1. Project Grant Applications

a. Project Grant applications will be rated on the basis of the criteria set forth below. SJI will accord the greatest weight to the following criteria:

(1) The soundness of the methodology;

(2) The demonstration of need for the project;

(3) The appropriateness of the proposed evaluation design;

(4) If applicable, the key findings and recommendations of the most recent evaluation and the proposed responses to those findings and recommendations;

(5) The applicant's management plan and organizational capabilities;

(6) The qualifications of the project's staff;

(7) The products and benefits resulting from the project, including the extent to which the project will have long-term benefits for state courts across the nation;

(8) The degree to which the findings, procedures, training, technology, or other results of the project can be transferred to other jurisdictions;

(9) The reasonableness of the proposed budget; and,

(10) The demonstration of cooperation and support of other agencies that may be affected by the project.

b. In determining which projects to support, SJI will also consider whether the applicant is a state court, a national court support or education organization, a non-court unit of government, or other type of entity eligible to receive grants under SJI's enabling legislation (see section II.); the availability of financial assistance from other sources for the project; the amount of the applicant's match; the extent to which the proposed project would also benefit the federal courts or help state courts enforce federal constitutional and legislative requirements; and the level of appropriations available to SJI in the current year and the amount expected to be available in succeeding fiscal years.

2. Technical Assistance (TA) Grant Applications

TA Grant applications will be rated on the basis of the following criteria:

a. Whether the assistance would address a critical need of the applicant;

b. The soundness of the technical assistance approach to the problem;

c. The qualifications of the consultant(s) to be hired or the specific criteria that will be used to select the consultant(s);

d. The commitment of the court or association to act on the consultant's recommendations; and,

e. The reasonableness of the proposed budget.

SJI also will consider factors such as the level and nature of the match that would be provided, diversity of subject matter, geographic diversity, the level of appropriations available to SJI in the current year, and the amount expected to be available in succeeding fiscal years.

3. Curriculum Adaptation and Training (CAT) Grant Applications

CAT Grant applications will be rated on the basis of the following criteria:

a. For curriculum adaptation projects:

(1) The goals and objectives of the proposed project;

(2) The need for outside funding to support the program;

(3) The appropriateness of the approach in achieving the project's educational objectives;

(4) The likelihood of effective implementation and integration of the modified curriculum into ongoing educational programming; and,

(5) Expressions of interest by the judges and/or court personnel who would be directly involved in or affected by the project.

b. For training assistance:

(1) Whether the training would address a critical need of the court or association;

(2) The soundness of the training approach to the problem;

(3) The qualifications of the trainer(s) to be hired or the specific criteria that will be used to select the trainer(s);

(4) The commitment of the court or association to the training program; and

(5) The reasonableness of the proposed budget. SJI will also consider factors such as the reasonableness of the amount requested; compliance with match requirements; diversity of subject matter, geographic diversity; the level of appropriations available to SJI in the current year; and the amount expected to be available in succeeding fiscal years.

4. Partner Grants

The selection criteria for Partner Grants will be driven by the collective priorities of SJI and other organizations and their collective assessments regarding the needs and capabilities of court and court-related organizations. Having settled on priorities, SJI and its financial partners will likely contact the courts or court-related organizations most acceptable as pilots, laboratories, consultants, or the like.

5. Education Support Program (ESP)

ESP awards are only for programs that either: (1) Enhance the skills of judges and court managers; or (2) are part of a graduate degree program for judges or court personnel. Awards are provided on the basis of:

a. The date on which the application and concurrence (and support letter, if required) were sent (''first-come, first-considered'');

b. The unavailability of state or local funds, or funding from another source to cover the costs of attending the program, or participating online;

c. The absence of educational programs in the applicant's state addressing the topic(s) covered by the educational program for which the award is being sought;

d. Geographic balance among the recipients;

e. The balance of ESP awards among educational providers and programs;

f. The balance of ESP awards among the types of courts and court personnel (trial judge, appellate judge, trial court administrator) represented; and

g. The level of appropriations available to SJI in the current year and the amount expected to be available in succeeding fiscal years.

The postmark or courier receipt will be used to determine the date on which the application form and other required items were sent.

C. Review and Approval Process

1. Project Grant Applications

SJI's Board of Directors will review the applications competitively. The Board will review all applications and decide which projects to fund. The decision to fund a project is solely that of the Board of Directors. The Chairman of the Board will sign approved awards on behalf of SJI.

2. Technical Assistance (TA) and Curriculum Adaptation and Training (CAT) Grant Applications

The Board will review the applications competitively. The Board will review all applications and decide which projects to fund. The decision to fund a project is solely that of the Board of Directors. The Chairman of the Board will sign approved awards on behalf of SJI.

3. Education Support Program (ESP)

A committee of the Board of Directors will review ESP applications quarterly. The committee will review the applications competitively. The Chairman of the Board will sign approved awards on behalf of SJI.

4. Partner Grants

SJI's internal process for the review and approval of Partner Grants will depend on negotiations with fellow financiers. SJI may use its procedures, a partner's procedures, a mix of both, or entirely unique procedures. All Partner Grants will be approved by the Board of Directors.

D. Return Policy

Unless a specific request is made, unsuccessful applications will not be returned. Applicants are advised that SJI records are subject to the provisions of the Federal Freedom of Information Act, 5 U.S.C. 552.

E. Notification of Board Decision

SJI will send written notice to applicants concerning all Board decisions to approve, defer, or deny their respective applications. For all applications (except ESP applications), if requested, SJI will convey the key issues and questions that arose during the review process. A decision by the Board to deny an application may not be appealed, but it does not prohibit resubmission of a proposal based on that application in a subsequent funding cycle.

F. Response to Notification of Approval

With the exception of those approved for ESP awards, applicants have 30 days from the date of the letter notifying them that the Board has approved their application to respond to any revisions requested by the Board. If the requested revisions (or a reasonable schedule for submitting such revisions) have not been submitted to SJI within 30 days after notification, the approval may be rescinded and the application presented to the Board for reconsideration. In the event an issue will only be resolved after award, such as the selection of a consultant, the final award document will include a Special Condition that will require additional grantee reporting and SJI review and approval. Special Conditions, in the form of incentives or sanctions, may also be used in other situations.

VI. Compliance Requirements

The State Justice Institute Act contains limitations and conditions on grants, contracts, and cooperative agreements awarded by SJI. The Board of Directors has approved additional policies governing the use of SJI grant funds. These statutory and policy requirements are set forth below.

A. Recipients of Project Grants

1. Advocacy

No funds made available by SJI may be used to support or conduct training programs for the purpose of advocating particular non-judicial public policies or encouraging non-judicial political activities (42 U.S.C. 10706(b)).

2. Approval of Key Staff

If the qualifications of an employee or consultant assigned to a key project staff position are not described in the application or if there is a change of a person assigned to such a position, the recipient must submit a description of the qualifications of the newly assigned person to SJI. Prior written approval of the qualifications of the new person assigned to a key staff position must be received from the Institute before the salary or consulting fee of that person and associated costs may be paid or reimbursed from grant funds (see section VIII.A.7.).

3. Audit

Recipients of project grants must provide for an annual fiscal audit which includes an opinion on whether the financial statements of the grantee present fairly its financial position and its financial operations are in accordance with generally accepted accounting principles (see section VII.K. for the requirements of such audits). ESP award recipients, Curriculum Adaptation and Training Grants, and Technical Assistance Grants are not required to submit an audit, but they must maintain appropriate documentation to support all expenditures (see section VIII.K.).

4. Budget Revisions

Budget revisions among direct cost categories that: (a) Transfer grant funds to an unbudgeted cost category, or (b) individually or cumulatively exceed five percent of the approved original budget or the most recently approved revised budget require prior SJI approval (see section VIII.A.1.).

5. Conflict of Interest

Personnel and other officials connected with SJI-funded programs must adhere to the following requirements:

a. No official or employee of a recipient court or organization shall participate personally through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise in any proceeding, application, request for a ruling or other determination, contract, grant, cooperative agreement, claim, controversy, or other particular matter in which SJI funds are used, where, to his or her knowledge, he or she or his or her immediate family, partners, organization other than a public agency in which he or she is serving as officer, director, trustee, partner, or employee or any person or organization with whom he or she is negotiating or has any arrangement concerning prospective employment, has a financial interest.

b. In the use of SJI project funds, an official or employee of a recipient court or organization shall avoid any action which might result in or create the appearance of:

(1) Using an official position for private gain; or

(2) Affecting adversely the confidence of the public in the integrity of the Institute program.

c. Requests for proposals or invitations for bids issued by a recipient of Institute funds or a subgrantee or subcontractor will provide notice to prospective bidders that the contractors who develop or draft specifications, requirements, statements of work, and/or requests for proposals for a proposed procurement will be excluded from bidding on or submitting a proposal to compete for the award of such procurement.

6. Inventions and Patents

If any patentable items, patent rights, processes, or inventions are produced in the course of SJI-sponsored work, such fact shall be promptly and fully reported to the Institute. Unless there is a prior agreement between the grantee and SJI on disposition of such items, SJI shall determine whether protection of the invention or discovery shall be sought. SJI will also determine how the rights in the invention or discovery, including rights under any patent issued thereon, shall be allocated and administered in order to protect the public interest consistent with ''Government Patent Policy'' (President's Memorandum for Heads of Executive Departments and Agencies, February 18, 1983, and statement of Government Patent Policy).

7. Lobbying

a. Funds awarded to recipients by SJI shall not be used, indirectly or directly, to influence Executive Orders or similar promulgations by federal, state or local agencies, or to influence the passage or defeat of any legislation by federal, state or local legislative bodies (42 U.S.C. 10706(a)).

b. It is the policy of the Board of Directors to award funds only to support applications submitted by organizations that would carry out the objectives of their applications in an unbiased

manner. Consistent with this policy and the provisions of 42 U.S.C. 10706, SJI will not knowingly award a grant to an applicant that has, directly or through an entity that is part of the same organization as the applicant, advocated a position before Congress on the specific subject matter of the application.

8. Matching Requirements

All grantees other than ESP award recipients are required to provide a match. A match is the portion of project costs not borne by the Institute. Match includes both cash and in-kind contributions. Cash match is the direct outlay of funds by the grantee or a third party to support the project. In-kind match consists of contributions of time and/or services of current staff members, new employees, space, supplies, etc., made to the project by the grantee or others (e.g., advisory board members) working directly on the project or that portion of the grantee's federally-approved indirect cost rate that exceeds the Guideline's limit of permitted charges (75 percent of salaries and benefits).

Under normal circumstances, allowable match may be incurred only during the project period. When appropriate, and with the prior written permission of SJI, match may be incurred from the date of the Board of Directors' approval of an award. The amount and nature of required match depends on the type of grant (see section III.).

The grantee is responsible for ensuring that the total amount of match proposed is actually contributed. If a proposed contribution is not fully met, SJI may reduce the award amount accordingly, in order to maintain the ratio originally provided for in the award agreement (see section VII.E.1.). Match should be expended at the same rate as SJI funding.

The Board of Directors looks favorably upon any unrequired match contributed by applicants when making grant decisions. The match requirement may be waived in exceptionally rare circumstances upon the request of the chief justice of the highest court in the state or the highest ranking official in the requesting organization and approval by the Board of Directors (42 U.S.C. 10705(d)). The Board of Directors encourages all applicants to provide the maximum amount of cash and in-kind match possible, even if a waiver is approved. The amount and nature of match are criteria in the grant selection process (see section V.B.1.b.).

Other federal department and agency funding may not be used for cash match.

9. Nondiscrimination

No person may, on the basis of race, sex, national origin, disability, color, or creed be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination under any program or activity supported by SJI funds. Recipients of SJI funds must immediately take any measures necessary to effectuate this provision.

10. Political Activities

No recipient may contribute or make available SJI funds, program personnel, or equipment to any political party or association, or the campaign of any candidate for public or party office. Recipients are also prohibited from using funds in advocating or opposing any ballot measure, initiative, or referendum. Officers and employees of recipients shall not intentionally identify SJI or recipients with any partisan or nonpartisan political activity associated with a political party or association, or the campaign of any candidate for public or party office (42 U.S.C. 10706(a)).

11. Products

a. Acknowledgment, Logo, and Disclaimer

(1) Recipients of SJI funds must acknowledge prominently on all products developed with grant funds that support was received from the SJI. The ''SJI'' logo must appear on the front cover of a written product, or in the opening frames of a multimedia product, unless another placement is approved in writing by SJI. This includes final products printed or otherwise reproduced during the grant period, as well as re-printings or reproductions of those materials following the end of the grant period. A camera-ready logo sheet is available on SJI's Web site: *www.sji.gov/forms.*

(2) Recipients also must display the following disclaimer on all grant products: ''This [document, film, videotape, etc.] was developed under [grant/cooperative agreement] number SJI-[insert number] from the State Justice Institute. The points of view expressed are those of the [author(s), filmmaker(s), etc.] and do not necessarily represent the official position or policies of the State Justice Institute.''

(3) In addition to other required grant products and reports, recipients must provide a one page executive summary of the project. The summary should include a background on the project, the tasks undertaken, and the outcome. In addition, the summary should provide the performance metrics that were used during the project, and how performance will be measured in the future.

b. Charges for Grant-Related Products/ Recovery of Costs

(1) SJI's mission is to support improvements in the quality of justice and foster innovative, efficient solutions to common issues faced by all courts. SJI has recognized and established procedures for supporting research and development of grant products (e.g. a report, curriculum, video, software, database, or Web site) through competitive grant awards based on merit review of proposed projects. To ensure that all grants benefit the entire court community, projects SJI considers worthy of support (in whole or in part), are required to be disseminated widely and available for public consumption. This includes open-source software and interfaces. Costs for development, production, and dissemination are allowable as direct costs to SJI.

(2) Applicants should disclose their intent to sell grant-related products in the application. Grantees must obtain SJI's prior written approval of their plans to recover project costs through the sale of grant products. Written requests to recover costs ordinarily should be received during the grant period and should specify the nature and extent of the costs to be recouped, the reason that such costs were not budgeted (if the rationale was not disclosed in the approved application), the number of copies to be sold, the intended audience for the products to be sold, and the proposed sale price. If the product is to be sold for more than $25, the written request also should include a detailed itemization of costs that will be recovered and a certification that the costs were not supported by either SJI grant funds or grantee matching contributions.

(3) In the event that the sale of grant products results in revenues that exceed the costs to develop, produce, and disseminate the product, the revenue must continue to be used for the authorized purposes of SJI-funded project or other purposes consistent with the State Justice Institute Act that have been approved by SJI (see section VII.G.).

c. Copyrights

Except as otherwise provided in the terms and conditions of a SJI award, a recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of a SJI-supported project, but SJI shall reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish,

or otherwise use, and to authorize others to use, the materials for purposes consistent with the State Justice Institute Act.

d. Due Date

All products and, for TA and CAT grants, consultant and/or trainer reports (see section VI.B.1 & 2) are to be completed and distributed (see below) not later than the end of the award period, not the 90-day close out period. The latter is only intended for grantee final reporting and to liquidate obligations (see section VII.L.).

e. Distribution

In addition to the distribution specified in the grant application, grantees shall send:

(1) Three (3) copies of each final product developed with grant funds to SJI, unless the product was developed under either a Technical Assistance or a Curriculum Adaptation and Training Grant, in which case submission of 2 copies is required; and

(2) An electronic version of the product in HTML or PDF format to SJI.

f. SJI Approval

No grant funds may be obligated for publication or reproduction of a final product developed with grant funds without the written approval of SJI. Grantees shall submit a final draft of each written product to SJI for review and approval. The draft must be submitted at least 30 days before the product is scheduled to be sent for publication or reproduction to permit SJI review and incorporation of any appropriate changes required by SJI. Grantees must provide for timely reviews by the SJI of Web site or other multimedia products at the treatment, script, rough cut, and final stages of development or their equivalents.

g. Original Material

All products prepared as the result of SJI-supported projects must be originally-developed material unless otherwise specified in the award documents. Material not originally developed that is included in such products must be properly identified, whether the material is in a verbatim or extensive paraphrase format.

12. Prohibition Against Litigation Support

No funds made available by SJI may be used directly or indirectly to support legal assistance to parties in litigation, including cases involving capital punishment.

13. Reporting Requirements

a. Recipients of SJI funds other than ESP awards must submit Quarterly Progress and Financial Status Reports within 30 days of the close of each calendar quarter (that is, no later than January 30, April 30, July 30, and October 30). The Quarterly Progress Reports shall include a narrative description of project activities during the calendar quarter, the relationship between those activities and the task schedule and objectives set forth in the approved application or an approved adjustment thereto, any significant problem areas that have developed and how they will be resolved, and the activities scheduled during the next reporting period. Failure to comply with the requirements of this provision could result in the termination of a grantee's award.

b. The quarterly Financial Status Report must be submitted in accordance with section VII.H.2. of this Guideline. A final project Progress Report and Financial Status Report shall be submitted within 90 days after the end of the grant period in accordance with section VII.L.1. of this Guideline.

14. Research

a. Availability of Research Data for Secondary Analysis

Upon request, grantees must make available for secondary analysis backup files containing research and evaluation data collected under an SJI grant and the accompanying code manual. Grantees may recover the actual cost of duplicating and mailing or otherwise transmitting the data set and manual from the person or organization requesting the data. Grantees may provide the requested data set in the format in which it was created and analyzed.

b. Confidentiality of Information

Except as provided by federal law other than the State Justice Institute Act, no recipient of financial assistance from SJI may use or reveal any research or statistical information furnished under the Act by any person and identifiable to any specific private person for any purpose other than the purpose for which the information was obtained. Such information and copies thereof shall be immune from legal process, and shall not, without the consent of the person furnishing such information, be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceedings.

c. Human Subject Protection

Human subjects are defined as individuals who are participants in an experimental procedure or who are asked to provide information about themselves, their attitudes, feelings, opinions, and/or experiences through an interview, questionnaire, or other data collection technique. All research involving human subjects shall be conducted with the informed consent of those subjects and in a manner that will ensure their privacy and freedom from risk or harm and the protection of persons who are not subjects of the research but would be affected by it, unless such procedures and safeguards would make the research impractical. In such instances, SJI must approve procedures designed by the grantee to provide human subjects with relevant information about the research after their involvement and to minimize or eliminate risk or harm to those subjects due to their participation.

15. State and Local Court Applications

Each application for funding from a state or local court must be approved, consistent with state law, by the state supreme court, or its designated agency or council. The supreme court or its designee shall receive, administer, and be accountable for all funds awarded on the basis of such an application (42 U.S.C. 10705(b)(4)). See section VII.C.2.

16. Supplantation and Construction

To ensure that SJI funds are used to supplement and improve the operation of state courts, rather than to support basic court services, SJI funds shall not be used for the following purposes:

a. To supplant state or local funds supporting a program or activity (such as paying the salary of court employees who would be performing their normal duties as part of the project, or paying rent for space which is part of the court's normal operations);

b. To construct court facilities or structures, except to remodel existing facilities or to demonstrate new architectural or technological techniques, or to provide temporary facilities for new personnel or for personnel involved in a demonstration or experimental program; or

c. Solely to purchase equipment.

17. Suspension or Termination of Funding

After providing a recipient reasonable notice and opportunity to submit written documentation demonstrating why fund termination or suspension should not occur, SJI may terminate or suspend funding of a project that fails to comply substantially with the Act,

the Guideline, or the terms and conditions of the award (42 U.S.C. 10708(a)).

18. Title to Property

At the conclusion of the project, title to all expendable and nonexpendable personal property purchased with SJI funds shall vest in the recipient court, organization, or individual that purchased the property if certification is made to and approved by SJI that the property will continue to be used for the authorized purposes of the SJI-funded project or other purposes consistent with the State Justice Institute Act. If such certification is not made or SJI disapproves such certification, title to all such property with an aggregate or individual value of $1,000 or more shall vest in SJI, which will direct the disposition of the property.

B. Recipients of Technical Assistance (TA) and Curriculum Adaptation and Training (CAT) Grants

Recipients of TA and CAT Grants must comply with the requirements listed in section VI.A. (except the requirements pertaining to audits in subsection A.3. above and product dissemination and approval in subsection A.11.e. and f. above) and the reporting requirements below:

1. Technical Assistance (TA) Grant Reporting Requirements

Recipients of TA Grants must submit to SJI one copy of a final report that explains how it intends to act on the consultant's recommendations, as well as two copies of the consultant's written report.

2. Curriculum Adaptation and Training (CAT) Grant Reporting Requirements

Recipients of CAT Grants must submit one copy of the agenda or schedule, outline of presentations and/or relevant instructor's notes, copies of overhead transparencies, power point presentations, or other visual aids, exercises, case studies and other background materials, hypotheticals, quizzes, and other materials involving the participants, manuals, handbooks, conference packets, evaluation forms, and suggestions for replicating the program, including possible faculty or the preferred qualifications or experience of those selected as faculty, developed under the grant at the conclusion of the grant period, along with a final report that includes any evaluation results and explains how the grantee intends to present the educational program in the future, as well as two copies of the consultant's or trainer's report.

C. Education Support Program (ESP) Recipients

1. ESP award recipients are responsible for disseminating the information received from the course to their court colleagues locally and, if possible, throughout the state.

Recipients also must submit to SJI a certificate of attendance from the program and a copy of the notice of any funding received from other sources. A state or local jurisdiction may impose additional requirements on ESP award recipients.

2. To receive the funds authorized by an ESP award, recipients must submit an ESP Payment Request (Form ESP–3) together with a paid tuition statement from the program sponsor.

ESP Payment Requests must be submitted within 90 days after the end of the course, which the recipient attended.

3. ESP recipients are encouraged to check with their tax advisors to determine whether an award constitutes taxable income under federal and state law.

D. Partner Grants

The compliance requirements for Partner Grant recipients will depend upon the agreements struck between the grant financiers and between lead financiers and grantees. Should SJI be the lead, the compliance requirements for Project Grants will apply, unless specific arrangements are determined by the Partners.

VII. Financial Requirements

A. Purpose

The purpose of this section is to establish accounting system requirements and offer guidance on procedures to assist all grantees, sub-grantees, contractors, and other organizations in:

1. Complying with the statutory requirements for the award, disbursement, and accounting of funds;
2. Complying with regulatory requirements of SJI for the financial management and disposition of funds;
3. Generating financial data to be used in planning, managing, and controlling projects; and
4. Facilitating an effective audit of funded programs and projects.

B. References

Except where inconsistent with specific provisions of this Grant Guideline, the following circulars are applicable to SJI grants and cooperative agreements under the same terms and conditions that apply to federal grantees. The circulars supplement the requirements of this section for accounting systems and financial record-keeping and provide additional guidance on how these requirements may be satisfied (circulars may be obtained on the OMB Web site at *www.whitehouse.gov/omb*).

1. *Office of Management and Budget (OMB) Circular A–21,* Cost Principles for Educational Institutions.
2. *Office of Management and Budget (OMB) Circular A–87,* Cost Principles for State and Local Governments.
3. *Office of Management and Budget (OMB) Circular A–102,* Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.
4. *Office of Management and Budget (OMB) Circular A–110,* Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations.
5. *Office of Management and Budget (OMB) Circular A–122,* Cost Principles for Non-profit Organizations.
6. *Office of Management and Budget (OMB) Circular A–133,* Audits of States, Local Governments and Non-profit Organizations.

C. Supervision and Monitoring Responsibilities

1. Grantee Responsibilities

All grantees receiving awards from SJI are responsible for the management and fiscal control of all funds. Responsibilities include accounting for receipts and expenditures, maintaining adequate financial records, and refunding expenditures disallowed by audits.

2. Responsibilities of the State Supreme Court

a. Each application for funding from a state or local court must be approved, consistent with state law, by the state supreme court, or its designated agency or council.

b. The state supreme court or its designee shall receive all SJI funds awarded to such courts; be responsible for assuring proper administration of SJI funds; and be responsible for all aspects of the project, including proper accounting and financial record-keeping by the subgrantee. These responsibilities include:

(1) Reviewing Financial Operations. The state supreme court or its designee should be familiar with, and periodically monitor, its sub-grantee's financial operations, records system, and procedures. Particular attention should be directed to the maintenance of current financial data.

(2) Recording Financial Activities. The sub-grantee's grant award or

contract obligation, as well as cash advances and other financial activities, should be recorded in the financial records of the state supreme court or its designee in summary form. Sub-grantee expenditures should be recorded on the books of the state supreme court or evidenced by report forms duly filed by the sub-grantee. Matching contributions provided by sub-grantees should likewise be recorded, as should any project income resulting from program operations.

(3) Budgeting and Budget Review. The state supreme court or its designee should ensure that each sub-grantee prepares an adequate budget as the basis for its award commitment. The state supreme court should maintain the details of each project budget on file.

(4) Accounting for Match. The state supreme court or its designee will ensure that sub-grantees comply with the match requirements specified in this Grant Guideline (see section VI.A.8.).

(5) Audit Requirement. The state supreme court or its designee is required to ensure that sub-grantees meet the necessary audit requirements set forth by SJI (see sections K. below and VI.A.3.).

(6) Reporting Irregularities. The state supreme court, its designees, and its sub-grantees are responsible for promptly reporting to SJI the nature and circumstances surrounding any financial irregularities discovered.

D. Accounting System

The grantee is responsible for establishing and maintaining an adequate system of accounting and internal controls and for ensuring that an adequate system exists for each of its sub-grantees and contractors. An acceptable and adequate accounting system:

1. Properly accounts for receipt of funds under each grant awarded and the expenditure of funds for each grant by category of expenditure (including matching contributions and project income);

2. Assures that expended funds are applied to the appropriate budget category included within the approved grant;

3. Presents and classifies historical costs of the grant as required for budgetary and evaluation purposes;

4. Provides cost and property controls to assure optimal use of grant funds;

5. Is integrated with a system of internal controls adequate to safeguard the funds and assets covered, check the accuracy and reliability of the accounting data, promote operational efficiency, and assure conformance with any general or special conditions of the grant;

6. Meets the prescribed requirements for periodic financial reporting of operations; and

7. Provides financial data for planning, control, measurement, and evaluation of direct and indirect costs.

E. Total Cost Budgeting and Accounting

Accounting for all funds awarded by SJI must be structured and executed on a ''Total Project Cost'' basis. That is, total project costs, including SJI funds, state and local matching shares, and any other fund sources included in the approved project budget serve as the foundation for fiscal administration and accounting. Grant applications and financial reports require budget and cost estimates on the basis of total costs.

1. Timing of Matching Contributions

Matching contributions should be applied at the same time as the obligation of SJI funds. Ordinarily, the full matching share must be obligated during the award period; however, with the written permission of SJI, contributions made following approval of the grant by the Board of Directors, but before the beginning of the grant, may be counted as match. If a proposed cash or in-kind match is not fully met, SJI may reduce the award amount accordingly to maintain the ratio of grant funds to matching funds stated in the award agreement.

2. Records for Match

All grantees must maintain records that clearly show the source, amount, and timing of all matching contributions. In addition, if a project has included, within its approved budget, contributions which exceed the required matching portion, the grantee must maintain records of those contributions in the same manner as it does SJI funds and required matching shares. For all grants made to state and local courts, the state supreme court has primary responsibility for grantee/sub-grantee compliance with the requirements of this section (see subsection C.2. above).

F. Maintenance and Retention of Records

All financial records, including supporting documents, statistical records, and all other information pertinent to grants, sub-grants, cooperative agreements, or contracts under grants, must be retained by each organization participating in a project for at least three years for purposes of examination and audit. State supreme courts may impose record retention and maintenance requirements in addition to those prescribed in this section.

1. Coverage

The retention requirement extends to books of original entry, source documents supporting accounting transactions, the general ledger, subsidiary ledgers, personnel and payroll records, canceled checks, and related documents and records. Source documents include copies of all grant and sub-grant awards, applications, and required grantee/sub-grantee financial and narrative reports. Personnel and payroll records shall include the time and attendance reports for all individuals reimbursed under a grant, sub-grant or contract, whether they are employed full-time or part-time. Time and effort reports are required for consultants.

2. Retention Period

The three-year retention period starts from the date of the submission of the final expenditure report.

3. Maintenance

Grantees and sub-grantees are expected to see that records of different fiscal years are separately identified and maintained so that requested information can be readily located. Grantees and sub-grantees are also obligated to protect records adequately against fire or other damage. When records are stored away from the grantee's/sub-grantee's principal office, a written index of the location of stored records should be on hand, and ready access should be assured.

4. Access

Grantees and sub-grantees must give any authorized representative of SJI access to and the right to examine all records, books, papers, and documents related to an SJI grant.

G. Project-Related Income

Records of the receipt and disposition of project-related income must be maintained by the grantee in the same manner as required for the project funds that gave rise to the income and must be reported to SJI (see subsection H.2. below). The policies governing the disposition of the various types of project-related income are listed below.

1. Interest

A state and any agency or instrumentality of a state, including institutions of higher education and hospitals, shall not be held accountable for interest earned on advances of project funds. When funds are awarded to sub-grantees through a state, the sub-

grantees are not held accountable for interest earned on advances of project funds. Local units of government and nonprofit organizations that are grantees must refund any interest earned. Grantees shall ensure minimum balances in their respective grant cash accounts.

2. Royalties

The grantee/sub-grantee may retain all royalties received from copyrights or other works developed under projects or from patents and inventions, unless the terms and conditions of the grant provide otherwise.

3. Registration and Tuition Fees

Registration and tuition fees may be considered as cash match with prior written approval from SJI. Estimates of registration and tuition fees, and any expenses to be offset by the fees, should be included in the application budget forms and narrative.

4. Income From the Sale of Grant Products

If the sale of products occurs during the project period, the income may be treated as cash match with the prior written approval of SJI. The costs and income generated by the sales must be reported on the Quarterly Financial Status Reports (Form F) and documented in an auditable manner. Whenever possible, the intent to sell a product should be disclosed in the application or reported to SJI in writing once a decision to sell products has been made. The grantee must request approval to recover its product development, reproduction, and dissemination costs as specified in section VI.A.11.b.

5. Other

Other project income shall be treated in accordance with disposition instructions set forth in the grant's terms and conditions.

H. Payments and Financial Reporting Requirements

1. Payment of Grant Funds

The procedures and regulations set forth below are applicable to all SJI grant funds and grantees.

a. Request for Reimbursement of Funds

Grantees will receive funds on a U.S. Treasury ''check-issued'' or electronic funds transfer (EFT) basis. Upon receipt, review, and approval of a Request for Reimbursement (Form R) by SJI, payment will be issued directly to the grantee or its designated fiscal agent. The Form R, along with the instructions for its preparation, and the SF 3881 Automated Clearing House (ACH/ Miscellaneous Payment Enrollment Form for EFT) are available on the Institute's Web site: *www.sji.gov/forms.*

b. Principle of Minimum Cash on Hand. Grantees should request funds based upon immediate disbursement requirements. Grantees should time their requests to ensure that cash on hand is the minimum needed for disbursements to be made immediately or within a few days.

2. Financial Reporting

a. General Requirements. To obtain financial information concerning the use of funds, the Institute requires that grantees/sub-grantees submit timely reports for review.

b. Due Dates and Contents. A Financial Status Report is required from all grantees, other than ESP award recipients, for each active quarter on a calendar-quarter basis. This report is due within 30 days after the close of the calendar quarter. It is designed to provide financial information relating to SJI funds, state and local matching shares, project income, and any other sources of funds for the project, as well as information on obligations and outlays. A copy of the Financial Status Report (Form F), along with instructions, are provided at www.sji.gov/forms. If a grantee requests substantial payments for a project prior to the completion of a given quarter, SJI may request a brief summary of the amount requested, by object class, to support the Request for Reimbursement.

3. Consequences of Non-Compliance With Submission Requirement

Failure of the grantee to submit required financial and progress reports may result in suspension or termination of grant payments.

I. Allowability of Costs

1. General

Except as may be otherwise provided in the conditions of a particular grant, cost allowability is determined in accordance with the principles set forth in *OMB Circulars A–21,* Cost Principles Applicable to Grants and Contracts with Educational Institutions; *A–87,* Cost Principles for State and Local Governments; and *A–122,* Cost Principles for Non-profit Organizations.

No costs may be recovered to liquidate obligations incurred after the approved grant period. Circulars may be obtained on the OMB Web site at *http://www.whitehouse.gov/omb.*

2. Costs Requiring Prior Approval

a. Pre-agreement Costs. The written prior approval of SJI is required for costs considered necessary but which occur prior to the start date of the project period.

b. Equipment. Grant funds may be used to purchase or lease only that equipment essential to accomplishing the goals and objectives of the project. The written prior approval of SJI is required when the amount of automated data processing (ADP) equipment to be purchased or leased exceeds $10,000 or software to be purchased exceeds $3,000.

c. Consultants. The written prior approval of SJI is required when the rate of compensation to be paid a consultant exceeds $800 a day. SJI funds may not be used to pay a consultant more than $1,100 per day.

d. Budget Revisions. Budget revisions among direct cost categories that (i) transfer grant funds to an unbudgeted cost category or (ii) individually or cumulatively exceed five percent (5%) of the approved original budget or the most recently approved revised budget require prior SJI approval (see section VIII.A.1.).

3. Travel Costs

Transportation and per diem rates must comply with the policies of the grantee. If the grantee does not have an established written travel policy, then travel rates must be consistent with those established by the federal government. SJI funds may not be used to cover the transportation or per diem costs of a member of a national organization to attend an annual or other regular meeting, or conference of that organization.

4. Indirect Costs

Indirect costs are only applicable to organizations that are not state courts or government agencies. These are costs of an organization that are not readily assignable to a particular project but are necessary to the operation of the organization and the performance of the project. The cost of operating and maintaining facilities, depreciation, and administrative salaries are examples of the types of costs that are usually treated as indirect costs. Although SJI's policy requires all costs to be budgeted directly, it will accept indirect costs if a grantee has an indirect cost rate approved by a federal agency. However, recoverable indirect costs are limited to no more than 75 percent of a grantee's direct personnel costs (salaries plus fringe benefits).

a. Approved Plan Available

(1) A copy of an indirect cost rate agreement or allocation plan approved for a grantee during the preceding two

years by any federal granting agency on the basis of allocation methods substantially in accord with those set forth in the applicable cost circulars must be submitted to SJI.

(2) Where flat rates are accepted in lieu of actual indirect costs, grantees may not also charge expenses normally included in overhead pools, e.g., accounting services, legal services, building occupancy and maintenance, etc., as direct costs.

J. Procurement and Property Management Standards

1. Procurement Standards

For state and local governments, SJI has adopted the standards set forth in Attachment O of *OMB Circular A–102.* Institutions of higher education, hospitals, and other non-profit organizations will be governed by the standards set forth in Attachment O of *OMB Circular A–110.*

2. Property Management Standards

The property management standards as prescribed in Attachment N of *OMB Circulars A–102* and *A–110* apply to all SJI grantees and sub-grantees except as provided in section VI.A.18. All grantees/sub-grantees are required to be prudent in the acquisition and management of property with grant funds. If suitable property required for the successful execution of projects is already available within the grantee or subgrantee organization, expenditures of grant funds for the acquisition of new property will be considered unnecessary.

K. Audit Requirements

1. Implementation

Each recipient of a Project Grant must provide for an annual fiscal audit. This requirement also applies to a state or local court receiving a sub-grant from the state supreme court. The audit may be of the entire grantee or sub-grantee organization or of the specific project funded by the Institute. Audits conducted in accordance with the Single Audit Act of 1984 and *OMB Circular A–133,* will satisfy the requirement for an annual fiscal audit. The audit must be conducted by an independent Certified Public Accountant, or a state or local agency authorized to audit government agencies. Grantees must send two copies of the audit report to the Institute. Grantees that receive funds from a federal agency and satisfy audit requirements of that federal agency must submit two copies of the audit report prepared for that federal agency to SJI in order to satisfy the provisions of this section.

2. Resolution and Clearance of Audit Reports

Timely action on recommendations by responsible management officials is an integral part of the effectiveness of an audit. Each grantee must have policies and procedures for acting on audit recommendations by designating officials responsible for: (1) Follow-up, (2) maintaining a record of the actions taken on recommendations and time schedules, (3) responding to and acting on audit recommendations, and (4) submitting periodic reports to SJI on recommendations and actions taken.

3. Consequences of Non-Resolution of Audit Issues

Ordinarily, SJI will not make a subsequent grant award to an applicant that has an unresolved audit report involving SJI awards. Failure of the grantee to resolve audit questions may also result in the suspension or termination of payments for active SJI grants to that organization.

L. Close-Out of Grants

1. Grantee Close-Out Requirements

Within 90 days after the end date of the grant or any approved extension thereof (see subsection L.2. below), the following documents must be submitted to SJI by grantees (other than ESP award recipients):

a. Financial Status Report. The final report of expenditures must have no unliquidated obligations and must indicate the exact balance of unobligated funds. Any unobligated/unexpended funds will be deobligated from the award by SJI. Final payment requests for obligations incurred during the award period must be submitted to the Institute prior to the end of the 90-day close-out period. Grantees who have drawn down funds in excess of their obligations/expenditures, must return any unused funds as soon as it is determined that the funds are not required. In no instance should any unused funds remain with the grantee beyond the submission date of the final Financial Status Report.

b. Final Progress Report. This report should describe the project activities during the final calendar quarter of the project and the close-out period, including to whom project products have been disseminated; provide a summary of activities during the entire project; specify whether all the objectives set forth in the approved application or an approved adjustment have been met and, if any of the objectives have not been met, explain why not; and discuss what, if anything, could have been done differently that might have enhanced the impact of the project or improved its operation. These reporting requirements apply at the conclusion of every grant other than an ESP award.

2. Extension of Close-Out Period

Upon the written request of the grantee, SJI may extend the close-out period to assure completion of the grantee's close-out requirements. Requests for an extension must be submitted at least 14 days before the end of the close-out period and must explain why the extension is necessary and what steps will be taken to assure that all the grantee's responsibilities will be met by the end of the extension period

VIII. Grant Adjustments

All requests for programmatic or budgetary adjustments requiring Institute approval must be submitted by the project director in a timely manner (ordinarily 30 days prior to the implementation of the adjustment being requested). All requests for changes from the approved application will be carefully reviewed for both consistency with this Grant Guideline and the enhancement of grant goals and objectives. Failure to submit adjustments in a timely manner may result in the termination of a grantee's award.

A. Grant Adjustments Requiring Prior Written Approval

The following grant adjustments require the prior written approval of SJI:

1. Budget revisions among direct cost categories that (a) transfer grant funds to an unbudgeted cost category or (b) individually or cumulatively exceed five percent (5%) of the approved original budget or the most recently approved revised budget (see section VII.I.2.d.).

2. A change in the scope of work to be performed or the objectives of the project (see subsection D. below).

3. A change in the project site.

4. A change in the project period, such as an extension of the grant period and/or extension of the final financial or progress report deadline (see subsection E. below).

5. Satisfaction of special conditions, if required.

6. A change in or temporary absence of the project director (see subsections F. and G. below).

7. The assignment of an employee or consultant to a key staff position whose qualifications were not described in the

application, or a change of a person assigned to a key project staff position (see section VI.A.2.).

8. A change in or temporary absence of the person responsible for managing and reporting on the grant's finances.

9. A change in the name of the grantee organization.

10. A transfer or contracting out of grant-supported activities (see subsection H. below).

11. A transfer of the grant to another recipient.

12. Pre-agreement costs (see section VII.I.2.a.).

13. The purchase of automated data processing equipment and software (see section VII.I.2.b.).

14. Consultant rates (see section VII.I.2.c.).

15. A change in the nature or number of the products to be prepared or the manner in which a product would be distributed.

B. Requests for Grant Adjustments

All grantees must promptly notify SJI, in writing, of events or proposed changes that may require adjustments to the approved project design. In requesting an adjustment, the grantee must set forth the reasons and basis for the proposed adjustment and any other information the program manager determines would help SJI's review.

C. Notification of Approval/Disapproval

If the request is approved, the grantee will be sent a Grant Adjustment signed by the SJI Executive Director. If the request is denied, the grantee will be sent a written explanation of the reasons for the denial.

D. Changes in the Scope of the Grant

Major changes in scope, duration, training methodology, or other significant areas must be approved in advance by SJI. A grantee may make minor changes in methodology, approach, or other aspects of the grant to expedite achievement of the grant's objectives with subsequent notification to SJI.

E. Date Changes

A request to change or extend the grant period must be made at least 30 days in advance of the end date of the grant. A revised task plan should accompany a request for an extension of the grant period, along with a revised budget if shifts among budget categories will be needed. A request to change or extend the deadline for the final financial report or final progress report must be made at least 14 days in advance of the report deadline (see section VII.L.2.).

F. Temporary Absence of the Project Director

Whenever an absence of the project director is expected to exceed a continuous period of one month, the plans for the conduct of the project director's duties during such absence must be approved in advance by the Institute. This information must be provided in a letter signed by an authorized representative of the grantee/sub-grantee at least 30 days before the departure of the project director, or as soon as it is known that the project director will be absent. The grant may be terminated if arrangements are not approved in advance by SJI.

G. Withdrawal of/Change in Project Director

If the project director relinquishes or expects to relinquish active direction of the project, SJI must be notified immediately. In such cases, if the grantee/sub-grantee wishes to terminate the project, SJI will forward procedural instructions upon notification of such intent. If the grantee wishes to continue the project under the direction of another individual, a statement of the candidate's qualifications should be sent to SJI for review and approval. The grant may be terminated if the qualifications of the proposed individual are not approved in advance by SJI.

H. Transferring or Contracting Out of Grant-Supported Activities

No principal activity of a grant-supported project may be transferred or contracted out to another organization without specific prior approval by SJI. All such arrangements must be formalized in a contract or other written agreement between the parties involved. Copies of the proposed contract or agreement must be submitted for prior approval of SJI at the earliest possible time. The contract or agreement must state, at a minimum, the activities to be performed, the time schedule, the policies and procedures to be followed, the dollar limitation of the agreement, and the cost principles to be followed in determining what costs, both direct and indirect, will be allowed. The contract or other written agreement must not affect the grantee's overall responsibility for the direction of the project and accountability to SJI.

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Jonathan D. Mattiello,

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[FR Doc. 2013–25461 Filed 10–28–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Change in Use of Aeronautical Property at Bowman Field Airport, Louisville, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comment.

SUMMARY: The Federal Aviation Administration is requesting public comment on request by the Louisville Regional Airport Authority to temporarily change a portion of airport property from aeronautical to non-aeronautical use at the Bowman Field Airport, Louisville, Kentucky. The request consists approximately of 0.41 acres of temporary use. This action is taken under the provisions of Section 125 of the Wendell H. Ford Aviation Investment Reform Act for the 21st Century (AIR 21).

DATES: Comments must be received on or before November 29, 2013.

ADDRESSES: Documents are available for review at the Louisville Regional Airport Authority, 700 Administration Drive, Louisville, KY 40209; and the FAA Memphis Airports District Office, 2600 Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. Written comments on the Sponsor's request must be delivered or mailed to: Mr. Phillip J. Braden, Manager, Memphis Airports District Office, 2600

Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482.

In addition, a copy of any comments submitted to the FAA must be mailed or delivered to Mr. Charles T. Miller, Executive Director, Louisville Regional Airport Authority, P.O. Box 9129, Louisville, KY 40209.

FOR FURTHER INFORMATION CONTACT: Mr. Tommy L. Dupree, Team Lead/Civil Engineer, Federal Aviation Administration, Memphis Airports District Office, 2600, Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. The application may be reviewed in person at this same location, by appointment.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the request to lease property for non-aeronautical purposes at Bowman Field Airport, Louisville, KY 42103. Under the provisions of AIR 21 (49 U.S.C. 47107(h)(2)).

On September 30, 2013, the FAA determined that the request to lease property for non-aeronautical purposes at Bowman Field Airport meets the procedural requirements of the Federal Aviation Administration. The FAA may approve the request, in whole or in part, no later than November 29, 2013.

The following is a brief overview of the request:

The Louisville Regional Airport Authority is proposing the lease of approximately 0.41 acres, a partial of Parcel 48, bounded by Roger E. Schupp Street to the north, Dutchman's Lane to the south, Tucker Boulevard to the east, and Gast Boulevard to the west. The non-aeronautical lease is for a period of 5 (five) years, with an option of 5 (five) years that can be exercised by the airport authority. The non-aeronautical lease is for the purpose of leasing said property to an adjacent land owner, The Jewish Family & Career Services of Louisville, Inc., to be used as a parking lot.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

Issued in Memphis, TN on September 30, 2013.

Phillip J. Braden,

Manager, Memphis Airports District Office, Southern Region.

[FR Doc. 2013–25585 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on the Stehekin Valley Road Improvement Project From the Stehekin River Corridor Implementation Plan: Chelan County, Washington

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT) and other Federal agencies.

ACTION: Notice of Limitations on Claims for Judicial Review of Actions by FHWA and other Federal agencies.

SUMMARY: This notice announces final environmental actions taken by the FHWA, the National Park Service (NPS), the United States Fish and Wildlife Service (USF&WS), and other Federal agencies that are final within the meaning of 23 U.S.C. § 139(*l*)(1). The actions relate to the Stehekin Valley Road Improvement project from the Stehekin River Corridor Implementation Plan in Chelan County, Washington. This action grants approval for the road improvement project element of the plan.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the roadway project will be barred unless the claim is filed on or before March 28, 2014. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Michelle Eraut, Acting Environmental Program Manager, FHWA, 610 East 5th Street, Vancouver, WA, Telephone: (360) 619–7967. For the NPS: Roy M. Zipp, Environmental Protection Specialist, North Cascades National Park, 810 State Route 20, Sedro-Wolley, WA 98284, Telephone: 360–854–7313. For the USF&WS, Greg Kurz, Central Washington Field Office, 215 Melody Lane, Suite 119, Wenatchee, WA 98801, Telephone: (509) 665–3508. The FHWA Stehekin Valley Road Improvement Project Record of Decision, NPS Stehekin River Corridor Implementation Plan Environmental Impact Statement (EIS) and Record of Decision (ROD), is available upon written request from the Federal Highway Administration at the address shown above. Comments or questions concerning this proposed action should be directed to the FHWA at the address provided above.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA, has taken final agency action subject to 23 U.S.C. § 139(*l*)(1) by issuing approval for the following highway project in the State of Washington: Stehekin Valley Road Improvement Project. The project is a component of the Stehekin River Corridor Implementation Plan (Plan) in the Lake Chelan National Recreation Area for which the U.S. Department of Interior National Park Service issued a Record of Decision dated March 13, 2013. FHWA served as a cooperating agency in the development of the EIS, and issued a FHWA Record of Decision, dated September 27, 2013. FHWA-administered funds will be used for the project and FHWA will administer the construction contact. The project will realign 1.8 miles of the existing 10 mile alignment, moving this section outside of the Stehekin River's channel migration zone to reduce flooding by the river and, consequently, the threat to public safety and access and maintenance costs. Another 7.4 miles of the road will undergo minor improvements including resurfacing and culvert replacement within the existing roadway prism. In addition, a 1200-foot long connector road will be built to provide access between the realigned portion of the road and the existing alignment. The actions by the Federal agencies and the laws under which such actions were taken are described in the Record of Decision issued on September 27, 2013. The NPS EIS, NPS ROD, and the FHWA ROD, are available by contacting the FHWA at the address provided above. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C 4321–4347]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; Section 6(f) of the Land and Water Conservation Fund Act (LWCF) [16 U.S.C. 460*l*–4—460*l*–11.].

4. *Wildlife:* Section 7 of the Endangered Species Act [16 U.S.C. 1531–1544]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667 (e)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16

U.S.C. 470aa–mm]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996].

7. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251–1376]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j–26)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Wetlands Mitigation [23 U.S.C. 103(b)(6)(M) and 133(b)(11)].

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites, E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1)

Issued On: October 11, 2013.

Clara H. Conner,

Division Engineer, Vancouver, WA.

[FR Doc. 2013–24966 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on US 26: MP 49.20–MP 57.45 Project: Clackamas County, OR

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of Limitations on Claims for Judicial Review of Actions by FHWA, United States Army Corps of Engineers (USACE), United States Forest Service (USFS), United States Fish & Wildlife Service (USF&WS), and other Federal agencies.

SUMMARY: This notice announces final environmental actions taken by the FHWA, USACE, USFS, USF&WS, NMFS and other Federal agencies that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway project, US 26: MP 49.20–MP 57.45. This action grants approval for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before March 28, 2014. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA, Michelle Eraut, Program Development Team Leader, Federal Highway Administration, 530 Center Street NE., Suite 420, Salem, Oregon 97301, Telephone: (503) 587–4716. The US 26: MP 49.20–MP 57.45 categorical exclusion is available upon written request from the Federal Highway Administration at the address shown above. Comments or questions concerning this proposed action and the US 26: MP 49.20–MP 57.45 should be directed to the FHWA at the address provided above. For USACE, Dominic Yballe, Regulatory Project Manager, (503) 808–4392, 333 SW. 1st Avenue, Portland, Oregon 97208–2946. For USFS, Bill Westbrook, Zigzag District Ranger, (503) 622–2001, 70220 E. Highway 26, Zigzag, Oregon 97049. For USF&WS, Kevin Maurice, (503) 231–6179, Wildlife Biologist, 2600 SE. 98th Avenue, Suite 100, Portland, Oregon 97266.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has taken final agency action subject to 23 U.S.C. 139(*l*)(1) by issuing approval for the following highway project in the State of Oregon: US 26: MP 49.20–MP 57.45. The project will improve safety along US 26 between Mile Point 49.2 and Mile Point 57.45 by enlarging an existing rock fall catchment area and widening the highway to extend existing passing lanes and install new median barrier. The project will preserve the existing pavement by removing the top 2 to 3 inches of the existing asphalt concrete pavement, recycling it, and repaving it back to the original grade line of the roadway. The actions by the Federal agencies and the laws under which such actions were taken are described in the categorical exclusion issued on August 22, 2013. The categorical exclusion is available by contacting the FHWA at the address provided above. The USACE permit (USACE Permit NWP–2012–510, issued April 5, 2013) is available by contacting USACE at the address provided above. The USFS Finding of Consistency with the Forest Plan issued on July 3, 2013, is available by contacting the USFS at the address provided above. The USF&WS Not Likely to Adversely Affect letter for Northern Spotted Owl issued on June 13, 2013, is available by contacting the USF&WS at the address above. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C 4321–4347]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; Section 6(f) of the Land and Water Conservation Fund Act (LWCF) [16 U.S.C. 460*l*–4—460*l*–11].

4. *Wildlife:* Section 7 of the Endangered Species Act [16 U.S.C. 1531–1544]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667 (e)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470aa-mm]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251–1376]; Wetlands Mitigation [23 U.S.C. 103(b)(6)(M) and 133(b)(11)].

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites, E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. § 139(*l*)(1)

Issued On: October 9, 2013.

Phillip A. Ditzler,

Division Administrator, Salem, Oregon.

[FR Doc. 2013–24960 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Final Federal Agency Actions on Proposed Highway in North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. § 139(l)(1). The actions relate to a proposed highway project, I–77 High Occupancy/Toll (HOT) lanes, from I–277 (Brookshire Freeway—Exit 11) to NC 150 (Exit 36), Mecklenburg and Iredell Counties, North Carolina. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filled on or before March 28, 2014. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. Clarence W. Coleman, P. E., Preconstruction and Environment Director, Federal Highway Administration, 310 New Bern Avenue, Suite 410, Raleigh, North Carolina, 27601–1418; Telephone: (919) 747–7014; email: *clarence.coleman@dot.gov.* FHWA North Carolina Division Office's normal business hours are 8 a.m. to 5 p.m. (Eastern Time). Mr. Richard W. Hancock., Project Development and Environmental Analysis Branch Manager, North Carolina Department of Transportation (NCDOT), 1548 Mail Service Center, Raleigh, North Carolina 27699–1548; Telephone (919) 707–6000, email: *rwhancock@dot.state.nc.us.* NCDOT—Project Development and Environmental Analysis Branch Office's normal business hours are 8 a.m. to 5 p.m. (Eastern Time).

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency action subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of North Carolina: I–77 High Occupancy/Toll (HOT) lanes, Federal Aid No. NHS–077–1(210), NHF–077–1(209)9, and IMF–1(183)299 from I–277 (Brookshire Freeway—Exit 11) to NC 150 (Exit 36) in the city and towns of Charlotte, Huntersville, Cornelius, and Davidson, Mecklenburg County, North Carolina and the Town of Mooresville in Iredell County, North Carolina. The project is also known as State Transportation Improvement Program (STIP) Projects I–3311C, I–5405, and I–4750AA. The project is approximately 26 miles long and includes the following actions:

(1) I–3311C—Construct two HOT lanes along I–77 from just north of the I–77/I–85 interchange (connecting to I–5405 HOT lane project) to and along I–277.

a. *Southbound I–77*—Construct one HOT lane from the southern terminus of the existing southbound HOT lane (south of I–85) to I–277; construct an additional HOT lane southbound from the southern terminus of I–5405 (north of I–85/I–77 interchange) to I–277.

b. *Northbound I–77*—Construct two HOT lanes northbound from I–277 to northbound southern terminus of I–5405 (north of I–85).

c. *Both directions of I–277*—Construct one HOT lane in each direction from I–77 to North Brevard Street (with HOT lane designation beginning and ending at North Tryon Street).

(2) I–5405—I–77 from I–277 (Brookshire Freeway) to Exit 28; convert existing HOV lanes to HOT lanes and extend northward to Exit 28. Add additional HOT lane in each direction beginning at I–85 to Exit 28 for a total of 2 HOT lanes in each direction.

(3) I–4750AA—Construct one HOT lane in each direction along I–77 from Exit 28 (connecting to I–5405 HOT lane project) to Brawley School Road (Exit 35), with construction ending approximately 5,500 feet north of the NC 150 bridge (Exit 36). Northbound and southbound HOT designations begin and end at Brawley School Road (Exit 35).

(4) Designation of HOT lanes as HOT 3+.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Finding of No Significant Impact (FONSI) for the project, approved on October 16, 2013, and in other documents in the FHWA administrative record. The FONSI and other documents in the FHWA administrative record file are available by contacting the FHWA or NCDOT at the addresses provided above.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

4. *Wildlife:* Endangered Species Act [16 USC 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Anadromous Fish Conservation Act [16 U.S.C. 757(a)-757(g)], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712], Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801 et seq.].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) et seq.]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)-2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act (Section 404, Section 401, Section 319) [33 U.S.C. 1251–1377]; Coastal Barrier Resources Act [16 U.S.C. 3501–3510]; Coastal Zone Management Act [16 U.S.C. 1451–1465]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)-300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; TEA–21 Wetlands Mitigation [23 U.S.C.

103(b)(6)(m), 133(b)(11)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

8. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA; 42 U.S.C. 11011 et seq.); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

9. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species; and E.O. 13186—Responsibilities of Federal Agencies to Protect Migratory Birds.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1)

Issued on: October 23, 2013.

Clarence W. Coleman,

Preconstruction and Environment Director, Raleigh, North Carolina.

[FR Doc. 2013–25606 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Illinois

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 USC § 139(l)(1). The actions relate to a proposed highway project, Circle Interchange, I–90/I–94 and I–290/Congress Parkway in Cook County, Illinois. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C .139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before March 28, 2014. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Ms. Catherine A. Batey, Division Administrator, Federal Highway Administration, 3250 Executive Park Drive, Springfield, Illinois 62703, Phone: (217) 492–4640, Email address: *Catherine.Batey@dot.gov.* The FHWA Illinois Division Office's normal business hours are 7:30 a.m. to 4:15 p.m. You may also contact Mr. John A. Fortmann, P.E., Illinois Department of Transportation, Deputy Director of Highways, Region One Engineer, 201 West Center Court, Schaumburg, Illinois 60196, Phone: (847) 705–4000. The Illinois Department of Transportation Region One's normal business hours are 8:00 a.m. to 4:15 p.m.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the following highway project in the State of Illinois: reconstruct and widen the Circle Interchange, I–90/I–94 and I–290/Congress Parkway, a total project length of approximately 2.7 miles including two new flyover ramps and nine cross street bridges. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) for the project approved on June 11, 2013 the Finding of No Significant Impact (FONSI) issued on September 17, 2013; and in other documents in the FHWA administrative record. The EA, FONSI, and other documents in the FHWA administrative record file are available by contacting the FHWA or the Illinois Department of Transportation at the addresses provided above. The EA and FONSI and all other supporting documentation can be viewed and downloaded from the project Web site at *www.circleinterchange.org.*

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351] Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. Air: Clean Air Act [42 U.S.C. 7401–7671(q)].

3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303 and 23 U.S.C. 138].

4. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)].

5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archaeological and Historic Preservation Act (AHPA) [16 U.S.C. 469–469(c)].

6. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

7. Wetlands and Water Resources: Clean Water Act (Section 401 and 404) [33 U.S.C. 1251–1377]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287].

8. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: September 25, 2013.

Catherine A. Batey,

Division Administrator, Springfield, Illinois.

[FR Doc. 2013–24969 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2013 0114]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel WEATHERVANE; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before November 29, 2013.

ADDRESSES: Comments should refer to docket number MARAD–2013–0114. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel WEATHERVANE is:

Intended Commercial Use of Vessel: ''Private 1.5 hour harbor tours for up to 6 paying persons''

Geographic Region: ''Massachusetts''

The complete application is given in DOT docket MARAD–2013–0114 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR Part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.

Dated: October 22, 2013.

Julie P. Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2013–25414 Filed 10–28–13; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. MCF 21055]

Celerity Partners IV, LLC, Celerity AHI Holdings SPV, LLC, and All Aboard America! Holdings, Inc.—Control—Sureride Charter Inc. d/b/a Sundiego Charter Company

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice tentatively authorizing finance transaction.

SUMMARY: All Aboard America! Holdings, Inc. (AHI), Celerity AHI Holdings SPV, LLC (Celerity Holdings), and Celerity Partners IV, LLC (Celerity Partners) (collectively, Applicants) have filed an application under 49 U.S.C. 14303 for their acquisition of control of Sureride Charter, Inc. d/b/a Sundiego Charter Company (Sundiego). The Board is tentatively approving and authorizing the transaction, and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules at 49 CFR 1182.5 and 1182.8.[1]

DATES: Comments must be filed by December 13, 2013. Applicants may file a reply by December 30, 2013. If no comments are filed by December 13, 2013, this notice shall be effective on December 14, 2013.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MCF 21055 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send copies of comments to Applicant's representative: Mark J. Andrews, Strasburger & Price, LLP, Suite 640, 1700 K Street NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Jonathon Binet, (202) 245–0368. Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.

SUPPLEMENTARY INFORMATION: AHI is a noncarrier corporation established under the laws of Delaware. A plurality of AHI's stock is held by a group of investors participating in Celerity Holdings, a noncarrier limited liability company organized under the laws of Delaware. Celerity Partners, the managing member of Celerity Holdings, is also a noncarrier limited liability company organized under the laws of Delaware. Applicants currently control two carriers, Hotard Coaches, Inc. (Coaches) and Industrial Bus Lines, Inc. d/b/a All Aboard America! (Industrial).[2] Coaches and Industrial hold authority from the Federal Motor Carrier Safety Administration (FMCSA) as motor carriers of passengers (license nos. MC–143881 and MC–133171, respectively). Coaches operates in Louisiana and southern Mississippi, while Industrial operates in Arizona, New Mexico, and Texas.

Sundiego is a California corporation and is controlled through stock ownership by Richard and Beverly Ann Illes (Mr. and Mrs. Illes), noncarrier individuals residing in California. Sundiego holds authority from the FMCSA as a motor carrier of passengers (MC–324772) and holds an intrastate registration from the California Public Utilities Commission (CPUC) as a Class B charter-party carrier of passengers. Applicants state that Sundiego operates 58 full-sized motor coaches and 9 smaller vehicles (including minibuses, vans, and a limousine). According to Applicants, Sundiego conducts charter, sightseeing, and various types of shuttle operations for a variety of customers out of its headquarters in National City, Cal., a suburb of San Diego. Applicants state that these operations are conducted to, from, and within California and adjoining states, as well as to Mexico. Applicants indicate that 65 percent of Sundiego's revenues are derived from contracted transit and dedicated shuttle operations, with the remainder from charter operations. Of those charter operations, airport transfers account for 10 percent and cruise ship transfers account for 4 percent of Sundiego's revenues.[3]

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[1] Due to the Government shutdown, this notice was not able to be published in the **Federal Register** within 30 days after the application was received. All dates and deadlines in this notice will be calculated based on the date of publication, October 29, 2013.

[2] *See Celerity Partners IV, LLC, Celerity AHI Holdings SPV, LLC, and All Aboard America! Holdings, Inc.—Control—Calco Travel, Inc., Hotard Coaches, Inc., and Industrial Bus Lines, Inc. d/b/a All Aboard America!,* MCF 21044 (STB served May 11, 2012).

[3] Applicants note that Sundiego also holds authority to operate a network of interstate regular route motor passenger common carrier operations

Under the proposed transaction, Applicants seek permission for AHI (and for Celerity Holdings and Celerity Partners indirectly) to acquire 100 percent control of Sundiego through a stock purchase agreement (SPA) between AHI and Mr. and Mrs. Illes. According to Applicants, top management at Sundiego would remain involved in the business after the acquisition, and Mr. and Mrs. Illes would become minority shareholders in AHI. Applicants state that closing of the proposed transaction is scheduled on or about December 10, 2013, if Board approval is obtained by then.

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds consistent with the public interest, taking into consideration at least: (1) The effect of the proposed transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees. Applicants have submitted information, as required by 49 CFR 1182.2, including the information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that Applicants' motor passenger carriers and Sundiego's aggregate gross operating revenues for the preceding 12 months exceeded $2 million, *see* 49 U.S.C. 14303(g).

With respect to the effect of the transaction on the adequacy of transportation to the public, Applicants state that the proposed acquisition would have no significant impact because Applicants do not intend to change substantially the physical operations historically conducted by Sundiego. Rather, Applicants anticipate enhancing operations by implementing vehicle sharing arrangements, by providing coordinated driver training and safety management services, and by centralizing various management support functions. With respect to fixed charges, Applicants state that their control of Sundiego would generate economies of scale that would reduce a variety of unit costs and that, with its increased market position, Applicants would be able to access financing on more favorable terms. In addition to better interest rates, Applicants expect that the combined carriers would be able to enhance modestly their volume purchasing power, thus reducing insurance premiums and achieve deeper volume discounts for equipment and fuel. Applicants state that the transaction would have a positive impact on employee interests, as the economies and efficiencies resulting from the proposed acquisition would directly benefit Sundiego's employees by maintaining job security and retaining or expanding the volume of available work.

Applicants further state that the acquisition would have no adverse impact on competition, because the geographic markets in which Sundiego and Coaches/Industrial compete are adjacent, but do not significantly overlap. Industrial's primary service areas in Arizona, New Mexico, and Texas are west of Sundiego's California-based market. Applicants note that round trips generated by each carrier might extend into overlapping states, but the beginning and end points seldom, if ever, overlap between Sundiego and Coaches/Industrial. Applicants also state that Sundiego faces other competition in both charter and shuttle services in San Diego and Los Angeles. Further, Applicants note that services provided under contract and on a ''spot basis'' also face competition from local and nationwide operators. Applicants state that competition includes five locally-based carriers, three carriers in the Los Angeles area, and four large nationwide providers of service.

On the basis of the application, the Board finds that the proposed acquisition is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective December 14, 2013, unless opposing comments are filed by December 13, 2013.

4. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590.

Decided: October 23, 2013.

By the Board, Chairman Elliott, Vice Chairman Begeman, and Commissioner Mulvey.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2013–25582 Filed 10–28–13; 8:45 am]

BILLING CODE 4915–01–P

involving the points of Los Angeles, El Paso, Las Vegas, and Denver. Applicants state that, because Sundiego does not currently operate any of these routes, they intend to file to have that authority revoked.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35774]

Youngstown & Southeastern Railway Company—Operation Exemption—Mule Sidetracks, L.L.C.

Youngstown & Southeastern Railway Company (Y&SR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to continue to operate a line of railroad that extends 35.7 miles between milepost 0.0 in Youngstown, Ohio, and milepost 35.7 in Darlington, Pa. (the Line). The Line is currently owned by Columbiana County Port Authority (CCPA) and has been operated by Y&SR under a lease from CCPA. In addition, Y&SR will operate as an agent of, and in the name of, Mule Sidetracks, L.L.C. (MSLLC), three miles of contiguous track segments, running east of milepost 0.0 and connecting to the Line, that are being permanently assigned by CCPA to MSLLC and will facilitate interchange with Norfolk Southern Railway Company (NSR) and CSX Transportation, Inc. (CSXT).[1]

[1] These operating rights are found in the following agreements: (1) Overhead Trackage Rights Agreement dated May 7, 2001, between Ohio & Pennsylvania Railroad Company (OHPA) and Central Columbiana & Pennsylvania Railway, Inc. (CQPA), to which CCPA is successor; (2) Letter Agreement regarding yard operations dated November 30, 2001, between OHPA, CQPA, and CCPA; (3) Interchange Agreement dated July 23, 2002, as amended and in effect, among CSXT, OHPA, and CQPA and Interline Service Agreement, effective April 1, 2004, between CSXT and CQPA, to which CCPA is successor; (4) Land Lease dated August 8, 2003, between CSXT and CQPA, which was assumed by CCPA, effective January 3, 2006; (5) Interchange Agreement dated May 1, 2001, and

Continued

This transaction is related to a verified notice of exemption filed in *Mule Sidetracks, L.L.C.—Acquisition Exemption—Columbiana County Port Authority,* FD 35773, by which MSLLC seeks an exemption to acquire from CCPA the Line as well as assignment of CCPA's agreements and operating rights to the three miles of connecting track east of milepost 0.0.

The transaction may be consummated on or after November 12, 2013, the effective date of the exemption.[2]

Y&SR certifies that its projected annual revenues as a result of this transaction will not exceed $5 million annually and will not result in Y&SR becoming a Class I or Class II carrier.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than November 5, 2013 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35774, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on John D. Heffner, Strasburger & Price, LLP, 1700 K Street NW., Suite 640, Washington, DC 20006.

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV*''.

Decided: October 24, 2013.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2013–25565 Filed 10–28–13; 8:45 am]

BILLING CODE 4915–01–P

Interline Service Agreement, effective October 5, 2004, between CQPA and NSR, to which CCPA is successor; (6) Easements granted by Allied Erecting & Dismantling Company, Inc. to The Pittsburgh and Lake Erie Railroad Company by agreements dated June 3, 1992, and November 10, 1993, and easements retained by PLE in deeds dated June 3, 1992, and November 10, 1993, from PLE to Allied (Allied Easements), which Allied Easements were conveyed by Youngstown and Southern Railway Company to Railroad Ventures, Inc. (RVI) by deed dated November 8, 1996, and by RVI to CCPA by deed dated January 23, 2001, and were included in the rights granted to CQPA by CCPA, including rights over the C.P. Graham Interlocking, and which collective rights were also conferred on CCPA by order of the Bankruptcy Court dated March 28, 2002, in *In re: Pittsburgh & Lake Erie Properties, Inc.,* Case No. 96–406, and to which CCPA is successor; and (7) Operating Rights Agreement between Matteson Equipment Company (Matteson) and CQPA; and Operating Rights Agreement between Eastern States Railroad, LLC (ESR) and Matteson dated July 14, 2006, to which CCPA is successor.

[2] This notice was scheduled to be published in the **Federal Register** during the time that the agency was closed due to a lapse in appropriations. Because publication of this notice has been delayed, the effective date of the exemption will also be delayed to provide adequate notice to the public.

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Bank Enterprise Award (BEA) Program; Programmatic and Administrative Aspects; Public Comment Request

AGENCY: Community Development Financial Institutions Fund, Department of the Treasury.

ACTION: Request for public comment.

SUMMARY: This notice invites comments from the public on certain programmatic and administrative aspects of the Community Development Financial Institutions Fund's (CDFI Fund) Bank Enterprise Award (BEA) Program, pursuant to the BEA Program regulations set forth at 12 CFR part 1806 (the Interim Rule). All materials submitted will be available for public inspection and copying.

DATES: All comments and submissions must be received by December 30, 2013.

ADDRESSES: Comments should be sent by mail to: CDFI Fund, BEA Program Office, U.S. Department of the Treasury, 1500 Pennsylvania Ave., NW., Washington, DC 20220; by email to *bea@cdfi.treas.gov;* or by facsimile at (202) 508–0089. This is not a toll free number.

FOR FURTHER INFORMATION CONTACT: Information regarding the CDFI Fund and its programs may be downloaded from the CDFI Fund's Web site at *http://www.cdfifund.gov.*

SUPPLEMENTARY INFORMATION: Through the BEA Program, the CDFI Fund encourages Insured Depository Institutions to increase their activities in the form of loans, investments, services, and technical assistance provided within Distressed Communities, as well as investments in Community Development Financial Institutions (CDFIs) through grants, stock purchases, loans, deposits, and other forms of financial and technical assistance. The increase in these activities is measured from a Baseline Period to an Assessment Period. Each capitalized term used in this Request for Public Comments is more fully defined either in the Interim Rule or the Notice of Funds Availability for the FY 2013 BEA Program award round (**Federal Register**/Vol. 78, No.109) (the NOFA). Through this notice, the CDFI Fund is seeking comments from the public regarding certain programmatic and administrative aspects of the CDFI Fund's BEA Program. Commentators are encouraged to consider, at a minimum, the following topics:

I. Eligibility

A. *CRA Rating:* The Community Reinvestment Act (CRA) encourages and examines efforts to service the banking needs of low- and moderate-income communities. The CDFI Fund considers a financial institution's CRA rating a key indicator of its efforts to serve the communities that it does business in and the effectiveness of those efforts in providing access to financial products and services to businesses and residents of those communities, including low-and-moderate income communities.

As stated in Section VII ''Application Review Information'' of the NOFA, the CDFI Fund may choose not to approve a BEA Program award at the time of application if the Applicant and/or its affiliates' most recent overall CRA assessment rating is below ''Satisfactory.'' This determination is made during the review of the application.

The CDFI Fund is considering making this an ''Eligibility'' requirement (Section III of the NOFA). If implemented, Section III of the NOFA would inform prospective Applicants that a CRA rating of below ''Satisfactory'' during the Baseline Period or the Assessment Period of the applicable BEA Program award round will result in ineligibility.

1. Should the CDFI Fund consider an Applicant ineligible if the Applicant's CRA rating is below ''Satisfactory'' and the CRA examination date was within the applicable Baseline or Assessment Period? If so, please indicate why. If not, please provide a specific reason why not.

2. Should the CDFI Fund consider an Applicant ineligible if the Applicant's most recent CRA rating is below ''Satisfactory'' but the CRA examination date was prior to the applicable Baseline or Assessment Period? If so, please indicate why. If not, please provide a specific reason why not.

3. Should the CDFI Fund perform additional due diligence to obtain an update on the status or progress made by the Applicant to improve its CRA rating prior to making an eligibility determination? If so, in which of the two scenarios above should additional due diligence be performed? Should that information be self-reported by the

Applicant, or provided directly by its Appropriate Federal Banking Regulatory Agency?

B. *Financial Health:* The BEA Program requires award recipients to deploy an amount equivalent to the award received in additional Qualified Activities in the calendar year following the receipt of the award. This requirement ensures that all BEA Program award proceeds are directly invested in distressed communities. Award recipients must remain in operation in order for their BEA Program award proceeds to be successfully deployed in Distressed Communities. Therefore, the financial health of an Applicant is an important factor in making an award determination. The CDFI Fund considers an audit opinion a key indicator of the financial health of an Applicant.

As stated in Section VII ''Application Review Information'' of the NOFA, the CDFI Fund may choose not to approve a BEA Program Award at the time of application if the Applicant received a going concern opinion on its most recent audit. This determination is made during the review of the application.

The CDFI Fund is considering making this an ''Eligibility'' requirement (Section III of the NOFA). If implemented, Section III of the NOFA would inform prospective Applicants that a going concern audit opinion during the Baseline Period or the Assessment Period of the applicable BEA Program award round will result in ineligibility.

1. Should the CDFI Fund consider an Applicant ineligible to apply for a BEA Program award if the Applicant received a going concern on its most recent audit report? If not, please provide a specific reason why not.

2. Is there additional financial health information that the CDFI Fund should consider in making eligibility determinations? If so, please describe.

II. Additional Program Considerations

A. *Integrally Involved Certified-CDFIs:* The Interim Rule defines CDFI Support Activity as assistance provided by an Applicant or its Subsidiary to a certified CDFI that meets criteria set forth by the CDFI Fund in the applicable NOFA, that is Integrally Involved in a Distressed Community. The NOFA defines Integrally Involved as having provided: (i) At least 10 percent of financial transactions or dollars transacted (e.g., loans or Equity Investments as defined in 12 CFR 1805.104(t)), or 10 percent of Development Service activities (as defined in 12 CFR 1805.104(s)), in the Distressed Community identified by the Applicant or the CDFI Partner, as applicable, in each of the three calendar years preceding the date of the applicable NOFA, (ii) having transacted at least 25 percent of financial transactions (e.g., loans or Equity Investments) in said Distressed Community in at least one of the three calendar years preceding the date of the applicable NOFA, or (iii) demonstrated that it has attained at least 10 percent of market share for a particular product in said Distressed Community (such as at least 10 percent of home mortgages originated in said Distressed Community) in at least one of the three calendar years preceding the date of the applicable NOFA.

1. Should the current definition of Integrally Involved be revised or replaced? If so, how should the CDFI Fund define Integrally Involved?

2. What other factors should the CDFI Fund consider when determining an updated definition of Integrally Involved?

B. *Updating the Types of BEA Qualified Activities:* The CDFI Fund is considering updating the types of activities eligible for BEA Program awards. This includes the specific types of activities currently considered eligible in the CDFI-Related, Distressed Community Financing, and Service Activity categories. The following activities are eligible CDFI-Related Activities: Equity-Like Loans (ELL), Grants (CG), Loans (LNS), CDFI Deposits/Shares (DS), and Technical Assistance (TA). The following activities are eligible Distressed Community Financing Activities: Affordable Home Mortgage Loans (AHM), Affordable Housing Development Loans and Project Investments (AHD), Home Improvement Loans (HIL), Education Loans (EDU), and Commercial Real Estate Loans and Project Investments (CRE). The following activities are eligible Service Activities: Deposits (D), Community Services (CS), Financial Services (FS), Targeted Financial Services (TFS), and Targeted Retail Savings/Investment Products (TSP).

1. Should the CDFI Fund revise, replace, or add to the existing types of CDFI-Related, Distressed Community Financing or Service Activities to include financial products or services relevant to the current economic environment? If so, please indicate the specific type of activity that should be considered, the reasons why it should be considered, and to the extent possible, the benefits of the activity to residents of Distressed Communities. If the suggestion is that a particular activity type be revised or replaced, please explain why.

C. *Pay for Success:* The CDFI Fund has received recent inquiries about broadening BEA Qualified Activities to include ''Pay for Success'' activities. The objective of the Pay for Success initiative is to improve social outcomes while more effectively allocating public resources, paying for services only when the desired results of social outcomes are achieved. Examples of social outcomes include: academic programs for disadvantaged youth that accelerate academic gains; programs that reduce recidivism rates; and elderly care services that reduce the number of elderly individuals placed in costly nursing home facilities. Pay for Success has been part of the President's annual budget since FY 2012. Pay for Success activities are typically structured through contracts between state agencies and social service providers. A financial institution can participate in Pay for Success activities by providing the funding component. The financial institution would be reimbursed by the federal government only if the agreed-upon outcomes are achieved and verified by an external evaluator. Since the anticipated social outcomes are achieved over a number of years, Pay for Success contracts are typically multiple-year commitments.

If a BEA applicant funds a certified CDFI that administers or supports a Pay for Success activity, the activity could qualify as a CDFI-related activity under the current Interim Rule. The CDFI Fund is considering revising the Distressed Community Financing Activities category to include the funding component of Pay for Success activities by FDIC-insured financial institutions as a qualified activity. An example of a Pay for Success activity which could qualify in the Distressed Community Financing Activities category, is a loan or investment made by an FDIC-insured financial institution to an organization that funds a Pay for Success activity located in a BEA Distressed Community. The Applicant would still need to be a FDIC-insured financial institution, and the borrower would still need to be located in a BEA Distressed Community in order for the transaction to qualify. Disbursement of a Pay for Success award would be contingent upon verification that the agreed upon social outcomes for which the award determination was based have been achieved.

1. Should the CDFI Fund add Pay for Success activities as an eligible Distressed Community Financing Activity? If so, please indicate why. If not, please indicate why not.

2. If Pay for Success activities are added, should the CDFI Fund cap the amount of BEA Program awards related to these activities? If so, explain why and be specific regarding the amount in award dollars and/or percentage.

3. Would the addition of Pay for Success activities as an eligible Distressed Community Financing Activity incentivize financial institutions to increase the funding of Pay for Success activities?

4. Do financial institutions currently fund Pay for Success activities? If so, what are the attributes of the financial institutions? For example, are they predominately certified-CDFIs, community banks, minority depository institutions, small banks, large banks, etc.?

D. *Limitations on Loans or Investments to Certain Types of Businesses:* The CDFI Fund is considering prohibiting loans or investments to certain types of businesses that otherwise meet other eligibility criteria from qualifying for the BEA Program.

1. Should the CDFI Fund prohibit loans or investments to certain types of businesses that otherwise meet other BEA Program eligibility requirements from qualifying for the BEA Program? For example, should the CDFI Fund consider a loan to a liquor store, gambling facility, etc. that otherwise meets other BEA Program eligibility requirements, an ineligible activity? If so, to which types of businesses should loans or investments be considered ineligible? If not, please provide a specific reason why not. Also, please discuss the positive or negative impact that loans or investments to these types of businesses may have on a Distressed Community.

E. *Award Size:* The CDFI Fund has received feedback regarding the continued reduction in the maximum BEA Program award size. Over the past three years, appropriated funds for the BEA Program have decreased from $25 million in FY 2010 to approximately $17.1 million in FY 2013. The CDFI Fund has continued to make an effort to award as many Applicants as possible with available appropriations. In order to do so, the CDFI Fund has lowered the award cap in the last three BEA Program award rounds, reducing the maximum award amount an individual Applicant can receive. For example, in FY 2010 the BEA Program was appropriated $25 million and the award cap was $600,000. In FY 2011, the BEA Program was appropriated $22 million and the award cap was $500,000. In FY 2012, the BEA Program was appropriated $18 million and the award cap was $415,000. The CDFI Fund is particularly interested in knowing how impactful BEA Program awards are to: community banks, certified CDFIs, minority depository institutions, and Small Banks based on CRA Asset Size Classification (assets of less than $296 million as of 12/31/2012).

1. How impactful are BEA Program awards to the recipient financial institutions?

2. Should the CDFI Fund consider making fewer, significantly larger awards? For example, with an appropriation of $18 million, the CDFI Fund could make 18 awards of $1 million each.

3. What other factors should the CDFI Fund consider regarding the size of BEA Program awards?

III. Reporting and Supporting Documentation

A. *Worksheet 2: BEA Report of Transactions:* The CDFI Fund requires BEA Applicants to complete and submit Worksheet 2: BEA Report of Transactions as part of the BEA application. Worksheet 2: BEA Report of Transactions captures the transaction data for the transactions an Applicant included in its application. The data currently captured is: (1) Name of Borrower/Investee/Service Provider; (2) Total Dollar Value or Amount of Transactions; (3) Amount Disbursed to Date; (4) Street Address; (5) City; (6) State; (7) Zip; (8) Census Tract; (9) Date of Execution; (10) Date of Initial Disbursement; (11) Date of Final Disbursement; (12) Type of Activity; and (13) Impact.

In addition to the information currently captured, the CDFI Fund is considering adding two columns to Worksheet 2: BEA Report of Transactions: (1) Description of Business Financed; and (2) NAICS Code of the Business Financed. These two columns would only apply to loans or investments provided to businesses.

1. Would the addition of these columns significantly increase the burden on Applicants or result in any potential issues that the CDFI Fund may not have considered?

2. Should the supporting documentation requirements apply to every transaction, to only certain specific transaction types, or to transactions of a certain amount?

B. *Supporting Documentation Provided by Applicants:* The CDFI Fund currently requires Applicants to provide supporting documentation for transactions greater than or equal to $250,000. The CDFI Fund is considering changing the supporting documentation requirements.

1. Should the CDFI Fund require Applicants to provide supporting documentation for loans or investments of less than $250,000? If so, what type of supporting documentation should be required?

2. Would lowering the threshold amount for requiring supporting documentation requirements significantly increase the burden on Applicants or result in any potential issues that the CDFI Fund may not have considered?

3. Should the supporting documentation requirements apply to every transaction, to only certain specific transaction types, or to transactions of a certain amount?

IV. Other

A. *General Feedback:* The CDFI Fund would also like to obtain general feedback on the BEA Program and recognizes that there are other topics that may not have been addressed in the questions above, but that are important to consider. This information is especially important given that the BEA Program statute is over 12 years old and the Program regulations are over three years old. Please provide any general feedback on any aspect of the BEA Program, including but not limited to, program design, direction, impacts, performance measures, etc.

Authority: 12 U.S.C. 1834a, 4703, 4703 note, 4713, 4717; 31 U.S.C. 321; 12 CFR part 1806.

Dated: October 23, 2013.

Donna J. Gambrell,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2013–25622 Filed 10–28–13; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2013–0019]

Mutual Savings Association Advisory Committee

AGENCY: Department of the Treasury, Office of the Comptroller of the Currency.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Office of the Comptroller of the Currency (OCC) announces a meeting of the Mutual Savings Association Advisory Committee (MSAAC).

DATES: A public meeting of the MSAAC will be held on Monday, November 18,

2013, beginning at 1:00 p.m. Central Standard Time (CST). Members of the public may submit written statements to the MSAAC. The OCC must receive written statements no later than Friday, November 8, 2013. Members of the public who plan to attend the meeting, and members of the public who require auxiliary aid, should contact the OCC by 5:00 p.m. Eastern Standard Time (EST) on Friday, November 15, 2013, to inform the OCC of their desire to attend the meeting and to provide the information that will be required to facilitate aid.

ADDRESSES: The November 18, 2013, meeting of the MSAAC will be held at the Crowne Plaza Chicago Metro, 733 West Madison, Chicago, IL 60661. Members of the public may submit written statements to *MSAAC@occ.treas.gov* or by mailing them in triplicate to Donna Deale, Designated Federal Official, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219. Members of the public who plan to attend the meeting should contact the OCC at *MSAAC@occ.treas.gov* or at 202–649–5420 to inform the OCC of their desire to attend the meeting so that the OCC can make the necessary arrangements for seating. Attendees should provide their full name, email address, and organization.

FOR FURTHER INFORMATION CONTACT: Donna Deale, Deputy Comptroller for Thrift Supervision, (202) 649–5420, Office of the Comptroller of the Currency, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: By this notice, the OCC is announcing that the OCC MSAAC will convene a meeting on Monday, November 18, 2013, at the Crowne Plaza Chicago Metro, 733 West Madison, Chicago, IL 60661. The meeting is open to the public and will begin at 1:00 p.m. CST. The agenda includes a discussion of current topics of interest to the industry. The purpose of the meeting is for the MSAAC to advise the OCC on the regulatory changes or other steps the OCC may be able to take to ensure the continued health and viability of mutual savings associations and other issues of concern to the existing mutual savings associations.

Dated: October 22, 2013.

Thomas J. Curry,

Comptroller of the Currency.

[FR Doc. 2013–25423 Filed 10–28–13; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–118412–10]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the Interim Final Rules, Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act.

DATES: Written comments should be received on or before December 30, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Kerry Dennis at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington DC 20224, or through the internet, at *Kerry.Dennis@irs.gov*

SUPPLEMENTARY INFORMATION:

Title: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act.

OMB Number: 1545–2178.

Regulation Project Number: REG–118412–10.

Abstract: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding status as a grandfathered health plan.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 56,347,000.

Estimated Total Annual Burden Hours: 323,000 Hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 18, 2013

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2013–25581 Filed 10–28–13; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 78 Tuesday,

No. 209 October 29, 2013

Part II

Department of Health and Human Services

Center for Medicare & Medicaid Services

42 CFR Part 485

Medicare Program: Conditions of Participation (CoPs) for Community Mental Health Centers; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 485

[CMS–3202–F]

RIN 0938–AP51

Medicare Program: Conditions of Participation (CoPs) for Community Mental Health Centers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes, for the first time, conditions of participation (CoPs) that community mental health centers (CMHCs) must meet in order to participate in the Medicare program. These CoPs focus on the care provided to the client, establish requirements for staff and provider operations, and encourage clients to participate in their care plan and treatment. The new CoPs enable CMS to survey CMHCs for compliance with health and safety requirements.

DATES: These regulations are effective on October 29, 2014.

FOR FURTHER INFORMATION CONTACT: Mary Rossi-Coajou, (410) 786–6051. Maria Hammel, (410) 786–1775.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

In 2012, 100 certified Community Mental Health Centers (CMHCs) billed Medicare for partial hospitalization services. Currently, there are no Conditions of Participation (CoPs) in place for Medicare-certified CMHCs. As such, an insufficient regulatory basis exists to ensure quality and safety for CMHC care. Sections 1102 and 1871 of the Social Security Act (the Act) give CMS the general authority to establish CoPs for Medicare providers. Therefore, we are establishing for the first time a set of requirements that Medicare-certified CMHCs must meet in order to participate in the Medicare program. These CoPs will help to ensure the quality and safety of CMHC care for all clients served by the CMHC, regardless of payment source.

These requirements focus on a short term, person-centered, outcome-oriented process that promotes quality client care. Requirements for CMHC services encompass—(1) personnel qualifications; (2) client rights; (3) admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client; (4) treatment team, active treatment plan, and coordination of services; (5) quality assessment and performance improvement; and (6) organization, governance, administration of services, and partial hospitalization services. Bridging these CMHC requirements are quality assessment and performance improvement program requirements that build on a provider's own quality management system to improve client care performance. We expect CMHCs to furnish health care that meets the essential health and quality standards that are established by this rule; therefore, a CMHC will be expected to use its own quality management system to monitor and improve its own performance and compliance.

B. Current Requirements for CMHCs

Section 1832(a)(2)(J) of the Act established coverage of partial hospitalization services for Medicare beneficiaries in CMHCs. Section 1861(ff)(2) of the Act defines partial hospitalization services as a broad range of mental health services ''that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish. . . .''

Section 4162 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) amended sections 1832(a)(2) and 1861(ff)(3) of the Act to allow CMHCs to provide partial hospitalization services. Under the Medicare program, apart from limited telehealth services, CMHCs are recognized as Medicare providers only for partial hospitalization services (see 42 CFR 410.110).

A CMHC, in accordance with section 1861(ff)(3)(B) of the Act, is an entity that meets applicable licensing or certification requirements for CMHCs in the State in which it is located, and provides the set of services specified in section 1913(c)(1) of the Public Health Service Act (PHS Act). However, CMS has learned that most States either do not have a certification or licensure program for these types of facilities, or have regulatory requirements that apply only to CMHCs that receive Medicaid or other direct state funding.

A CMHC may receive Medicare payment for partial hospitalization services only if it meets the core requirements at § 410.2 and provides partial hospitalization program (PHP) services that are in accordance with regulations at § 424.24(e).

When the partial hospitalization program benefit in CMHCs was first enacted, CMHCs were certified based on self-attestation. Currently, CMHCs are Medicare-certified and Medicare-enrolled based on a CMS Regional Office determination that the provider meets the definition of a CMHC at section 1861(ff)(3)(B) of the Act and provides the core services described in section 1913(c)(1) of the PHS Act. CMS has received complaints regarding some CMHCs, such as their ceasing to provide services once the CMHC has been certified, physically mistreating clients, and providing fragmented care. As there are no CoPs in place for CMHCs, many participating CMHCs have never had an onsite survey visit by CMS after their initial certification. Furthermore, there are currently only limited circumstances in which CMS can terminate a CMHC from Medicare participation based on the result of a complaint investigation. Without such health and safety standards in place, CMS's oversight of CMHCs is severely limited.

C. Rationale for Establishing CMHC CoPs

Medicare is responsible for establishing requirements to promote the health and safety of care provided to its beneficiaries. We believe that basic health and safety standards should be established for CMHCs in order to protect clients and their families. Establishing CMHC CoPs will enable CMS to survey providers, through State survey and certification agencies, to ensure that the care being furnished meets the standards.

On August 20, 2012, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) published a report entitled Questionable Billing by Community Mental Health Centers, OEI–04–11–00100 *http://oig.hhs.gov/oei/reports/oei-04-11-00100.asp.* In this report it was found that in 2010 approximately half of the CMHCs met or exceeded thresholds that indicated unusually high billing for at least one out of nine questionable billing characteristics. Approximately one-third of these CMHCs had at least two of the characteristics. Additionally, approximately two-thirds of the CMHCs with questionable billing were located in eight metropolitan areas. Finally, 90 percent of the CMHCs with questionable billing were located in States that do not require CMHCs to be licensed or certified. The OIG had four specific recommendations including the finalization of the proposed conditions

of participation for CMHCs. Due to the possibility of significant gaps in State requirements to ensure the health and safety of CMHC clients, we chose to propose and are finalizing a core set of health and safety requirements that will apply to all CMHCs receiving Medicare funds, regardless of the State in which the CMHC is located. These requirements will ensure a basic level of services provided by qualified staff, and will be consistent with the recommendations of the OIG. As with CoPs applied to other provider types, these requirements will apply for all clients served by the CMHC, not just Medicare beneficiaries.

D. Principles Applied in Developing the CMHC CoPs

We developed the CMHC requirements based on the following principles:

- A focus on the continuous, integrated, mental health care process that a client experiences across all CMHC services.
- Activities that center around client assessment, the active treatment plan, and service delivery.
- Use of a person-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the client's needs.
- Promotion and protection of client rights.

Based on these principles, we proposed and are finalizing the following six CoPs: (1) Personnel qualifications; (2) client rights; (3) admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client; (4) treatment team, active treatment plan, and coordination of services; (5) quality assessment and performance improvement; and (6) organization, governance, administration of services, and partial hospitalization services.

The ''Personnel qualifications'' CoP establishes staff qualifications for the CMHC.

The ''Client rights'' CoP emphasizes a CMHC's responsibility to respect and promote the rights of each CMHC client.

The ''Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client'' CoP reflects the critical nature of a comprehensive assessment in determining appropriate treatments and accomplishing desired health outcomes.

The ''Treatment team, active treatment plan, and coordination of services'' CoP incorporates a person-centered interdisciplinary team approach, in consultation with the client's primary health care provider (if any).

The ''Quality assessment and performance improvement'' CoP challenges each CMHC to build and monitor its own quality management system to monitor and improve client care performance.

The ''Organization, governance, administration of services, and partial hospitalization services'' CoP charges each CMHC with the responsibility for creating and implementing a governance structure that focuses on and enhances its coordination of services to better serve its clients.

Two of the CoPs, ''Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client'' and ''Treatment team, active treatment plan, and coordination of services,'' establish a cycle of individualized client care. The client's care needs will be comprehensively assessed, enabling the interdisciplinary team, with the client, to establish an active treatment plan. The active treatment plan will be implemented, and the results of the care will be evaluated by updating the comprehensive assessment and active treatment plan.

These CoPs present an opportunity for CMHCs, States, and CMS to join in a partnership for improvement. CMHC programming will reflect a person-centered approach that will affect how State survey and certification agencies and CMS manage the survey process. This approach provides opportunities for improvement in client care.

II. Provisions of the Proposed Rule and Analysis and Response to Public Comments

We published a proposed rule in the **Federal Register** (76 FR 35684) on June 17, 2011. In that rule, we proposed to establish a new subpart J under the regulations at part 485 to incorporate the proposed CoPs for CMHCs.

We specified that the new subpart J would include the basis and scope of the subpart, definitions, and the six CoPs and requirements.

We provided a 60-day public comment period in which we received a total of 203 timely comments from accrediting bodies, consumer advocacy organizations, CMHCs, individuals, national health care provider organizations, State agencies, and State health care provider organizations. Overall, the majority of commenters were supportive of the proposed changes. Summaries of the major issues and our responses are set forth below.

A. Basis and Scope (§ 485.900)

At § 485.900, we proposed to cite the statutory authority for CMHCs to provide services that are payable under Medicare Part B. In addition, we proposed to describe the scope of provisions in proposed subpart J.

B. Definitions (§ 485.902)

At § 485.902, we proposed to define the following terms to be used in the CoPs for CMHCs under the proposed subpart J: ''active treatment plan,'' ''community mental health center (CMHC),'' ''comprehensive assessment,'' ''employee of a CMHC,'' ''initial evaluation,'' ''representative,'' ''restraint,'' ''seclusion,'' and ''volunteer''.

Comment: Some commenters expressed concern related to the requirement that all volunteers meet the standard training requirements under § 485.918(d). The commenters believe it is unreasonable to require CMHCs to provide the specific training and competency assessments required under § 485.918(d)(1) and (d)(3) for volunteers. Other commenters believe an initial orientation tailored to the actual work a volunteer will be doing ensures that volunteers will receive the information and guidelines they need from CMHCs without imposing an unnecessary and impractical barrier to using volunteers.

Response: We appreciate the feedback related to the definition of a volunteer and associated training requirements. We agree with the commenters that orientation should be tailored to the actual work the volunteer will be doing. However, the volunteer would need additional training in areas such as CMHC care and services, as well as specific in-service training and education, depending on the role of the volunteer. For example, if a volunteer role is to work in the CMHC client waiting area, we would expect the CMHC to educate the volunteer in areas such as the CMHC privacy policy, de-escalation techniques, and other pertinent training that may affect the role of that volunteer. Therefore, we are finalizing the definition of volunteer and their training requirements as proposed.

Comment: One commenter stated that it is difficult to imagine a situation where a client's representative would be terminating medical care on the client's behalf. The commenter stated that the definition should reflect the principles of client involvement and the protection of client rights, including emphasizing the right of a client to make decisions regarding treatment. The commenter stated that one possibility would be to

change the definition to state that a representative is ''an individual legally authorized to make decisions on behalf of a client who is mentally and physically incapacitated,'' and eliminate any reference to terminating medical care.

Response: We appreciate the feedback and suggestions related to the definition of ''representative''. We agree that it would be more common for a client to have a representative who would be authorizing care, not terminating care. However, CMS uses the term ''representative'' across many different provider types. Therefore, we are finalizing the definition of ''representative'' as proposed.

CMHC CoP: Personnel Qualifications (§ 485.904)

We proposed to add a new CoP at § 485.904 to establish staff qualifications for CMHCs. The proposed CoP was divided into two standards.

At § 485.904(a), ''Standard: General qualification requirements,'' we proposed to require that all professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC, be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and be required to act only within the scope of their State licenses, certifications, or registrations. We also proposed that all personnel qualifications would have to be kept current at all times.

At § 485.904(b), ''Standard: Personnel qualifications for certain disciplines,'' we proposed to require staff qualifications to be consistent with, or similar to, those set forth in CoPs for other provider types in the Medicare regulations. Specifically, we proposed personnel requirements for the following disciplines: Administrator of a CMHC, Clinical Psychologist, Clinical Social Worker, Mental Health Counselor, Occupational Therapist, Physician, Psychiatric Registered Nurse, and Psychiatrist.

Comment: Several commenters agreed with requiring that ''all professionals who furnish services directly must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of their State licenses.'' They also stated that most states allow individuals with Master's level degrees, such as social work and psychology, to provide services under the supervision of a licensed professional. Commenters stated that a period of supervision is required for these professionals to receive licenses. In addition, commenters stated that many peer educators and Bachelor's level professionals do not have a process for becoming licensed, or must work in a supervised position for a certain number of hours to obtain certification.

Response: We thank the commenters for the information regarding professionals who furnish services in a CMHC. We believe that the regulations at § 485.904 allow for professionals with a Master's degree in psychology or social work to provide services under a licensed professional as long as it is within their scope of practice and allowed by the State. If a State decides that Baccalaureate level professionals need to be supervised for a certain number of hours to meet State licensure requirements to obtain their license, we defer to that State's decision. Our proposed language did not impose additional restrictions or require that States establish additional licensing programs or requirements. Therefore, we are finalizing § 485.904(a) as proposed.

Comment: A few commenters agreed that it is important that personnel qualifications be defined by CMS. However, they believe that the facility should qualify their staff and make sure their staff is competent to perform their job responsibilities. Commenters stated that this could be achieved by using the education, experience, and services the individual is able to perform under the scope of his or her license and based on the laws of his or her state. Commenters also believe it is important that CMS recognize that there are many different types of mental health professionals who are qualified to perform the clinical responsibilities within the CMHC, regardless of the ''title of their degree.'' According to the commenters, it is imperative that CMS not limit the CMHC provider to one specific degree and or license (that is, clinical social worker vs. mental health counselor) to perform ''certain'' roles in the CMHC, as this would be an impossible task to adhere to and an administrative and financial burden that is unnecessary to the CMHC.

Commenters also stated that CMS is required to accept the scope of state licensure of various mental health care professionals in the context of Medicare's partial hospitalization program benefit. Congress explicitly stated in the Social Security Act that individual and group therapy services provided within a partial hospitalization program at a CMHC can be conducted by physicians, psychologists or ''other mental health professionals to the extent authorized under State law'', as noted in Section 1861(ff)(2)(A) of the Act.

Response: We thank the commenters for the comments regarding licensure, education, and experience as they relate to the personnel requirements. Our goal in requiring specific personnel requirements is to protect the health and safety of the clients served by the CMHC. That said, we agree that practitioners should not be restricted by our rules from acting within the scope of practice authorized under State law and any applicable licensing requirements. We have amended the language in this final rule to assist in ensuring that practitioners can practice to the full extent of their State licensure.

Comment: A few commenters are concerned that, in their view, CMHCs may have inadequate boards of directors, and that the board and administrator of the CMHC are permitted to be one and the same. Commenters stated that anyone with limited investment capital and no knowledge of psychiatric care can open and operate a CMHC, and that this is one of the system's greatest weaknesses. Commenters requested that, in cases where the administrator has a financial (that is, controlling) interest in the CMHC, minimum professional standards should apply.

Response: We thank the commenters for the information regarding the administrator and board of directors. We agree that in some cases there is potential for the administrator and the governing body to be one and the same. However, we do not believe that modifying the language under personnel requirements for the administrator is the best place to address this issue. Therefore, we are finalizing the administrator personnel requirements as proposed. We have also modified the language at § 485.918(a)(1) related to the governing body to require two or more persons to serve on the governing body, one of whom must possess knowledge and experience as a mental health clinician. The administrator will be able to serve as a member of the governing body, but we will require at least one (or more) additional person(s) to be part of the governing body. For example, if the administrator has no psychiatric health background, either one of the CMHC's clinicians or another qualified professional should be appointed to serve as a member of the governing body.

Comment: At proposed § 485.904(b)(6), a few commenters noted that CMS used the definition of physician found in section 1861(r) of the Act. The commenters requested that CMS further limit the statutory

definition of physician by limiting it to section 1861(r)(1), which lists a doctor of medicine or osteopathy. The commenter believes that this will help ensure that clients in a CMHC receive quality care from appropriately trained doctors of medicine or osteopathy legally authorized to practice medicine and surgery by the State.

Response: We thank the commenters for the comment regarding the definition of a physician, now located at § 485.904(b)(7). We understand the commenters' concerns with the broadness of the definition, and believe that requiring the physician to have experience in providing mental health services to clients will assure that these physicians are qualified to provide CMHC services. Therefore, the requirements will remain as proposed.

Comment: Some commenters expressed concern with the psychiatric registered nurse personnel requirements. Specifically, the commenters expressed concern about the requirement of 2 years of education and training in psychiatric nursing. Some commenters believe the training requirement should be reduced to 1 year. Other commenters stated that non-profit CMHCs face competition for professional staff and cannot always offer salaries as high as those offered by other providers, such as hospitals. CMHCs in rural areas have an added hurdle to recruiting and retaining clinicians. One way CMHCs can attract staff at the salaries they are able to pay is by offering recent graduates the opportunity to gain more experience working in community behavioral health. The commenters stated that it is unclear whether the two-year education and/or training requirement would disqualify recent nursing school graduates from working at non-profit CMHCs. The commenters are requesting clarification of this requirement to include approved nursing school graduates who have ''education and/or training in psychiatric nursing,'' without specifying a length of time.

Other commenters stated that psychiatric registered nursing is specialized nursing care and an integral component in the provision of services at CMHCs. As a result, those commenters recommended that CMS remove the word ''registered'' and broaden the definition of ''psychiatric nurse'' so that it includes all licensed nurses who possess the requisite education and experience as outlined in the CoP. Furthermore, the commenters requested that the personnel requirement for psychiatric registered nurses remain in accordance with § 410.43(a)(4)(iii), ''trained psychiatric nurses,'' and eliminate the word ''Registered.'' Commenters also requested that psychiatric nurses be permitted to facilitate education groups and to perform mental health assessments in the CMHC setting, as allowed by state law.

Response: We appreciate the comments regarding personnel requirements of the psychiatric registered nurse. We understand that some CMHCs may have more difficulty than others hiring a psychiatric registered nurse, due to location, salaries and competition. However, we believe that the role of the psychiatric registered nurse is specialized and essential to the care of a CMHC client. Therefore the requirements will remain as proposed. We note that, in addition to the psychiatric registered nurse, the CMHC may hire nurses such as licensed practical nurses (LPNs) or licensed vocational nurse (LVNs), as long as they meet the personnel requirements at 485.904(a). In response to commenters' concerns about the proposed work experience requirements, we have modified the time to 1 year in this final rule, and will allow the time spent in a psychiatric nursing rotation during nursing education to count towards the 1-year training requirement. We will provide further sub-regulatory guidance regarding the work experience requirements in the State operations manual, which will include interpretive guidelines for this section.

Comment: Several commenters requested that CMS add definitions for ''Advanced Practice Registered Nurse,'' ''Nurse Practitioner,'' or ''NP'' to the personnel requirements. Commenters also requested that CMS require the Advanced Practice Registered Nurse to be educated specifically in psychiatric and mental health nursing with a minimum of a Master's degree, to have experience which includes both didactic and clinical components, advanced knowledge in nursing theory, physical and psychosocial assessment, nursing interventions, and management of health care. They also stated that the NP should be practicing under a collaborative practice agreement with a board eligible psychiatrist and may perform services to the extent established by the governing bylaws, but not beyond the scope of license, certificate or other legal credentials as defined by the State in which he/she is licensed or certified. Additionally, commenters stated that advanced practice nurses—both psychiatric mental health nurse practitioners (PMHNPs) and psychiatric mental health clinical nurse specialists (PMHCNSs) need to be included in the mix of health care providers who are authorized as gatekeepers to mental health services.

Response: We appreciate the comments regarding the utilization of advanced practice nurses (APNs) in a CMHC. We agree that non-physician practitioners, such as the APN, are essential to the care of clients served in a CMHC. To address the comments related to the use of an APN for assessment and as a member of the treatment team, we modified language in both § 485.914, ''Admission, initial assessment, comprehensive assessment and discharge or transfer of the client'' and § 485.916, ''Treatment team, person-centered active treatment plan and coordination of services.'' These changes allow for APNs to serve in these roles, as permitted by State licensure. We also added a new element at § 485.904(b)(9), ''Advanced practice nurse,'' which covers the personnel requirements for both the nurse practitioner and the clinical nurse specialist.

Comment: A few commenters requested that CMS include language in the definition of ''psychiatrist'' for the purpose of CMHC oversight, as set out at § 482.62(b)(1): ''A physician is qualified to take the examinations for board certification upon successful completion of a psychiatric residency program approved by the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry and Neurology.'' Commenters agreed that qualified physician oversight of CMHC programs is of paramount importance. However, they stated that it is important that CMS clarify the personnel requirements to include psychiatrists who are board-certified or eligible to be board-certified. This clarification mirrors the CoP definition currently applied to inpatient psychiatric hospitals.

Response: We appreciate the comments regarding the personnel requirements for a psychiatrist or psychiatrist eligible to be board-certified. We believe the comment partially misquoted the regulation text. However, we agree with the commenters that it is of utmost importance to hire a board-certified psychiatrist. We also understand that it may not always be possible for a rural CMHC to employ a board-certified psychiatrist. In the rare cases that the CMHC has demonstrated that it is unable to employ a board-certified psychiatrist, we would expect the CMHC to hire a highly qualified psychiatrist who has documented equivalent education, training or experience, and is fully licensed to practice medicine in the State in which

he or she practices. Therefore, in response to comments, we have modified that language by adding ''board certified or is eligible to be board certified''. Additional information and guidance regarding this requirement will be available in State operations manual, which includes the interpretive guidelines.

Comment: A few commenters requested that we add ''activity therapist'' to the personnel definitions. The commenters stated that an activity therapist is an individual who possesses a Bachelor's-level education in behavioral science or a related field, and who is certified or licensed by the state to facilitate activity groups.

Response: We appreciate the comments related to activity therapists. An activity therapist falls under the general qualifications requirement at § 485.904. CMHCs that employ activity therapists will be expected to employ individuals who are legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and they must act within the scope of any State licenses, certifications, or registrations that apply to these employees. We also expect CMHCs to have defined personnel requirements for these individuals.

Comment: Several commenters suggested CMS avoid the use of specific licensure requirements in the definition of ''Clinical Social Worker''(CSW) and instead reflect the clinician's education and experience level. The commenters recommended that CMS consider and adopt the following alternative: ''CMHCs must employ a full time Director of Social Services who is a Master's degree level clinician with a minimum of 2 years experience in providing care to the mentally ill and is licensed or certified to perform psychotherapy by the laws of the State in which the services are performed. Other clinicians may be utilized to provide psychotherapy provided they are licensed or certified to perform psychotherapy in the state in which the services are performed.'' The commenters' suggested language eliminates the use of licensing titles which are not uniform in all states and may potentially eliminate clinicians who are licensed and certified to provide services. Another commenter stated that unlike other health care settings, CSWs in CMHCs do not operate independently, but rather operate as part of a clinical team of personnel/staff rendering treatment services. They recommended that CMS' definition require that CSWs providing care in CMHCs possess a Master's degree and have a minimum of at least 2 years' experience in providing treatments to clients with mental disorders or severe disabilities. Commenters also stated that CSWs working in the CMHC setting should be licensed or certified to perform psychotherapy by the laws of the state in which the services are performed. According to the commenters, CMS should specify that additional types of clinicians may provide psychotherapy in the CMHC setting, provided these professionals are licensed or certified to perform psychotherapy in the state in which the services are performed.

Some commenters believe that the clinical social worker definition should be expanded to reflect the services that they perform. The definition recommended by the commenters was ''Clinical social work services include the assessment, diagnosis, treatment, and prevention of mental illness, emotional, and other behavioral disturbances.''

Response: We appreciate the comments regarding the personnel requirements of the clinical social worker. We agree that addressing the education and experience level of the CSW may be a more appropriate means to ensure quality treatment and to meet the needs of the different types of clients served in a CMHC. This will ensure that appropriate personnel will work with each client to meet individual needs. We agree that eliminating the use of licensing titles, which are not uniform in all states and may potentially eliminate clinicians who are licensed and certified to provide services, is appropriate in these circumstances. We believe that all CMHCs must strive to employ qualified individuals to provide social work services to clients and their families. To ensure CMHCs employ a qualified individual as a clinical social worker, we are requiring that at least one of the CMHC clinical social worker(s) must meet the qualifications at § 410.73. If the CMHC chooses to also employ a social worker that does not meet § 410.73, then, at a minimum, the social worker must meet one of the following requirements:

- Have a Bachelor's degree in social work (BSW) from an institution accredited by the Council on Social Work Education; or a Bachelor's degree in psychology or sociology, and be supervised by an MSW who meets the qualifications set out at § 410.73 of this chapter.

If a CMHC chooses to employ a social worker with a Bachelor's degree in social work, psychology or sociology, the services of the social worker must be provided under the supervision of a clinical social worker with an MSW or a doctoral degree in social work from a school of social work accredited by the Council on Social Work Education. Such BSW must also meet the qualifications set out at § 410.73 of this chapter. We believe that requiring MSW supervision of BSW services will help ensure that client needs are met. The MSW supervisor role is that of an active advisor, consulting with the BSW on assessing the needs of clients, developing and updating the social work portion of the active treatment plan, and delivering care to clients. The supervision may occur over the telephone, through electronic communication, or any combination thereof.

Comment: A few commenters recommended that CMS add additional language to the definition of mental health counselors. Commenters also stated that CMS should allow for the mental health counselors to provide mental health assessments, as permitted by state law, in addition to the other service areas included in the proposed rule. Commenters clarified that under the Joint Commission's standards, mental health counselors are qualified to perform assessments. They stated that since providing mental health assessments for state mental health entities is a core service area required of CMHCs by Federal law, it is important that the assessments be listed among the services provided by mental health counselors as outlined in the proposed rule.

Response: We appreciate the comments related to mental health counselors. The role of the mental health counselor is located at § 485.904(b)(5) under the personnel requirements. We agree the mental health counselors can provide mental health assessments, as defined by State law. Therefore, we modified the regulation text at § 485.904(b)(5), Mental health counselor, to include ''assessments.'' We have also modified the language at § 485.914, ''Admission, initial evaluation, comprehensive assessment and discharge or transfer of the client,'' to allow for mental health counselors to provide the assessment of the client. Specifically, we have modified the language at § 485.904(b)(5) by broadening the requirement to allow for a licensed mental health professional (acting within his or her state scope of practice requirements) to complete the initial evaluation and the comprehensive assessment.

Comment: Some commenters stated that the personnel requirement for clinical psychologists at § 485.904(b)(2) is vague and lacks quality assurance

needed to protect Medicare beneficiaries. Commenters requested that CMS consider specifying that the clinical psychologist must have graduated from a doctoral program that is accredited by the American Psychological Association or designated by the Association of State and Provincial Psychology Boards/National Register of Health Service Providers in Psychology.

Some commenters raised concern that the standard contains no verification that the psychologists are trained in health service provisions and that only requiring a generic license to authorize the individual to engage in a variety of psychological services does not distinguish between individuals who are trained and experienced in health service provision and those who are trained in research, teaching, or industrial/organizational fields.

Response: We appreciate the comments related to the psychologist personnel requirements. We agree that properly educated and trained health service psychologists will be strong CMHC team leaders. These standards will help improve client treatment, and hold CMHCs accountable for their care.

We also agree that protecting the clients served by the CMHC is of great importance. The personnel requirements for psychologists at § 485.904(b)(2) reference the clinical psychologist qualification requirements at § 410.71(d). We understand the importance of requiring the schools to be accredited. However, we do not have any data indicating that clinical psychologists graduating from non-accredited programs reduces the level of quality care provided to clients served. Without formal evidence, modifying the psychologist personnel requirement in the CoPs would create a discrepancy between the conditions of participation and the payment policy requirements at § 410.71(d).

Comment: A few commenters recommended the inclusion of physician assistants (PAs) in the proposed community mental health center conditions of participation to enable CMHCs to utilize this group of practitioners as legally authorized in accordance with applicable federal, State and local laws. Commenters believe that the lack of specific inclusion of PAs in a standard can imply to surveyors that PAs are not authorized to deliver certain medical services. Other commenters stated that PAs in psychiatry expand access to mental health services. They often work in behavioral health facilities and psychiatric units of rural and public hospitals, where psychiatrists are in short supply. The commenters defined a physician assistant as ''an individual who meets the qualifications and conditions as defined in section 1861(s)(2)(K)(i) of the Act and provides services, in accordance with State law, at § 410.74.''

Response: We appreciate the comments regarding PAs. We agree that PAs play an important role in behavioral health. Therefore we have modified the language at § 485.904(b)(8) to set requirements for PAs, and have re-designated the remaining elements accordingly.

Comment: One commenter requested that CMS recognize psychiatric technicians. The commenter stated that in California, and elsewhere in the United States, these direct-care staff are used by providers.

Other commenters requested that CMS add requirements for mental health technicians and drivers. The commenters also expressed concern regarding the level of supervision of these employees. Furthermore, the commenters stated that many CMHCs employ drivers who also work as ''Mental Health Techs''. It is unclear if these medically unlicensed individuals have direct contact with clients and if so, what level of supervision should be expected.

Response: We appreciate the comments and suggestions regarding psychiatric technicians, mental health technicians and drivers. Psychiatric technicians, mental health technicians, and CMHC drivers all play important roles in the care of clients. However, we do not believe that we need to add personnel requirements for these positions at this time. We expect the CMHCs that utilize psychiatric technicians, mental health technicians, and drivers to clearly define their roles and functions (utilizing accepted standards of practice) within the CMHC's own policies, procedures and personnel requirements. We would also expect the CMHC to educate and train these staff members, just as they educate and train their other staff, related to the functions of the CMHC and care of the CMHC clients, confidentiality, safety, and any other areas the CMHC assesses as needed. For states that have licensing and regulatory requirements for the psychiatric technician, mental health technician, and driver we would expect the psychiatric technician, mental health technician, and driver to provide services in accordance with State law.

CMHC CoP: Client Rights (§ 485.910)

We proposed to add a new CoP at § 485.910. The proposed CoP was divided into six standards.

At § 485.910(a), ''Standard: Notice of rights and responsibilities,'' we proposed to set forth certain rights to which CMHC clients would be entitled, and to require that CMHCs inform each client verbally of these rights in a language and manner that the client or client's representative (if appropriate) or surrogate understands.

We also proposed to require that the client be provided a written copy of client rights information. This information would have to be accessible to persons who have limited English proficiency (LEP).

At § 485.910(a)(1), we proposed that the notice of rights and responsibilities, including information concerning how to file a grievance, would be given to the client, the client's representative or surrogate, as appropriate, during the initial evaluation, as described at proposed § 485.914(b).

At § 485.910(b), ''Standard: Exercise of rights and respect for property and person,'' we proposed that a client be able to exercise his or her rights, have his or her property and person respected, voice grievances, and not be subjected to discrimination or reprisal for exercising his or her rights.

Furthermore, at § 485.910(b)(2), we proposed procedures if the client has been adjudged incompetent under State law. At (b)(3), the proposed rule addressed the appointment of a legal representative. We also proposed at § 485.910, ''Standard: Rights of the client,'' that the client would have the right to—(1) participate in the active treatment planning process; (2) refuse care or treatment; (3) have his or her records kept confidential; (4) be free from mistreatment, neglect, abuse, and misappropriation of his or her personal property; (5) receive information about limitations on CMHC services; and (6) not be compelled to perform services for the CMHC.

At § 485.910(d), ''Standard: Addressing violations of client rights,'' we proposed that CMHC personnel be required to report all complaints of alleged violations of clients' rights to the CMHC administrator. We also proposed that the CMHC immediately investigate all alleged violations, take intermediate actions to prevent further potential client rights violations during the investigation period, and take appropriate corrective action, where necessary. Furthermore, we proposed that the CMHC report the violations to appropriate authorities having jurisdiction within 5 working days of the CMHC becoming aware of the verified violations of client rights.

We proposed the client rights CoP to act as a safeguard of client health and

safety. Open communication between CMHC staff and the client, and client access to information are vital to enhancing the client's participation in his or her coordinated active treatment plan. We also proposed to require all CMHCs to comply with Federal rules concerning the privacy of individually identifiable health information set out at 45 CFR parts 160 and 164.

At § 485.910(e), ''Standard: Restraint and seclusion,'' we addressed the use of restraints and seclusion in a CMHC. We proposed that all clients have the right to be free from physical or mental abuse, and corporal punishment. Since accidental injuries and deaths have been documented in medical facilities due to the use of restraint and seclusion, we want to strongly discourage the use of restraints or seclusion in a CMHC environment where the clients are receiving services on an outpatient basis. However, we are aware that under extremely rare instances their application may be warranted for brief periods of time, and only while awaiting transport of the client to a hospital for evaluation and treatment when exhibiting behavior that threatens immediate harm to the client or others. In response to accidental injuries and deaths, we published hospital restraint and seclusion requirements on December 8, 2006 (71 FR 71378) that included a new standard at § 482.13. The hospital restraint and seclusion CoP is the basis for the proposed CMHC restraint and seclusion CoP, with modifications to the regulatory requirements to accommodate this outpatient setting.

The proposed restraint and seclusion standard was divided into five elements. These elements focused on the proper use of seclusion and restraints and the need for CMHC personnel to receive training and education on the proper use of seclusion and restraint application and techniques, as well as the use of alternative methods for handling situations that arise. The standard proposed specific requirements for physician orders for seclusion or restraint, along with a corresponding order for the client's immediate transfer to a hospital when restraint or seclusion is ordered. The standard also included a requirement that there must be specific documentation in the client's clinical record regarding the use of restraints.

At § 485.910(f), ''Standard: Restraint or seclusion: Staff training requirements,'' we address the training of the CMHC staff. The training consists of specific intervals, content and trainer requirements. § 485.910(g), ''Standard: Death reporting requirements'' states that a CMHC would have to report to its CMS regional office no later than close of business the next business day, any death that occurs while a client is restrained or in seclusion while awaiting transfer to the hospital.

Comment: A few commenters stated that all CMHCs should establish written policies and procedures regarding clients' rights.

Response: We appreciate the feedback on establishing policies and procedures for clients' rights. We believe it is already current standard of practice and the responsibility of each CMHC to establish written policies and procedures regarding clients' rights and the rights of the client's representative (if appropriate) or surrogate. We have provided requirements for clients' rights that facilitate the development of these policies and procedures. We are clarifying that the client's representative or surrogate must be able to exercise the rights of the client if the client is unable to represent himself or herself.

Comment: Commenters stated that the CMHC should be required to attempt to communicate with the client, and should be required to accommodate the client's communication needs, before opting to rely on a representative or surrogate.

Additionally, commenters also stated that there should also be additional emphasis on the provision of sign language interpretation for individuals who are deaf, and alternative written formats such as Braille and large print for individuals who are visually impaired.

Response: We agree that all CMHCs should attempt to communicate with the client first, and accommodate the client's communication needs. CMHCs must take appropriate steps to ensure effective communication with their clients and provide auxiliary aids and services to accommodate the client's communication needs. There are specific civil rights statutes that address the obligation of covered entities to provide appropriate auxiliary aids and services, such as Braille and large print to individuals with disabilities.

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of disability in programs or activities that receive Federal financial assistance. Therefore, as recipients of Federal financial assistance (that is, loans, grants, or Medicare or Medicaid reimbursements), CMHCs must comply with the nondiscrimination requirements. Furthermore, there are also several sections of the Americans with Disabilities Act (ADA) that require facilities, such as CMHC providers, to provide appropriate accommodations for their clients. Since section 504 and the ADA provisions are applicable to CMHCs, we are not addressing the specifics of these requirements in the CoPs.

Comment: One commenter suggested that CMS should require a CMHC with a clientele that is more than 25 percent non-English speaking to provide written translations of clients' rights information in the relevant language(s).

Response: We appreciate the feedback that if the CMHC clientele is over 25 percent non-English speaking, the CMHC must provide written translations of clients' rights information in the relevant languages. We recognize that this is an area of concern for CMHCs, as it may be challenging for CMHCs to communicate with clients who speak languages other than English. The HHS guidance on Title VI (August 8, 2003, 68 FR 47311) applies to those entities that receive Federal financial assistance from HHS, including CMHCs. CMHCs are already expected to comply with the HHS guidance, which requires the CMHC to take reasonable steps to provide meaningful access to its programs or activities. CMHCs should take reasonable steps to provide meaningful access to persons with LEP. This may involve securing a qualified interpreter for CMHC-client communications, including those involving the notice of clients' rights. Providing meaningful access may also involve the CMHC translating written copies of the notice of rights available in the language(s) that are commonly spoken in the CMHC service area. As explained in the HHS LEP guidance at *http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf* (section VI B), use of an oral interpreter presents a set of complex issues. For example, use of family members or friends as interpreters may be actively sought by some patients but may present a danger to the patient in other cases. What is required of CMHCs in particular communities will depend on what HHS terms a ''four factor analysis,'' taking into account availability of interpreters, how many languages are commonly or rarely encountered among CMHC clients, and other situational factors. For additional information related to LEP, the Department of Health and Human Services recently released a new document highlighting the departments commitment to LEP, which is located at the following Web site: *http://www.hhs.gov/open/execorders/13166/index.html.*

Comment: Some commenters stated that a 5-day timeframe for violation reporting is too long. Other commenters

stated that the reliance on internal procedures and self-regulation may cause CMHCs to determine that most violations do not require any type of corrective action or reporting because of the fear of repercussions from State regulatory agencies or CMS.

Response: We understand that the 5 working days timeframe may seem too long. However, the CMHC may require a shorter timeframe through its policies and procedures. The CMHC is required to immediately report an incident to the administrator, who must immediately investigate all alleged violations. The CMHC must take action to prevent further potential violations while the alleged violation is being verified. This process begins as soon as the alleged violation is discovered and will likely be resolved sooner than 5 days. Additionally, because CMHCs are not residential facilities, it is unlikely that the involved client will be in the facility during the entire 5-day period.

We also understand the commenters' concern with the CMHC internal investigation procedures. We believe requiring CMHCs to investigate potential violations of client rights by CMHC staff (including contracted or arranged services) may represent a conflict of interest, or insufficient to protect clients and their families.

For this reason, we are amending the requirement at § 485.910(d)(4) to require that all violations be reported to State survey and certification agencies, and verified by the appropriate investigator, violations also be reported to State and local entities having jurisdiction. While we understand the commenters' concern with the CMHC internal investigation procedures, we believe requiring CMHCs to investigate potential violations of client rights by CMHC staff (including contracted or arranged services) will protect clients and their families. Reporting violations, when verified in accordance with CMHC policies and procedures and any applicable State and local laws and regulations related to client health and safety, is an integral part of improving the quality of CMHC care provided to Medicare beneficiaries. Ultimately the CMHC must follow Federal and State laws related to client health and safety, as well as follow its own internal policies and procedures. We expect significant violations, such as illegal actions by CMHC staff, to be reported to State and local authorities. We believe that the framework in this regulation, coupled with a CMHC's own policies and procedures and State and local requirements related to client health and safety, will allow CMHCs to adapt the requirements to the particular needs and concerns of their client populations now and in the future.

If State requirements for reporting violations are stricter than our Federal requirements, the stricter State requirements would take precedence. Stricter State requirements may be those that require violations to be reported regardless of whether they are verified, or requirements that verified violations be reported in less than five days. However, if State requirements are less stringent than Federal requirements, then the Federal requirements will take precedence.

Comment: One commenter stated that there should be a limit to the number of clients attending a group session. Specifically, the commenter requested that CMS add an additional requirement at § 485.910(c), ''Standard: Rights of the client,'' limiting a PHP group maximum size to 12–15 clients. The commenter stated that this would help to ensure all clients receive full benefit from PHP sessions.

Response: We appreciate the commenter's concern regarding the number of clients attending a group session. We believe that the CMHC would need to determine, through its policies, procedures, and guidelines related to group therapy sessions, what is appropriate for each client. There are many different acuity levels and needs for CMHC clients which may require larger or smaller group sizes. All the participants within a given group should have the same acuity level and group session treatment goal. A group's size should be based on the needs and abilities of its participants. A group should not be too small to prevent the benefit of learning and sharing from other participants that occurs in a ''group,'' nor too large as to prevent all members from the benefit of actively participating. We expect the CMHC and the client's therapist or team will exhibit sound clinical judgment and clinical practice when assigning a client to a particular group or group psychotherapy and when developing the actual group. Therefore, we will leave it up to the clinical expertise and sound professional judgment of the CMHC trained staff to determine what works best for each client. For each client there is a periodic reassessment and review of the client's progress. This review will allow adjustments for such treatments, including the size of the group to which the client belongs or the need for individualized therapy.

Comment: Several commenters stated that restraint and seclusion are not used in CMHCs. Therefore, they believe training of staff should focus on de-escalation techniques. Commenters stated that following established procedures for involuntary hospitalization should minimize or completely eliminate the need to use restraint and/or seclusion. Likewise, other commenters stated that State law prohibits CMHCs from using seclusion and restraint in any program. As a result, CMHCs no longer train staff on these prohibited practices. Instead, CMHCs train staff in de-escalation techniques and crisis management. Furthermore, some commenters stated that there is no evidence that CMHCs' use of seclusion or restraint is a concern, and the training and reporting requirements would create administrative and financial burdens.

Response: We appreciate the feedback from the commenters on restraint and seclusion. We agree that if State law is more stringent than Federal law, State law takes precedence. That is, if the use of seclusion and restraint is prohibited by the State, then the CMHC is not allowed to use seclusion and restraint techniques in the process of providing services to CMHC clients. The requirements at § 485.910(f)(1) and (f)(2) state that training of CMHC staff focuses on techniques to identify staff and client behaviors, events and environmental factors that may trigger circumstances that require the use of restraint or seclusion, as well as the use of nonphysical intervention skills. We believe that training CMHC staff to identify potential triggers and to use positive behavioral intervention supports and nonphysical intervention skills, also known as de-escalation techniques, is compatible with State law even in states that expressly prohibit the use of seclusion and restraint techniques. While the concepts are related, identifying triggers and using nonphysical interventions are not the same as using seclusion and restraint techniques. Therefore, all CMHCs, even those located in states that prohibit the use of seclusion and restraint techniques, are required to train their staff in the use of nonphysical interventions in order to assure the safety of all clients and staff. Training on nonphysical interventions could be incorporated into the CMHC staff in-service training requirements at § 485.918(d)(3). This type of training meets the requirements of the regulation.

We emphasize that in states where the use of seclusion and restraint techniques are permitted, they may only be used to protect the client or others from immediate harm, and their use would trigger immediate transportation to a hospital. In the rare occurrence that a restraint and seclusion order is

needed, the duration of the order is for 1 hour. If there is a delay in the arrival of client transport extending past the 1 hour order duration, a second order would need to be obtained. We believe that if this delay occurs, it is in the best interest of the health and safety of the client that a re-assessment of the client's condition be made to determine if restraints remain necessary, before the second order is obtained.

Comment: A few commenters stated that restraint and seclusion death reporting should be expanded to include the reporting of deaths that occur as the result of abuse or neglect. Other commenters requested an additional requirement, such as reporting the incident to the relevant protection and advocacy agency. One commenter recommended that CMS be very specific in defining what it means by ''attributed to.'' Commenters recommended that reporting should be required only when restraint and seclusion was determined to be a direct cause of death. Additionally, commenters stated that CMS should investigate the death as part of the complaint survey investigation process.

Response: We agree with the commenters on reporting deaths that occur as a result of abuse or neglect. We expect that a health care provider or agency that believes a CMHC client is the subject of abuse or neglect will report the concern to the proper State authorities. This requirement falls under § 485.910(d)(1), to ensure that all alleged violations involving abuse or neglect are reported immediately to the CMHC administrator. An investigation should immediately occur and procedures should be put in place to prevent further potential violations while the alleged violation is investigated. The CMHC is then required to take appropriate corrective action in accordance with State law (which may include contacting appropriate advocacy agencies), if the alleged violation is verified by the CMHC administration or verified by an outside entity having jurisdiction.

Should a seclusion or restraint-related death occur, our intent is to ensure that the CMHC immediately notify CMS and begin to fully investigate the death. Waiting to determine if the death was directly caused by the use of restraint or seclusion could potentially have negative impact on other clients being served by the CMHC. We acknowledge that seclusion and restraint are rarely, if ever, used and that the likelihood of death ever having to be reported is extremely low. However, it is imperative that the CMHC report any instance where a death of a client is associated with the use of seclusion or restraint. Should a seclusion or restraint-related death occur, we would initiate an onsite complaint survey of the CMHC in accordance with the existing complaint investigation process.

CMHC CoP: Admission, Initial Evaluation, Comprehensive Assessment and Discharge or Transfer of the Client (§ 485.914)

We proposed to add a new CoP at § 485.914 to establish requirements for admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client. The proposed CoP at § 485.914 identified general areas that would be included in a client assessment and the timeframes for completing the assessments to help the CMHC ensure it was identifying the needs in all areas in a timely fashion. The proposed CoP was divided into five standards.

At § 485.914(a), ''Standard: Admission,'' we proposed to require the CMHC to determine whether a client is appropriate for the services the CMHC provides. At § 485.914(b), ''Standard: Initial evaluation,'' we proposed to require the CMHC psychiatric registered nurse or clinical psychologist to complete the initial evaluation. We stated that the care needs identified in the initial evaluation would include, but would not be limited to, those necessary for treatment and management of the psychiatric illness. We also specified that the initial assessment would be completed within 24 hours of the client admission to the CMHC.

At § 485.914(c), ''Standard: Comprehensive assessment,'' we proposed that a physician-led interdisciplinary team, in consultation with the client's primary health care provider (if any), complete the comprehensive assessment. We stated that the comprehensive assessment would build from the initial evaluation and identify the client's physical, psychological, psychosocial, emotional and therapeutic needs. The interdisciplinary team would be composed of a doctor of medicine, osteopathy or psychiatry; a psychiatric registered nurse, a clinical psychologist, a clinical social worker, an occupational therapist, and other licensed mental health counselors, as necessary. Each member of the team would provide input within the scope of that individual's practice. As proposed, the comprehensive assessment would include information about the client's psychiatric illness and history, complications and risk factors, drug profile review, and the need for referrals and further evaluations by appropriate health care professionals. The comprehensive assessment would be completed within 3 working days after the admission to the CMHC.

At § 485.914(d), ''Standard: Update of the comprehensive assessment,'' we proposed that the CMHC would update the comprehensive assessment via the physician-led interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), no less frequently than every 30 days, and when changes in the client's status, response to treatment, or goals occurred. The update would have to include information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals. We believe that these frequent reviews are necessary since clients with ongoing mental illness may be subject to frequent and/or rapid changes in status, needs, acuity, and circumstances, and the client's treatment goals may change, thereby affecting the type and frequency of services that should be furnished. The physician-led interdisciplinary treatment team would use assessment information to guide necessary reviews and/or changes to the client's active treatment plan.

At § 485.914(e), ''Standard: Discharge or transfer of the client,'' we proposed that the CMHC complete a discharge summary and forward it to the receiving facility/provider, if any, within 48 hours of discharge or transfer from the CMHC. If the client is being discharged due to non-compliance with the treatment plan, the CMHC would forward the discharge summary and, if requested, other pertinent clinical record information to the client's primary health care provider (if any). The discharge summary would be required to include—(1) a summary of the services provided while a client of the CMHC, including the client's symptoms, treatment and recovery goals and preferences, treatments, and therapies; (2) the client's current active treatment plan at the time of discharge; (3) the client's most recent physician orders; and (4) any other documentation that would assist in post-discharge continuity of care. Furthermore, under this standard we proposed that the CMHC would have to adhere to all Federal and State-related requirements pertaining to medical privacy and the release of client information. We believe this standard would help ensure that the information flow between the CMHC and the receiving entity was smooth, and that the appropriate care continued without being compromised (where applicable).

Comment: Several commenters stated that under Medicaid and State law, CMHCs are allowed a wide range of staff to provide initial evaluations, from unlicensed, Master's level practitioners (under supervision of a licensed professional) to licensed Master's level clinicians, including social workers and counselors. Commenters also stated that State laws allow for licensed clinical social workers (LCSWs) or other mental health counselors to conduct initial evaluations. Other commenters stated that use of a psychiatric RN or clinical psychologist to conduct the initial evaluation should only apply to PHP programs.

Response: We appreciate the comments regarding the appropriate staff to conduct an initial evaluation. We understand currently that there may be several different staff the CMHC uses to conduct an initial evaluation, and that the types of staff used may vary from State to State. While it may be appropriate for a psychiatric RN or psychologist to conduct an initial evaluation on a client, we understand that this may not be appropriate for all clients and is not necessarily a standard of practice in the CMHC setting. We would expect the CMHC to assign the most appropriate mental health professionals to conduct the initial evaluation. Therefore, the CMHC may add additional requirements under their policy and procedures to require the initial evaluation on all PHP clients to be conducted by a psychiatric RN, acting within his or her State's scope of practice, or by a clinical psychologist, who meets the qualifications in § 410.71(d), acting within his or her State's scope of practice. We have removed the requirement that a psychiatric RN or clinical psychologist conduct the initial evaluation.

We also understand that there may be unlicensed staff (completing their education or licensure requirements) conducting initial evaluations under the supervision of a licensed professional. We believe that the initial evaluation is paramount in meeting the immediate needs of the client and beginning the active treatment plan. Therefore, we have amended the language at § 485.914(b)(1) to allow a licensed mental health professional acting within his or her State scope of practice to conduct the initial evaluation. We will allow staff working towards completing their education or licensure requirements to complete the initial evaluation under the direct supervision of a licensed mental health professional (as required by all State law and regulations related to the supervision of unlicensed professionals and students) employed by the CMHC.

Comment: One commenter stated the CMHC should be required to notify a client's primary care provider, if any, in lieu of a formal consultation. The commenter stated that such notification would be contingent upon a client's understanding and consent.

Response: This comment was somewhat unclear. We believe it is referring to communication between the CMHC and the client's primary care provider during the comprehensive assessment. We agree with the commenter that the CMHC should obtain consent from the client when sharing information between the CMHC and the PCP. Therefore, we have amended the language at § 485.914(c)(4)(ii) regarding the CMHC receiving the client's consent before client information is obtained or shared with the client's primary care provider.

Comment: Commenters asked to add additional assessment criteria such as environmental factors. Commenters stated that strengths and barriers related to a client's home, work, or social environments can play a critical role in the success or failure of key interventions.

Response: We agree that it is important to assess environmental factors related to the home and work environments in the overall development and coordination of the active treatment plan. Furthermore, we believe the assessment and coordination of information related to environmental factors such as housing and employment services, as well as the client's preferences and personal goals, are essential in developing a recovery focused active treatment plan and to meeting the client's recovery goals. Therefore we amended the assessment language at § 485.14(b)(4)(v) to include environmental factors and at § 485.16(e)(5) to include coordination of services with other healthcare and non-medical providers.

We would like to stress the importance of client privacy and confidentiality and remind CMHCs that HIPAA applies to release of protected health information by CMHCs; it is generally prohibited to release client information to non-health care entities without the express consent of the client. If CMHCs do release such information to state or local agencies, they must generally obtain consent from the client before such release.

Comment: Some commenters believe that the medication review should be limited to requiring that the partial hospitalization program maintain only a current list of the individual's medications, prescriptions and over-the-counter medications, as well as contact information for the treating practitioner of the individual served.

Response: We appreciate the comments on medication review. We believe that listing the current medications (both prescription and over-the-counter) is extremely important for all clients during the initial evaluation. The information documented will be reviewed during the comprehensive assessment and may impact the development of the active treatment plan. Therefore, we believe that the documentation of current medications is essential to the start of care for the CMHC clients.

Comment: Commenters stated that a psychiatrist should be required to address medication management.

Response: We appreciate the comments regarding a psychiatrist addressing medication management. The initial evaluation requires documentation of both prescription and over-the-counter medications. The comprehensive assessment requires a drug profile that includes a review of all of the client's prescription and over-the-counter medications; herbal remedies; and other alternative treatments or substances that could affect drug therapy. We expect the drug profile section of the comprehensive assessment to be completed by a CMHC licensed mental health professional (such as the psychiatrist, MD or nurse practitioner) with the appropriate knowledge, skills, and certification or licensure, and acting within his or her State's scope of practice, to assess drug therapy.

Comment: Commenters stated that a CMHC should be assessing the social service needs of pediatric clients. They also stated that, when appropriate, a referral should be made to social services, child welfare, and/or the juvenile justice system for pediatric clients.

Response: We agree that assessing for the social service needs of pediatric clients is very important. We expect that the assessment of a pediatric client would include social service and child welfare questions. We also expect that a referral be made to social services and/or child welfare services, if appropriate. Therefore, we have added language at § 485.914(c)(4)(xiv) to address the pediatric assessment.

Comment: Some commenters stated that additional assessment criteria should be added to the comprehensive assessment. Commenters stated that CMHCs should assess for client strengths and goals, as well as a history of trauma.

Response: We agree that it is important to assess the client for strengths, goals and a history of trauma. We believe that a history of trauma is already incorporated into the regulation language at § 485.914(c)(4)(ii) and (iii). These sections outline the assessment expectation of the psychiatric evaluation, which would review medical history and severity of symptoms, as well as assessment information concerning previous and current medical status, including but not limited to, previous therapeutic interventions and hospitalizations. Section § 485.915(c)(4)(viii) addresses clients' goals and requires the client to be assessed for functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals.

Comment: Some commenters stated that CMS should change the comprehensive assessment timeframe from 3 working days to 7 program days. Other commenters stated the assessment time-frames should be extended from 3 working days to 5 working days.

Response: We appreciate the comments related to the assessment timeframe. However, we are unclear on what the commenters meant by ''program days''. The commenters did not clarify or give examples regarding the term ''program days''. We use the term ''working days'', which allows the CMHC to not count the days that the CMHC is closed. Other commenters asked that we extend the time-frame for completion of the assessment. We understand that the clients a CMHC may see vary greatly in their treatment needs and that assessing a complex client may take longer than 3 working days. However, we believe that all clients should be assessed in a timely manner regardless of their diagnosis. Therefore, we have amended the timeframe for the assessment at § 485.914(c)(2) from 3 working days to 4 working days, with day 1 starting the day after admission. For example, if a client is admitted on a Friday, the CMHC would need to have the comprehensive assessment completed within 4 working days, which would be by Thursday.

Comment: A few commenters requested that we extend the permissible timeframe for a CMHC to prepare and forward a discharge summary to a receiving facility or provider, if any, to 30 days from the date of discharge. The commenters stated that the proposed 48-hour requirement is inconsistent with the existing requirement for inpatient psychiatric providers and unnecessarily places an administrative burden upon CMHCs.

Response: We appreciate the comments related to forwarding the discharge summary. We acknowledge that there is a 30-day discharge paperwork requirement for discharge from an inpatient psychiatric facility. However, the inpatient discharge expectation is that the client summary information is sent at the time of discharge to the receiving entity. Best practices would suggest that at discharge there would be no break in service and that the receiving entity receive the appropriate information to continue to meet the needs of the client. However, we understand that a CMHC is open during regular business hours and requiring a 48-hour timeframe may be unreasonable. Therefore, we modified the language at § 485.914(e)(1) to require the CMHC to forward the discharge summary to the receiving entity or practitioner within 2 working days after the discharge. For example, if a client discharges from the CMHC on Friday the discharge summary should be sent to the receiving provider by close of business on Tuesday.

Comment: A few commenters asked who should be responsible for ensuring the discharge plan is complete.

Response: The discharge process is part of the client's active treatment plan and should be discussed and incorporated in the plan from the initial evaluation. The interdisciplinary team is responsible for the care and services for each client. Moreover, § 485.916(a)(2) requires the CMHC to determine the appropriate licensed mental health professional, who is a member of the client's interdisciplinary treatment team, to coordinate care and treatment decisions with each client, to ensure that each client's needs are assessed, and to ensure that the active treatment plan is implemented as indicated. Best practices would suggest that this coordinator would also manage the discharge process of the client. However, the CMHC has the flexibility to have any licensed professional who serves on the client's interdisciplinary treatment team coordinate the discharge plan.

Comment: One commenter asked that we eliminate the requirements regarding discharge for non-compliance.

Response: While we understand the commenter's concern regarding discharge for non-compliance, and believe that this rarely happens, we believe the CMHC wants to serve its clients to the best of its ability. Unfortunately, when a client is non-compliant with his or her active treatment plan, it may be in the best interest for both the client and the CMHC to discharge the client to a care level that meets the client's needs. If non-compliance became an issue for a client, the client's interdisciplinary team would need to document that it addressed the issue and tried repeatedly to work with the client and family, and that discharge was the last option. The CMHC must ensure that the client's discharge information is forwarded to the appropriate practitioner as required in § 485.914(e).

CMHC CoP: Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services (§ 485.916)

We proposed to add a new CoP at § 485.916 to establish requirements for an active treatment plan and coordination of services.

At § 485.916(a), ''Standard: Delivery of services,'' we proposed that the CMHC designate a physician-led interdisciplinary team for each client. We proposed that the interdisciplinary team include a psychiatric registered nurse, clinical psychologist, or a Master's level prepared or Doctoral level prepared social worker, who would be a coordinator responsible, with the client, for directing, coordinating and managing the care and services provided to the client. The team would be composed of individuals who would work together to meet the physical, medical, psychosocial, emotional, and therapeutic needs of CMHC clients.

The CMHC would designate a psychiatric registered nurse, clinical psychologist or clinical social worker who was a member of the interdisciplinary treatment team to coordinate care, ensure the continuous assessment of each client's needs, and ensure the implementation and revision of the active treatment plan. Depending on the number and/or type of clients served by the CMHC, the CMHC may have more than one interdisciplinary team. If so, the CMHC is required to designate one treatment team responsible for establishing policies and procedures governing the day-to-day operations of the CMHC, and the care and services provided to clients.

At § 485.916(b), ''Standard: Active treatment plan,'' we proposed to require that all CMHC services furnished to clients follow a written active treatment plan established by the CMHC physician-led interdisciplinary treatment team and the client (and representative, if any), in accordance with the client's psychiatric needs and goals within 3 working days after the client's admission to the CMHC. The CMHC would have to ensure that each client and, if relevant, primary

caregiver(s), received education and training that was consistent with the client's and caregiver's responsibilities, as identified in the client-specific active treatment plan. Education is necessary to ensure that the client and caregiver understand the services and treatments contained in the active treatment plan, and their roles in actively participating in, and following the plan.

At § 485.916(c), ''Standard: Content of the active treatment plan,'' we proposed to require that each client's active treatment plan reflects client goals and interventions for problems identified in the comprehensive and updated assessments. This proposed requirement would ensure that care and services were appropriate to the level of each client's specific needs. The active treatment plan would include all of the services necessary for the care and management of the psychiatric illness. We would also require a detailed statement of the type, duration and frequency of services, including social work, counseling, psychiatric nursing and therapy services. Services furnished by other staff trained to work with psychiatric clients necessary to meet the specific client's needs should also be documented. The interdisciplinary treatment team should document the client's and representative's (if any) understanding, involvement, and agreement with the active treatment plan, in accordance with the CMHC's own policies. This would include information about the client's need for services and supports, and treatment goals and preferences.

At § 485.916(d), ''Standard: Review of the active treatment plan,'' we proposed that a revised active treatment plan be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. The active treatment plan would have to be reviewed at intervals specified in the plan, but no less frequently than every 30 calendar days.

At § 485.916(e) ''Standard: Coordination of services,'' we proposed to require that the CMHC maintain a system of communication and integration to enable the interdisciplinary treatment team to ensure the overall provision of care and the efficient implementation of day-to-day policies and procedures. This proposed standard would also make it easier for the CMHC to ensure that the care and services are provided in accordance with the active treatment plan, and that all care and services provided are based on the comprehensive and updated assessments of the client's needs. An effective communication system also enables the CMHC to ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services are being provided by employees or by individuals under contract with the CMHC.

Comment: Several commenters stated that the family and/or significant other should be included in the active treatment planning process.

Response: We appreciate the suggestion to add family and/or significant other involvement in the active treatment plan. We agree with the commenters, but prefer to use the term ''primary caregiver'' instead of family and/or significant other. The term ''primary caregiver'' is a broader term that encompasses family and significant others but also represents caregivers such as friends or significant others. Therefore, we have amended the language at § 485.916(b), ''Standard: Active treatment plan'' to add ''primary caregiver.''

Comment: Many commenters believe that the proposed CoPs were over-reaching in requiring an interdisciplinary team (IDT) which ''would include'' many disciplines. Commenters stated that CMS should replace ''would include'' with ''may include'' in order to allow for the individualization of the treatment planning for each client. Other commenters disagreed with CMS regarding the staff requirements for the IDT being standard medical practice.

Response: We agree with the comments related to the members of the IDT. We understand that CMHC clients vary from clients receiving PHP to clients receiving short term counseling or medication management. We believe there may be clients who, based on their diagnosis and assessment, may only need a one-person IDT to meet their care needs. For example, a client who is being treated for medication management may be required to be seen by a practitioner a couple of times a year. Therefore, the proposed ''one size fits all'' approach to the IDT membership may not serve the client's interests and potentially takes away from the CMHC's flexibility to serve the client's needs, and the needs of other clients. Therefore, we have amended the language at § 985.916(a)(2) to allow the CMHC to determine (based on the findings of the client's comprehensive assessment), the appropriate licensed mental health professionals and other CMHC staff to serve on the client's interdisciplinary team. The amended language now states that the interdisciplinary team may include: A doctor of medicine, osteopathy or psychiatry (who is an employee of or under contract with the CMHC), a psychiatric registered nurse, a clinical social worker, a clinical psychologist, an occupational therapist, other licensed mental health professionals, and other CMHC staff, as necessary. We note that the interdisciplinary team membership must be based on the client's assessed needs. CMHCs will be expected to demonstrate a correlation between the client's comprehensive assessment, assessed needs, members serving on the interdisciplinary team, and the active treatment plan. Therefore a PHP client's interdisciplinary team members are likely to be different than the client who is being treated by the CMHC for short-term counseling or medication management.

Comment: A few commenters stated that CMHCs often do not have the resources to engage a physician in leading team care, treatment, and services planning. According to commenters, there is no recognized data to demonstrate improved outcomes in PHPs by having a physician leading the care team. Other commenters stated that the concept of a collaborative healthcare team should not be restricted to a ''physician-led interdisciplinary team'' as it may be more achievable if viewed as an interdisciplinary team that includes a physician. The commenters also believe that a physician-led interdisciplinary team limits the capacity of advanced practice registered nurses, nurse practitioners and clinical psychologists, who are qualified and licensed to lead interdisciplinary teams.

Response: We appreciate the comments regarding the physician leading the interdisciplinary team. We proposed this standard to ensure physician involvement in the interdisciplinary team process. However, we agree that there is no documented research that demonstrates improved outcomes in PHPs by having a physician leading the team, and such a requirement may limit collaboration and the role of the other qualified practitioners. Therefore, based on the client's needs, in addition to a physician, we have amended the language at § 485.916(a)(1), to now allow for a nurse practitioner, a clinical nurse specialist, a clinical psychologist, a physician assistant, or clinical social worker to serve as the leader of the team, if permitted by State law and within his or her scope of practice. This allows the CMHC greater flexibility to meet the client's needs. We stress that while this change allows additional

advanced practice practitioners to lead the team, it in no way minimizes the physician's involvement in managing the medical component of the client's care and/or serving on the interdisciplinary group.

In the instance of partial hospitalization, clients need acute services and must be under the care of a physician. According to the statutory requirements, which are implemented in CMS regulations at 42 CFR 424.24(e), PHP services must be prescribed by a physician and under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program). Furthermore, upon admission, a physician must certify that in absence of PHP services, the person would otherwise require inpatient psychiatric treatment. If continued PHP treatment is necessary, a physician must recertify as of the 18th day of treatment and no less than every 30 days after that documenting the need for this level of service. Therefore, a physician is inextricably involved in a PHP client's treatment team.

Comment: Several commenters stated that advanced practice nurses, including both psychiatric mental health nurse practitioners (PMHNPs) and psychiatric mental health clinical nurse specialists (PMHCNSs), need to be included in the list of professionals who can lead multidisciplinary teams. Other commenters stated that occupational therapists, social workers and other licensed mental health counselors should be added to the list of professionals who can serve as coordinators.

Response: We appreciate the comments regarding leading the interdisciplinary team. There are two different requirements in the proposed CoPs where we discuss leadership of the interdisciplinary team. In § 485.916(a)(1), we proposed that the interdisciplinary team be led by a physician. We proposed this standard to ensure physician involvement in the interdisciplinary team process. However, we agree that allowing a nurse practitioner, a clinical nurse specialist, a physician assistant, or a psychologist would allow the CMHC greater flexibility to meet the client's needs. While we allow for additional advanced practice practitioners to lead the team, that in no way minimizes the physician involvement in managing the medical component of the client's care.

At § 485.916(a)(2), we proposed a psychiatric registered nurse, a clinical psychologist, or a clinical social worker, who is a member of the interdisciplinary team to coordinate care and treatment decisions with each client, to ensure that each client's needs were assessed and to ensure the active treatment plan was implemented as indicated. We understand that there may be other licensed mental health professionals serving on the interdisciplinary team that could be appropriate to coordinate the client's care. Therefore, we have amended the language at § 485.916(a)(2) to allow the CMHC to determine (based on the findings of the client's comprehensive assessment) which appropriate licensed mental health professional(s) on the client's interdisciplinary team should coordinate care and treatment decisions with each client. This coordinator role would work to ensure that each client's needs are assessed and to ensure that the active treatment plan is implemented as indicated.

Comment: A few commenters stated that social workers and occupational therapists are not needed for every client, but should be available.

Response: Services offered to a client should be based on the client's assessed needs. If a client is assessed to need the services of a social worker and/or an occupational therapist, we would expect those disciplines to be part of the interdisciplinary team. We note that the needs of CMHC clients vary from clients receiving PHP to clients receiving short term counseling. Therefore, the proposed approach to the interdisciplinary team membership may not serve the client's interests and potentially takes away from the CMHC's flexibility to serve the client's needs. Therefore, we have amended the language at § 485.916(a)(2) to allow for the CMHC to determine (based on the findings of the client's comprehensive assessment) the appropriate licensed mental health professional(s) and other CMHC staff that will serve on the client's interdisciplinary team.

Comment: One commenter stated that a Licensed Professional Counselor (LPC) can fulfill the clinical, psychological, and social work needs of clients.

Response: We appreciate the comment regarding LPCs fulfilling multiple client needs. We agree there are times when an LPC may be able to meet several different assessed needs of the client, as long as the State licensure permits them to do so. We would expect to see documentation by the LPC of the progress toward the client's goals. The expectation is that if goals are not being met and additional needs are assessed, the interdisciplinary team will bring in additional team members to address the client's needs.

Comment: One commenter stated that a peer specialist or family peer advocate should be added to the IDT. Another commenter stated that CMS should require support of the recovery model by allowing for peers (persons with lived experience of mental illness, or peer specialists) to be part of the treatment team.

Response: We appreciate the comments regarding peer specialists and family peer advocates. We agree that, depending on the CMHC's client needs and programs, peer specialists or family peer advocates may be appropriate to meet individual client needs. Therefore, we have amended the language at § 485.916(a)(2)(vii) to permit other CMHC staff or volunteers to serve on the interdisciplinary team, as necessary.

Comment: A few commenters stated that the timeframe for developing the active treatment plan should be extended from 3 working days to 5 working days.

Response: We appreciate the commenters' request for extension of the active treatment plan timeframe. We believe that completing the assessment in a timely manner is very important. In this final rule, we have amended the timeframe of the comprehensive assessment to be completed within 4 working days. Therefore, we also amended the language at § 485.916(b) to extend the timeframe for completion of the active treatment plan to 7 working days.

In the instances of partial hospitalization, due to the acuity level of the clients served, we expect the partial hospitalization program to meet the requirement at § 424.24.

Comment: A few commenters recommended amending the treatment plan language to allow organizations to document the understanding of either the individual served or, if the individual served is unable to acknowledge his or her understanding and/or agreement, the representative's understanding of, and agreement with, the treatment plan.

Response: We appreciate the commenters' suggestion. We agree that having the CMHC document the client's and/or the client representative's understanding of the active treatment plan is necessary. We would expect the CMHC to document the client's understanding and involvement in his or her active treatment plan. If the client is unable to understand the active treatment plan, the CMHC would document the client's representative's understanding and involvement in the active treatment plan. Therefore, we

have amended the language in § 485.916(c)(7).

Comment: A few commenters stated that we should include the individual's preferences and personal goals in the active treatment plan. Another commenter recommended that we revise the standards to reflect current recovery-focused care planning to better align with the recommendations previously set forth by the Substance Abuse and Mental Health Services Administration.

Response: We appreciate both commenters' suggestions to include the client's preferences and personal goals in the active treatment plan and to have a recovery focused active treatment plan. We agree with both of the commenters, and have amended § 485.916(b) accordingly. We expect that the interdisciplinary team will work together to establish the client's individual active treatment plan in accordance with the client's recovery goals and preferences.

Comment: One commenter recommended that we require the development of a crisis plan for each client.

Response: We agree with the commenter that crisis planning is important for the health and safety of clients. However, the individual client's risk factors are assessed during the comprehensive assessment and the information gathered in the assessment and active treatment plan would be used to guide the care of the client if an emergency should occur. Therefore, we do not believe it is necessary to add an additional regulatory requirement addressing crisis planning.

CoP: Quality Assessment and Performance Improvement (Proposed § 485.917)

We proposed to add a new CoP at § 485.917 to specify the requirements for a quality assessment and performance improvement program (QAPI). The proposed QAPI CoP was divided into five standards.

At § 485.917(a), ''Standard: Program scope,'' we proposed that a CMHC QAPI would include, but not be limited to, an ongoing program that is able to show measureable improvement in indicators linked to improving client care outcomes and behavioral health support services. We expect that a CMHC would use standards of care and the findings made available in current literature to select indicators to monitor its program. The CMHC would have to measure, analyze, and track quality indicators, including areas such as adverse client events and other aspects of performance that assess processes of care, CMHC services and operations. The term ''adverse client events,'' as used in the field, refers to occurrences that are harmful or contrary to the targeted client outcomes, including sentinel events such as an unexpected occurrence involving death or serious injury. The use of restraint or seclusion is contrary to targeted client outcomes; therefore, we would consider the use of restraint or seclusion to be an adverse client event that would be tracked and analyzed as part of the QAPI program.

At § 485.917(b), ''Standard: Program data,'' we proposed to require the CMHC to incorporate quality indicator data, including client care data and other relevant data, into its QAPI program. A fundamental barrier in identifying quality care is lack of measurement tools. Measurement tools can identify opportunities for improving medical care and examining the impact of interventions.

We did not propose to require CMHCs to use any particular process, tools or quality measures. However, a CMHC that uses available quality measures could expect an enhanced degree of insight into the quality of its services and client satisfaction.

The CMHC could also develop its own data elements and measurement process as part of its program. A CMHC would be free to develop a program that meets its needs. We recognize the diversity of provider needs and concerns with respect to QAPI programs. As such, a provider's QAPI program would not be judged against a specific model. We expect the CMHC to develop and implement a continuous QAPI program that stimulates the CMHC to constantly monitor and improve its own performance, and to be responsive to the needs and satisfaction levels of the clients it serves.

At § 485.917(b), we proposed to require that data collected by the CMHC, regardless of the source of the data elements, would be collected in accordance with the detail and frequency specifications established by the CMHC's governing body. Once collected, the CMHC would use the data to monitor the effectiveness and safety of services, and target areas for improvement. The main goal of the proposed standard would be to identify and correct ineffective and/or unsafe care. We expect CMHCs to assess their potential client load and identify circumstances that could lead to significant client care issues, and concentrate their energies in these areas.

At § 485.917(c), ''Standard: Program activities,'' we proposed to require the CMHC to set priorities for its performance improvement activities that focus on high risk, high volume or problem-prone areas; consider the prevalence and severity of identified problems; and give priority to improvement activities that affect client safety, and quality of client outcomes. We expect that a CMHC would take immediate action to correct any identified problems that would directly or potentially threaten the care and safety of clients. Prioritizing areas of improvement is essential for the CMHC to gain a strategic view of its operating environment and to ensure consistent quality of care over time.

We also proposed to require the CMHC to track adverse client events, analyze their causes, and implement preventive actions that include feedback and learning throughout the CMHC. In implementing its QAPI program, a CMHC is expected to treat staff and clients/representatives as full partners in quality improvement. Staff members and clients/representatives are in a unique position to provide the CMHC with structured feedback on, and suggestions for, improving the CMHC's performance. We expect the CMHC to demonstrate how the staff and clients have contributed to its quality improvement program.

At § 485.917(d), ''Standard: Performance improvement projects,'' we proposed to require that the number and scope of improvement projects conducted annually would reflect the scope, complexity and past performance of the CMHC's services and operations. The CMHC would document what improvement projects were being conducted, the reasons for conducting them and the measurable progress achieved by them.

At § 485.917(e), ''Standard: Executive responsibilities,'' we proposed to require that the CMHC's governing body would be responsible and accountable for ensuring that the ongoing quality improvement program is defined, implemented, maintained, and evaluated annually. The governing body would ensure that the program addressed priorities for improved quality of care and client safety. The governing body would also have to specify the frequency and level of detail of the data collection and ensure that all quality improvement actions were evaluated for effectiveness. The governing body's most important role would be to ensure that staff was furnishing, and clients were receiving, safe, effective, quality care. Therefore, it would be incumbent on the governing body to lend its full support to agency quality improvement and performance improvement efforts.

Comment: One commenter suggested that as an alternative to the requirement

that CMHCs develop their own QAPI programs, CMS could point CMHCs to specific, existing programs, such as NCQA's Managed Behavioral Health Organization (MBHO) Certification program, to ensure consistency among facilities in delivering high quality care.

Response: We acknowledge that there are existing programs that may be used by CMHCs in their efforts to meet the QAPI standards. We would caution, however, that participation in such programs does not guarantee that the CMHCs are in compliance with this requirement. As required in § 485.917(b)(2)(ii), CMHCs must use the quality indicator data that they have gathered to identify and prioritize opportunities for improvement. In addition, § 485.917(a)(1) requires the CMHC QAPI program to show measurable improvement in the areas related to improved behavioral health outcomes and CMHC services specific to the individual facility. Furthermore, § 485.917(d)(1) requires that the scope and number of a CMHC's performance improvement projects are to be based on the unique needs of the CMHC and its client population. These requirements require the CMHC to develop, implement, and assess performance improvement projects that reflect the areas of weakness, as identified through the data they have collected, and the needs of their organization. If a CMHC participates in a certification program that does not address one more of the areas of weakness, or if that performance improvement project will not enable the CMHC to demonstrate measurable improvement in areas identified as needing to be addressed, then participation in a certification program alone would not meet the QAPI requirements in this rule.

CMHCs utilizing resources from a quality improvement organization will still be expected to provide separate documentation evidencing their QAPI program.

Comment: Several commenters stated their strong support for the proposed rule regarding QAPI. According to the commenters, the existence of a QAPI program ensures the provision of quality services, identifies weaknesses in the care process, and encourages the provider to make changes in order to improve their current practices. A few commenters stated that they were committed to supporting CMHCs in developing better data systems and using that data to improve service quality and efficiency.

Response: We appreciate the overall support for the data collection and QAPI requirements, as this support will help ensure that CMHCs develop a data-driven program for continuous quality improvement that reflects the needs of the clients and CMHCs alike.

Comment: Several commenters supported CMS' decision to work with the NCQA and Mathematica to develop measures for use in inpatient psychiatric facilities, and requested that CMS facilitate the development and adoption of robust, harmonized, tested, and validated measures around schizophrenia that could also be used in other settings, such as CMHCs. In addition, the commenters encouraged further development of functional measures, such as the ability to return to work, that could be used as important indicators of successful treatment, especially for those clients with negative symptoms such as delusional behavior. The commenters stated that such measures would provide CMHCs with an important tool for use in evaluating their own quality programs.

Response: We appreciate the support for CMS' work with the NCQA. At this time there are no plans for CMS to develop measures specific to CMHCs. However as CMS works with NCQA and the Substance Abuse and Mental Health Services Administration (SAMHSA), we will continue to pursue measures appropriate for the CMHC setting. CMHCs can use the search term ''mental health'' on the National Quality Forum Web site at *http://www.qualityforum.org/Qps/QpsTool.aspx* to find additional measures-related resources.

Comment: Several commenters strongly agree that CMHCs should track ''adverse client events'' and immediately ''correct any identified problems that would directly or potentially threaten the care and safety of clients.'' Commenters stated that all existing CMHCs should not have any issues complying with this requirement.

Response: We appreciate the support for tracking adverse events. We believe it is essential to the CMHC QAPI program to begin tracking and analyzing adverse events at the same time it begins collecting client level outcomes measures data elements and CMHC-wide measures that are available. Adverse events generally result in harm to a client; they serve as important indicators for areas of potential improvement. If CMHCs do not collect adverse event information, they may be missing important data from which to assess their performance.

CMHC CoP: Organization, Governance, Administration of Services, and Partial Hospitalization Services (§ 485.918)

We proposed to add a new CoP at § 485.918, to set out the CMHC's administrative and governance structure and to clarify performance expectations for the governing body. As explained in the proposed rule, the overall goal of this CoP is to ensure that the management structure is organized and accountable. The proposed CoP was divided into seven standards.

In the proposed organization and administration of services CoP, we proposed to list the services that the statute (section 1861(ff)(3) of the Act) requires CMHCs to furnish. We also proposed a standard that would require a CMHC to provide in-service training to all employees and staff, including those under contract or under arrangements, who have client contact. This requirement would assist in ensuring that all staff serving CMHC clients was up to date on current standards of practice. The CMHC would be required to have written policies and procedures describing its methods for assessing staff skills and competency, and to maintain a written description of in-service training offered during the previous 12 months.

At § 485.918(a), ''Standard: Governing body and administrator,'' we proposed to emphasize the responsibility of the CMHC governing body (or designated persons so functioning) for managing all CMHC facilities and services, including fiscal operations, quality improvement, and the appointment of the administrator. The administrator would be responsible for the day-to-day operation of the CMHC and would report to the governing body. The administrator would have to be a CMHC employee, and meet the education and experience requirements established by the CMHC's governing body. The specifics of the administration of the CMHC would be left to the discretion of the governing body, thereby affording the CMHC's management with organizational flexibility. The proposed governing body standard reflects our goal of promoting the effective management and administration of the CMHC as an organizational entity without dictating prescriptive requirements for how a CMHC must meet that goal.

At § 485.918(b), ''Provision of services,'' we proposed to specify a comprehensive list of services that a CMHC would be required to provide. At § 485.918(b)(1)(v), we proposed to require the CMHC to provide at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Act (Medicare). This proposed requirement would track the changes to § 410.2 set out in the November 24, 2010 Outpatient Prospective Payment System (OPPS)

final rule (75 FR 71800, 72259). Both the CMHC proposed rule and the OPPS final rule changes implement the statutory changes made by section 1301(a) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (HCERA).

Enactment of section 1301(a) of HCERA revised the definition of a CMHC set forth at section 1861(ff)(3)(B) of the Act by adding a provision to the existing requirements for CMHCs, effective on the first day of the first calendar quarter that began at least 12 months after the date of enactment (that is, April 1, 2011). As of that date, a Medicare-participating CMHC must provide at least 40 percent of its services to individuals who are not eligible for benefits under Medicare.

We proposed to measure whether a CMHC is providing at least 40 percent of its services to individuals who are not eligible for Medicare benefits by the amount of reimbursement for all services furnished. Additionally, we proposed to measure the 40 percent of its services on an annual basis. We solicited public comments on whether we should determine if a CMHC meets the 40 percent requirement annually or at some other interval. We also solicited comments on both the definition of terms used in any approach to measuring the 40 percent threshold and the data sources for that measurement. Specifically, since the measure proposed to determine the 40 percent threshold was total reimbursement from all payers, for all services provided, we were interested in comments on how we should define reimbursement.

We also requested feedback on whether the proposed calculation should include uncompensated care or any other aspect of reimbursement, and on whether CMS should require the CMHCs to attest to whether they meet the 40 percent requirement, or whether we should subject them to verification auditing.

Furthermore, we stated our interest in receiving comments on any other approaches that could constitute a measure of the 40 percent threshold. We stressed that we were concerned that the implementation of this provision not negatively impact access to care.

Medicare-certified CMHCs are already required to provide most of the services set out in the proposed provision of services standard through the existing CMS payment rules (42 CFR 410.2, § 410.110, and § 424.24(e)). It is essential for CMHCs to have sufficient numbers of appropriately educated and trained staff to meet these service expectations. For example, CMHCs that provide partial hospitalization services could provide the services of ''other staff trained to work with psychiatric clients'' (42 CFR 410.43(a)(3)(iii)). Non-specified staff might be responsible for supervising clients and ensuring a safe environment. CMHCs would be expected to have a sufficient number of appropriately-trained staff to meet these responsibilities at all times.

At § 485.918(c), ''Standard: Professional management responsibility,'' we proposed to require that where services are furnished by other than CMHC staff, a CMHC would have to have a written agreement with another agency, individual, or organization that furnishes the services. Under this agreement, the CMHC would retain administrative and financial management and oversight of staff and services for all arranged services. The CMHC would have to have a written agreement that specified that all services would have to be authorized by the CMHC, be furnished in a safe and effective manner, and be delivered in accordance with established professional standards, the policies of the CMHC and the client's active treatment plan. As part of retaining financial management responsibility, the CMHC would retain all payment responsibility for services furnished under arrangement on its behalf.

At § 485.918(d), ''Standard: Staff training,'' which would apply to all employees, staff under contract, and volunteers, we proposed to require a CMHC to take steps to develop appropriate in-service programs, including initial orientation for each new employee or volunteer furnishing services. The new employee orientation would address specific job duties. The CMHC could also provide staff training under arrangement.

We would not require a specific staff in-service training program; rather, we would expect each CMHC to determine the scope of its own program, including the manner in which it chose to deliver the training, assess competence levels, determine training content, determine the duration and frequency of training for all employees, and track the training on a yearly basis.

At § 485.918(e)(1), ''Standard: Environmental conditions,'' and (e)(2), ''Building,'' we proposed to require the CMHC to provide services in an environment that is safe, functional, sanitary, comfortable, and in compliance with all Federal, State, and local health and safety standards, as well as State health care occupancy regulations. We indicated that these proposed requirements would help to ensure that CMHC services are provided in a physical location that is both safe and conducive to meeting the needs of CMHC clients.

At § 485.918(e)(3), ''Infection control,'' we proposed to address the seriousness and potential hazards of infectious and communicable diseases. We would require a CMHC to develop policies, procedures, and monitoring, as well as take specific actions to address the prevention and control of infections and disease.

We believe that a CMHC should follow nationally accepted infection control standards of practice and ensure that all staff know and use current best preventive practices. Periodic training is one way to assure staff understanding, and we would expect the CMHC to establish a method to ensure that all staff receives appropriate training. Where infection and/or communicable diseases are identified, we would expect actions be taken to protect all the clients and staff.

At § 485.918(e)(4), ''Therapy sessions,'' we proposed that the CMHCs ensure that all individual and group therapy sessions be conducted in a manner that maintains client privacy and dignity. We believe that a safe, private environment would enhance the effectiveness of the therapy sessions.

At § 485.918(f), ''Standard: Partial hospitalization services,'' we proposed that all partial hospitalization services would be required to meet all applicable requirements of 42 CFR parts 410 and 424.

At § 485.918(g), ''Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients,'' we proposed that the CMHC and its staff be required to operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of clients. If State or local law provided for licensing of CMHCs, the CMHC would have to be licensed. In addition, the CMHC staff would have to follow the CMHC's policies and procedures.

Comment: Many commenters strongly agree with the overall goal of the administrative standard at § 485.918(a). They believe it would ensure that the management structure is organized and accountable.

Response: We appreciate the overall support for the administrative standard. This support would help ensure efficient operation of the CMHC and that the CMHC meets the needs of the clients and CMHCs alike.

Comment: Some commenters strongly support the option of allowing the CMHCs to receive oversight from the Joint Commission, or other accrediting

bodies. Other commenters encouraged CMS to defer to the states regarding deemed status, by recognizing deeming authority for CMHCs in those states that allow deeming. However, some commenters stated that CMS should not adopt deeming authority for CMHCs.

Response: We appreciate the wide array of comments related to deeming. As stated in the proposed rule, we are not proposing to amend our regulations at § 488.6 to grant deeming authority for CMHCs to accrediting organizations. CMS's regulation at § 488.6 does not permit deeming for CMHCs. To allow for deeming authority to occur for CMHCs, there would need to be a regulatory change. We will take this under advisement for future rulemaking.

Comment: Many commenters stated that CMS should use the language in Section 1301 of HCERA to calculate the 40 percent threshold. Specifically, they noted that the Congress used the phrase ''40 percent of its services to individuals'' without making any reference at all to reimbursement or payment in the statute. Commenters also stated that to be consistent with the major themes of the Affordable Care Act (which incorporates HCERA), the legislative language in Section 1301 of HCERA indicates the need for a patient-centric approach rather than a reimbursement-based approach. Additionally, many commenters stated that using an independent auditing agency to review CMHC financial statements to certify compliance with the 40 percent threshold would be overly burdensome and confusing for the CMHC.

Response: We agree with the commenters on the 40 percent calculation. We proposed several different potential ideas for calculating the 40 percent. After carefully considering all the comments received, we are adopting a patient-centric approach and will require that the calculation of 40 percent be based on CMHC services to individuals.

Comment: Commenters offered very detailed recommendations on how to calculate the 40 percent threshold, the implementation process, the timeframes, and the consequences if the CMHC does not meet the 40 percent threshold. Also, commenters stated that the calculation to determine the 40 percent threshold should be based on a patient-centric methodology, including the following elements:

- Numerator: The numerator would include an unduplicated census of individuals who rely solely on health care coverage provided through private sector insurance or public health programs other than Medicare, indigent individuals and any other uninsured or inadequately insured individuals who receive behavioral health services from the CMHC.
- Denominator: The denominator would include an unduplicated census for all clients who receive services from the CMHC.
- Validation: For each reporting period, the CMHC could attest to the accuracy of the numbers reported to CMS for the patient-centric numerator and denominator identified above. Medicare providers are required to prepare attestations in other contexts involving eligibility to receive Medicare reimbursement, including, but not limited to, the attestations used in the calculation of bad debt.
- Annual Reporting Period: Adopt an annual reporting period based on a facility's cost reporting year.
- Failure to Meet Performance Level: Providers that fail to meet the 40 percent threshold by more than five percent during a particular year should be placed on probation for 12 months and required to develop and implement a corrective action plan to bring the facility into compliance with the 40 percent requirement. If a facility fails to meet the threshold for a second consecutive year, that CMHC should be rendered ineligible for Medicare reimbursement during the subsequent year.

Response: We agree with the commenters' recommendations for calculating the 40 percent threshold. Therefore, we amended the proposed § 485.918 (b)(1)(v) to read ''provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act.'' We have removed the subsequent phrase, which read ''as measured by the total revenues received by the CMHC that are payments from Medicare versus payers other than Medicare.'' We agree that the numerator should include an unduplicated census of individuals who receive services not paid for in whole or in part by Medicare. This may include individuals who rely solely on health care coverage provided through private sector insurance or public health programs other than Medicare, or whose insurance doesn't cover the behavioral health services they receive from the CMHC. The denominator would consist of an unduplicated census of all clients who receive services from the CMHC, including Medicare beneficiaries. The calculation will determine the total percentage of individuals who are not eligible for benefits under title XVIII of the Act. The CMHC needs to assure continued compliance with the 40 percent threshold on an annual basis—that is, 40 percent of the clients served by the CMHC during each intervening 12 month period must be individuals for whom services are not paid for by Medicare.

We will not be using the proposed language on reimbursement or cost report information to calculate the 40 percent. Rather, we will require all CMHCs to verify their compliance with the 40 percent requirement by sending documentation to the appropriate Part A/Part B Medicare Administrative Contractor (A/B MAC) from an independent entity such as an accounting technician, which will certify that it has reviewed the client care data for the CMHC. The documentation must be sent upon initial application for Medicare provider status, and upon revalidation, including off cycle revalidation, thereafter to the relevant A/B MAC (see revalidation requirements at § 424.515). The documentation must state whether the CMHC met or did not meet the 40 percent requirement for the prior 3 months (in the case of the initial application) or for each of the intervening 12 month periods between initial enrollment and revalidation. If the CMHC did not meet the 40 percent threshold, the A/B MAC will notify the CMHC that they have 30 days to correct the issue or their Medicare enrollment and billing privileges will be denied for non-compliance (see § 424.530(a)(1)) or revoked for non-compliance (see § 424.535(a)(1)).

If an A/B MAC denies or revokes a CMHC's Medicare billing privileges, the CMHC is afforded provider enrollment appeal rights, and may reapply or seek reinstatement into the Medicare program subject to the provisions found in § 424.535.

We appreciate the commenters' suggestions related to failure to meet the 40 percent threshold. However, we disagree with the proposed probationary period and the suggestion of a 5 percent margin. The law does not allow for a probationary period or margins. This final rule becomes effective one year after publication of this rule in the **Federal Register**. This means all CMHCs will have one year to implement the provisions of this rule before the independent entity audit or a survey would occur.

Comment: Several commenters stated that volunteers should not be included in the staff education component described by § 485.918(d)(1) and recommended that any reference to volunteers in this section be removed.

Response: We appreciate the commenters' opinions. However, we believe that educating volunteers about CMHC care and services and person-centered planning is just as important for the volunteer as it is for the staff member. Volunteers are asked to interact with clients in many different situations, such as the waiting room and reception area. For the safety of the client and the volunteer, volunteers should have a basic understanding of the types of clients served and the workings within the CMHC.

Comment: A few commenters stated that § 485.918(d)(3) requires that CMHCs ''assess the skills and competence of all individuals furnishing care….'' They stated that it is not clear what such a skills and competency assessment would contain, and how much time it would take to develop and administer such assessments for each position within every CMHC. Commenters suggested that this requirement would be met by QAPI. Other commenters suggested that the requirement for CMHC staff to receive consistent and ongoing continuing education is best enforced through the personnel requirements. Commenters stated that licensure and credentialing laws typically include requirements for ongoing continuing education. Other commenters stated that while in-service training may be appropriate in some circumstances, CMS should recognize and support existing continuing education practices required for practitioner licensure and certification.

Response: To clarify, we are requiring the CMHC to create policies and procedures by which to evaluate their employees relevant to the duties assigned to each employee, which can be tied to the CMHC policies related to personnel requirements. The specifics of these policies and procedures would be up to each individual CMHC. The commenters are correct that this could also be part of the QAPI program. If an area of concern is recognized by staff administering the QAPI program, or the CMHC administration, then it is expected that the CMHC would conduct in-service training related to the area of concern. We understand that there may be specific individual provider licensure requirements based on State laws and regulations; however, this would be specific to the provider type, such as nurse or therapist to maintain his or her license or certification. Section 485.918(d)(3) is specifically related to overall training of the CMHC staff, whether it is specific to issues brought up through the QAPI program or new or edited policies and/or procedures within the CMHC. In-service training can also be used to meet other State and/or Federal requirements, such as infection control.

Comment: A few commenters stated that assessing for self-harm is not enough. Commenters stated that CMHCs need to educate and train staff on suicide prevention. Commenters believe that these regulations could help address a well-established training deficit among service providers and their organizations and could reduce consumer suicide-related morbidity and mortality. Commenters also stated that if staff are untrained and cannot demonstrate competency in the clinical assessment of suicide risk, clients may be at risk.

Response: We agree with the commenter that the importance of suicide prevention education is critical to all staff within the CMHC. Therefore, we have modified the language at § 485.914(b)(4)(ix) to read: ''Factors affecting client safety or the safety of others, including behavioral and physical factors as well as suicide risk factors.'' This is an example of where the use of in-service training in § 485.918(c)(3) would benefit the entire CMHC staff and meet the in-service training requirements. It is very important that CMHCs follow current standards of practice and continually monitor and educate their staff as it relates to current standards of practice such as suicide prevention.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We published a proposed rule in the **Federal Register** (76 FR 35684) on June 17, 2011. The comment period closed on August 16, 2011. We did not receive any comments related to the PRA section of this rule.

We have made several assumptions and estimates in order to assess the time that it will take for a CMHC to comply with the provisions and the associated costs of compliance. CMHC client data from outside sources are limited; therefore, our estimates are based on available Medicare data. We have detailed these assumptions and estimates in Table 1 below. We have also detailed many of the standards within each CoP, and have noted whether or not there is an impact for each in the section below. However, the requirements contained in many of the CoPs are already standard medical or business practices and, as a result, do not pose an additional burden on CMHCs.

TABLE 1—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE COLLECTION OF INFORMATION AND IMPACT ANALYSIS SECTIONS

Number of Medicare CMHCs nationwide (Based on CY 2012 CMS data)	100
Number of CMHC clients nationwide * (Estimate based on CY 2010 data)	22,700
Number of clients per average CMHC	227
Hourly rate of psychiatric nurse	$47
Hourly rate of clinical psychologist	$54
Hourly rate of administrator	$66
Hourly rate of clinical social worker	$35
Hourly rate of mental health counselor	$31
Hourly rate of auditing or accounting clerk	$24

* Reflects 13,600 Medicare clients and 9,100 non-Medicare clients.

Note: All salary estimates include benefits and overhead package worth 48 percent of the base salary. Salary estimates were obtained from *http://www.bls.gov/*.

A. ICRs Related to Condition of Participation: Client Rights (§ 485.910)

Section 485.910(a) requires that the CMHC develop a notice of rights statement to be provided to each client. We estimate that it will require 8 hours on a one-time basis to develop this notice, and the CMHC administrator would be responsible for this task, at a cost of $528 per CMHC and $52,800 for all CMHCs nationwide. In addition, this standard requires that the CMHC obtain the client's and client representative's (if appropriate) signature confirming that he or she has received a copy of the notice of rights and responsibilities. The CMHC will have to retain the signed documentation showing that it complied with the requirements, and that the client and the client's representative demonstrated an understanding of these rights. We estimate that the time it will take for the CMHC to document the information will be 2.5 minutes per client or approximately 9.47 hours per CMHC. At an average of 2.5 minutes (.0417 hours) per client to complete both tasks, we estimate that all CMHCs will use 947 hours to comply with this requirement (.0417 hours per client × 22,700 clients). The estimated cost associated with these requirements is $44,509, based on a psychiatric nurse performing this function (947 hours × $47 per hour).

We note that we do not impose any new language translation or interpretation requirements. Under Title VI of the Civil Rights Act of 1964, recipients of federal financial assistance, such as CMHCs, have long been prohibited from discriminating on the basis of race, color, or national origin. Language interpretation is required under some circumstances under that statute and the HHS regulations at 45 CFR part 80 (see previous discussion of Office for Civil Rights guidance issued in 2003). Because we impose no new requirements not already fully encompassed in that regulation and guidance, we have estimated no paperwork burden.

Section 485.910(d)(2) requires a CMHC to document a client's or client representative's complaint of an alleged violation and the steps taken by the CMHC to resolve it. The burden associated with this requirement is the time it will take to document the necessary aspects of the issues. In late 2007, the American Association of Behavioral Health and The Joint Commission informed us that we could anticipate 52 complaints per year per CMHC and that it will take the administrator 5 minutes per complaint at the rate of $66/hr to document the complaint and resolution activities, for an annual total of 4.33 hours per CMHC or 433 hours for all CMHCs. The estimated cost associated with this requirement is $28,578.

Section 485.910(d)(4) requires the CMHC to report within 5 working days of becoming aware of the violation, all confirmed violations to the state and local bodies having jurisdiction. We anticipate that it will take the administrator 5 minutes per complaint to report, for an annual total of 4.33 hours per CMHC or 433 hours for all CMHCs. The estimated cost associated with this requirement is $28,578.

Section 485.910(e)(2) requires written orders for a physical restraint or seclusion, and § 485.910(e)(4)(v) requires physical restraint or seclusion be supported by a documentation in the client's clinical record of the client's response or outcome. The burden associated with this requirement is the time and effort necessary to document the use of physical restraint or seclusion in the client's clinical record. We estimate that it will take 45 minutes per event for a nurse to document this information. Similarly, we estimate that there will be 1 occurrence of the use of physical restraint or seclusion per CMHC annually. The estimated annual burden associated with this requirement for all CMHCs is 75 hours. The estimated cost associated with this burden for all CMHCs is $3,525.

Section 485.910(f) specifies restraint or seclusion staff training requirements. Specifically, § 485.910(f)(1) requires that all client care staff working in the CMHC be trained and able to demonstrate competency in the application of restraints and implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion, and on the use of alternative methods to restraint and seclusion. Section 485.910(f)(4) requires that a CMHC document in the personnel records that each employee successfully completed the restraint and seclusion training and demonstrated competency in the skill. We estimate that it will take 35 minutes per CMHC to comply with these requirements. The estimated total annual burden associated with these requirements is 58 hours. The estimated cost associated with this requirement is $2,726.

Section 485.910(g) requires the CMHC to report any death that occurred while a CMHC client was in restraint or seclusion in the CMHC while awaiting transfer to a hospital. We have a parallel requirement in all other CMS rules dealing with programs and providers where restraint or seclusion may be used (for example, in our hospital conditions of participation). Based on informal discussions with the CMHC industry and The Joint Commission, we believe restraints and seclusion are rarely, if ever, used in CMHCs, and that there are very few deaths (if any) that occur due to restraint or seclusion in a CMHC. Several commenters stated that the majority of CMHCs have a restraint or seclusion free policy. Therefore, restraint or seclusion is not permitted in these agencies. Hence, we believe the number of deaths associated with this requirement is estimated at zero. Under 5 CFR 1320.3(c)(4), this requirement is not subject to the PRA as it would affect

fewer than 10 entities in a 12-month period.

B. ICRs Related to Condition of Participation: Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

Section 485.914(b) through (e) requires each CMHC to conduct and document in writing an initial evaluation and a comprehensive client-specific assessment; maintain documentation of the assessment and any updates; and coordinate the discharge or transfer of the client. The burden associated with these requirements is the time required to record the initial evaluation and comprehensive assessment, including changes and updates. We believe that documenting a client's initial evaluation and comprehensive assessment is a usual and customary business practice under 5 CFR 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

Section 485.914(e) requires that, if the client were transferred to another facility, the CMHC is required to forward a copy of the client's CMHC discharge summary and clinical record, if requested, to that facility. If a client is discharged from the CMHC because of noncompliance with the treatment plan or refusal of services from the CMHC, the CMHC is required to provide a copy of the client's discharge summary and clinical record, if requested, to the client's primary health care provider. The burden associated with this requirement is the time it takes to forward the discharge summary and clinical record, if requested. This requirement is considered to be a usual and customary business practice under 5 CFR 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

C. ICRs Related to Condition of Participation: Treatment Team, Active Treatment Plan, and Coordination of Services (§ 485.916)

Section 485.916(b) requires all CMHC care and services furnished to clients and their families to follow a written active treatment plan established by the interdisciplinary treatment team. The CMHC is required to ensure that each client and representative receives education provided by the CMHC, as appropriate, for the care and services identified in the active treatment plan.

The provisions at § 485.916(c) specify the minimum elements that the active treatment plan must include. In addition, in § 485.916(d), the interdisciplinary team is required to review, revise, and document the active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's updated comprehensive assessment, and must document the client's progress toward the outcomes specified in the active treatment plan. The burden associated with these requirements is the time it takes to document the active treatment plan (.1667 hours per client or approximately 3,784 hours nationally) estimated to be a total of $1,778 per CMHC or $177,848 nationally. Additionally, we estimate any revisions to the active treatment plan (approximately 5 minutes) will cost $525 per CMHC or $88,877 nationally (1891 hours × $47/hour).

Section 485.916(e) requires a CMHC to develop and maintain a system of communication and integration to ensure compliance with the requirements contained in § 485.916(e)(1) through (e)(5). The burden associated with this requirement will be the time and effort required to develop and maintain the system of communication in accordance with the CMHC's policies and procedures. We believe that the requirement is usual and customary business practice under 5 CFR 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

D. ICRs Related to Condition of Participation: Quality Assessment and Performance Improvement (§ 485.917)

Section 485.917 requires a CMHC to develop, implement, and maintain an effective ongoing CMHC-wide data driven quality assessment and performance improvement (QAPI) program. The CMHC is required to maintain and demonstrate evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS. The CMHC is required to take actions aimed at performance improvement and, after implementing those actions, must measure its success and track its performance to ensure that improvements were sustained. The CMHC is required to document what quality improvement projects were conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

The burden associated with these requirements is the time it takes to document the development of the quality assessment and performance improvement and associated activities. We estimate that it will take each CMHC administrator an average of 4 hours per year at the rate of $66/hr to comply with these requirements for a total of 400 hours annually. The estimated cost associated with this requirement is $26,400.

E. ICRs Related to Condition of Participation: Organization, Governance, Administration of Services, and Partial Hospitalization Services (§ 485.918)

Section 485.918(b) lists care and services a Medicare CMHC must be primarily engaged in regardless of payer type. Specifically, § 485.918(b)(1)(v) requires the CMHC to provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act as measured by the total number of CMHC clients treated by the CMHC and not paid for by Medicare, divided by the total number of clients treated by the CMHC. The burden associated with this requirement is the time it takes for an independent entity contracted by the CMHC to calculate compliance with the 40 percent requirement and create a letter for the CMHC to submit to CMS. We estimate it will take the independent entity an average of 5 hours per new CMHC applicant and 5 hours for each CMHC that is due for its every 5 year revalidation to calculate compliance with the 40 percent requirement and create a letter to CMS. We estimate there will be 10 new CMHC applicants per year for a total of 50 hours annually and an estimated cost of $1,200. We estimate there will be 20 CMHCs up for revalidation each year for a total of 100 hours for all CMHCs, with an estimated cost of $2,400. Therefore, the annual reporting for new CMHC applicants and CMHC revalidation is estimated at 150 hours with a total cost of $3,600.

Section 485.918(c) lists the CMHC's professional management responsibilities. A CMHC could enter into a written agreement with another agency, individual, or organization to furnish any services under arrangement. The CMHC is required to retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. The burden associated with this requirement is the time and effort necessary to develop, draft, execute, and maintain the written agreements. We believe these written agreements are part of the usual and customary business practices of CMHCs under 5 CFR 1320.3(b)(2) and, as such, the burden associated with them is exempt from the PRA.

Section 485.918(d) describes the standard for training. In particular, § 485.918(d)(2) requires a CMHC to

provide an initial orientation for each employee, contracted staff member, and volunteer that addresses the employee's or volunteer's specific job duties. Section 485.918(d)(3) requires a CMHC to have written policies and procedures describing its method(s) of assessing competency. In addition, the CMHC is required to maintain a written description of the in-service training provided during the previous 12 months. These requirements are considered to be usual and customary business practices under 5 CFR 1320.3(b)(2) and, as such, the burden associated with them are exempt from the PRA.

Section 485.918(e)(3) requires the CMHC to maintain policies, procedures, and monitoring of an infection control program for the prevention, control and investigation of infection and communicable diseases. The burden associated with this requirement is the time it takes to develop and maintain policies and procedures and document the monitoring of the infection control program. We believe this documentation is part of the usual and customary medical and business practices of CMHCs and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(2).

Table 2 below summarizes the estimated reporting and recordkeeping burden for this final rule.

TABLE 2—ESTIMATED REPORTING AND RECORDKEEPING BURDENS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 485.910(a)(1)	0938–New	100	100	8	800	66	52,800	0	52,800
§ 485.910(a)(3)	0938–New	100	22,700	.0417	947	47	44,509	0	44,509
§ 485.910(d)(2)	0938–New	100	5,200	.0833	433	66	28,578	0	28,578
§ 485.910(d)(4)	0938–New	100	5,200	.0833	433	66	28,578	0	28,578
§ 485.910(e)(4)(v)	0938–New	100	100	.75	75	47	3,525	0	3,525
§ 485.910(f)(4)	0938–New	100	700	.0833	58	47	2,726	0	2,726
§ 485.916(c)	0938–New	100	22,700	.1667	3784	47	177,848	.....	177,848
§ 485.916(d)	0938–New	100	22,700	.0833	1891	47	88,877	0	88,877
§ 485.917	0938–New	100	100	4	400	66	26,400	0	26,400
§ 485.918(b)	0938–New	30	30	5	150	24	3,600	0	3,600
Total	.....	100	79,530	18.7083	.....	.....	457,441	.....	457,441

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–3202–F]; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The overall economic impact for all new CoPs in this final rule is estimated to be $3 million in the first year of implementation and $2.2 million annually thereafter. Therefore, this is not an economically significant or major final rule.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, most CMHCs are considered to be small entities, either by virtue of their nonprofit or government status or by having revenues of less than $10 million in any one year (for details, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf*). We estimate there are approximately 100 CMHCs with average admissions of approximately 227 clients per CMHC.[1]

We estimate that implementation of this rule will cost CMHCs approximately $3 million, or approximately $30,000 per average CMHC, in the first year of implementation and $2.2 million, or approximately $22,000 per average CMHC, after the first year of implementation and annually thereafter. Therefore, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities, because the cost impact of this rule is less than 1 percent of total CMHC Medicare revenue (approximately $218 million per year, as shown by CY 2010 claims data).

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number

[1] In order to develop this estimate we divided the total number of Medicare beneficiaries who received partial hospitalization services in 2010 by the total number of Medicare-participating CMHCs in 2010 to establish the average number of Medicare beneficiaries per CMHC. This resulted in 136 beneficiaries per CMHC. We then assumed that, in order to comply with the 40 percent requirement, those 136 beneficiaries only accounted for 60 percent of an average CMHC's total patient population. This meant that an average CMHC also treated another 91 clients who did not have Medicare as a payer source, for a total of 227 clients (Medicare + non-Medicare) in an average CMHC.

of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals since there are few CMHC programs in those facilities. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately $141 million. This final rule will not have an impact on the expenditures of State, local, or tribal governments in the aggregate, or on the private sector of $141 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule has no Federalism implications.

B. Anticipated Effects on CMHCs

We are establishing a new subpart J under the regulations at 42 CFR part 485 to incorporate the CoPs for CMHCs (which will be effective 12 months after the publication of this final rule). The new subpart J includes the basis and scope of the subpart, definitions, and six conditions.

Section III of this rule, Collection of Information Requirements, provides a detailed analysis of the burden hours and associated costs for all burdens related to the collection of information by CMHCs that are required by this rule. That section, in tandem with this regulatory impact analysis section, presents a full account of the burdens that are imposed by this rule. As shown above in table 2 the total cost of all information collection requirements in the first year is estimated to be $457,441. In addition, table 3 below presents the total first year cost of $2,596,809 for all other requirements. Therefore, the total cost for implementing all CoP requirements, including information collection and other costs that CMHCs must meet in order to participate in the Medicare program, is estimated to be $3 million in the first year of implementation and 2.2 million annually thereafter.

TABLE 3—TOTAL ESTIMATES FOR ALL REQUIREMENTS DESCRIBED IN THIS SECTION

	Total time (hours) per average CMHC	Total industry time (hours)	Total cost per average CMHC	Total industry cost
Client rights	1st year: 167.47 Annual: 67.47	1st year: 16,747 Annual: 6,747	1st year: $10,968 Annual: $3,449	1st year: $1,096,809 Annual: $344,909
Treatment team. Active Treatment Plan, and Coordination of Services	265	26,500	$11,568	$1,156,800
Quality Assessment and Performance Improvement	20	2,000	$1,320	$132,000
Organization, Governance, Administration of Services	1st year: 32 Annual: 24	1st year: 3,200 Annual: 2,400	1st year: $2,112 Annual: $1,584	1st year: $211,200 Annual: $158,400
Totals	1st year: 484.47 Annual: 376.47	1st year: 48,447 Annual: 37,647	1st year: $25,968 Annual: $17,921	1st year: $2,596,809 Annual: $1,792,109

Note: Costs presented in this table do not include those accounted for in Section III. Collection of Information Requirements.

We have detailed, below, many of the standards within each CoP, and have noted whether or not there is an impact for each. However, the requirements contained in many of the provisions are already standard medical or business practices. These requirements will, therefore, not pose additional burden to CMHCs because they are already standards of practice. *Client Rights (§ 485.910)*

Section 485.910(a), ''Standard: Notice of rights and responsibilities,'' requires that during the initial evaluation, the CMHC must provide the client and the client's representative or surrogate (if appropriate) with verbal and written notice of the client's rights and responsibilities in a language and manner that the individual understands. Communicating with clients, and their representatives or surrogates, in a manner that meets their communication needs is a standard practice in the health care industry. Because we are implementing a requirement that is fully compatible with existing civil rights requirements and guidance, we believe that the requirement to communicate with clients in a manner that meets their communication needs will impose no additional costs.

In addition, this standard requires a CMHC to provide each CMHC client and representative verbal and written notification of the CMHC client's rights. We estimate the burden for the time associated with providing the verbal notice will be 2.5 minutes (0.0417 hours) per client or approximately 9.47 hours per CMHC. We note that the burden associated with providing the written notice is discussed in the Collection of Information section of this rule. We estimate that all CMHCs will use 947 hours to comply with this requirement (0.0417 hours per client × 22,700 clients). The estimated cost associated with these requirements is $44,509, based on a psychiatric registered nurse performing this function (947 hours × $47 per hour).

With respect to the CoP for client rights, the standard addressing violations of client rights requires a CMHC to investigate alleged client rights violations, and take corrective actions when necessary and appropriate. We estimate that the CMHC administrator will spend, on average, 25 minutes investigating each alleged client rights violation. For purposes of our analysis, we assume that an average CMHC will investigate 1 alleged violation per week, for a total of 22 hours annually, at a cost of $1,452

annually per CMHC. All CMHCs nationwide require 2,200 hours, with an average labor cost of $66 per hour for the administrator, the estimated nationwide cost of $145,200.

In addition, we are implementing three standards under the CoP for client rights pertaining to restraint and seclusion, staff training requirements for restraints and seclusion, and death reporting requirements. These standards include requirements that guide the appropriate use of seclusion and restraint interventions in CMHCs, when necessary, to ensure the physical safety of the client and others while awaiting the client's transport to a hospital. They are adapted from the clients' rights CoP for hospitals published as a final rule in the **Federal Register** on December 8, 2006 (71 FR 71378), and codified at § 482.13.

We anticipate that CMHCs will be minimally impacted by these standards. Several public commenters stated that restraints and seclusion are never used in CMHCs and therefore are not needed in CMHCs. However, we are still estimating the burden to facilities for restraint and seclusion use. We do not have access to several key pieces of information to estimate the burden. For example, we do not have data on the volume of staff in CMHCs, or the varying levels and qualifications of CMHC staff that may use restraint and seclusion. Factors such as size of facility, services rendered, staffing, and client populations vary as well. We are hesitant to make impact estimates in this rule that may not account for these and other unforeseen variations. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

The restraint and seclusion standards set forth the client's rights in the event that he or she is restrained or secluded, and sets limits on when and by whom restraint or seclusion can be implemented. We recognize that there will be some impact associated with performing client assessment and monitoring to ensure that seclusion or restraint is only used in a safe and effective manner, when necessary, to protect the client and others from immediate harm, pending transport to the hospital. However, client assessment and monitoring are standard components of client care, and this requirement does not pose a burden to a CMHC.

The standards on staff training for restraint or seclusion that we are codifying at § 485.910(f) set out the staff training requirements for all appropriate client care involving the use of seclusion and restraint in the CMHC. Training is important for the provision of safe and effective restraint or seclusion use. We require that before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded client, or provide care for a restrained or secluded client, the staff be trained and able to demonstrate competency in the performance of these actions. The staff training requirements will address the following broad areas: Training intervals, training content, trainer requirements, and training documentation.

To reduce regulatory burden and create a reasonable requirement while assuring client safety, we are mandating that only those staff who would be involved in the application of restraint or seclusion or performing associated monitoring and assessment of, or providing care for, restrained or secluded clients would be required to have this training.

In this final rule, we are finalizing broad topics to be covered in training, and are not requiring that staff be trained by an outside organization. We believe that in-house training could be more economical than sending staff off site for instruction. However, CMHCs will have the option of sending either selected or all staff to outside training if they believe this is warranted.

Therefore, we have based our burden estimate on a CMHC nurse being trained by an outside organization (for example, the Crisis Prevention Institute) to provide such training. We believe that most CMHCs then will have this nurse function as a program developer and as a trainer of the appropriate CMHC staff. In addition, we believe in most instances this professional will be a psychiatric registered nurse.

Train-the-trainer programs are the way many CMHCs provide staff instruction. For example, the 4-day instructor certification program given by the Crisis Prevention Institute (CPI, Inc.) costs $1,999 for tuition plus travel, lodging, and participant salary. More detailed information regarding the train-the-trainer programs can be found on CPI, Inc.'s Web site at *http://www.crisisprevention.com*.

We estimate, on average, that the cost to train one nurse will include the following expenses: (1) Round trip travel at approximately $400 to cover the need for either local or distant travel; (2) lodging for 3 nights (at $120 per night) for approximately $360; and (3) meals and incidental expenses for 4 days (at $50 per day) for approximately $200, depending upon the location within the particular State. Therefore, we anticipate the cost to train one nurse is approximately $2,959 plus the nurse's total salary of $1,504 for 4 days (at $376 per day). The total estimated training cost for all CMHCs is approximately $446,300.

We believe that CMHCs will add seclusion and restraint training onto their in-service training programs. The train-the-trainer program described above provides CMHCs with the necessary personnel and materials to implement a staff-wide seclusion and restraint training program. We estimate that developing this staff-wide training program requires 40 hours of the trainer's time on a one-time basis for all affected CMHCs, at a cost of $1,880 per CMHC.

We are requiring that each individual who could potentially be involved in restraint and seclusion of a client have training in the proper techniques. According to the National Association of Psychiatric Health Systems (NAPHS), initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Due to a lack of data on the average number of employees in a CMHC, for purposes of this analysis only, we assume that an average CMHC will need to train seven employees in seclusion and restraint techniques. Based on one psychiatric registered nurse trainer conducting an 8-hour training course for seven CMHC staff members, we estimate that this requirement will cost $2,728 as calculated below.

- 8 trainer hours at $47/hr = $376
- 56 trainee hours at $42/hr = $2352
- $376 trainer cost + $2,352 trainee costs = $2,728

We are also requiring that each individual receive documented, updated training. Again, according to National Association of Psychiatric Health Systems (NAPHS), annual updates involve about four hours of staff and instructor time per employee who has direct client contact. We assume an average size CMHC has seven employees with direct client contact who must be trained in de-escalation techniques. Therefore, we estimate that it will cost $1,364 annually to update each person's training as shown below.

- 4 trainer hours at $47/hr = $188
- 28 trainee hours at $42/hr = $1,176
- $188 trainer costs + $1,176 trainee costs = $1,364

We require that each CMHC revise its training program annually as needed. We estimate this task, which must be completed by the trainer, to take approximately 4 hours annually per CMHC and have calculated below the

estimated total annual cost for all CMHCs.

- 4 hours × $47/hr = $188 per CMHC
- $188 per CMHC × 100 CMHCs = $18,800 nationwide

Table 4 below shows the initial year (one-time) and annual estimated CMHC burden, respectively, associated with the standards for the client rights CoP.

TABLE 4—CLIENT RIGHTS BURDEN ASSESSMENT

Standard	Time per average CMHC	Total time (in hours)	Cost per average CMHC	Total cost
Client rights notification	9.47 hours	947	$445	$44,509
Addressing violations	22 hours	2,200	1,452	145,200
4 day trainer training *	32 hours	3,200	4,463	446,300
Staff training program development *	40 hours	4,000	1,880	188,000
Staff training *	64 hours	6,400	2,728	272,800
Staff training update	32 hours	3,200	1,364	136,400
Staff training program update	4 hours	400	188	18,800
Totals 1st year	167.47	16,747	10,968	1,096,809
Totals Annually	67.47	6,747	3, 449	344,909

* Initial year (one-time) burden items.

Admission, Initial Evaluation, Comprehensive Assessment and Discharge or Transfer of the Client (§ 485.914)

With respect to the CoP for admission, initial evaluation, comprehensive assessment and discharge or transfer of the client, we believe that several of the standards associated with the CoP are unlikely to impose a burden on CMHCs. Specifically, the requirements for admitting a client, initially evaluating a client, and completing a comprehensive assessment of each client's needs are standard medical practice; therefore, they do not impose a burden upon a CMHC.

Moreover, the requirement to update the comprehensive assessment does not impose a burden upon CMHCs. Currently, all CMHCs are required by CMS payment rules (§ 424.24(e)(3)) to recertify a Medicare client's eligibility for partial hospitalization services. Therefore, the 13,600 Medicare beneficiaries who received partial hospitalization services have already received an updated assessment in order for the CMHC to recertify their eligibility. In addition, updating client assessments is part of standard medical practice to ensure that care is furnished to meet current client needs and treatment goals. Therefore, we believe that this requirement does not impose a burden upon a CMHC. Further, as part of the CMHC care model, it is assumed that clients will eventually be discharged or transferred from the CMHC's care. As such, CMHCs routinely plan for and implement client discharges and transfers. Therefore, we believe that the standard for the discharge or transfer of the client is part of a CMHC's standard practice and does not pose additional burden to CMHCs.

Treatment Team, Active Treatment Plan, and Coordination of Services (§ 485.916)

Under the CoP for treatment team, active treatment plan, and coordination of services, we assessed the potential impact of the following standards on CMHCs: Delivery of services, active treatment plan, content of the active treatment plan, review of the active treatment plan, and coordination of services. First, the standard for delivery of services sets forth the required members of each CMHC's client's active treatment team and requires these members to work together to meet the needs of each CMHC client. We believe it is standard practice within the CMHC industry to include these identified members in an active treatment team and, therefore, this requirement does not pose a burden.

Furthermore, this standard requires the CMHC to determine the appropriate licensed mental health processional, who is a member of the client's interdisciplinary treatment team, to be designated for each client as a care coordinator. The designated individual will be responsible for coordinating an individual client's care, including ensuring that the client's needs are fully assessed and reassessed in a timely manner, and that the client's active treatment plan is fully implemented. CMHCs may choose to assign a single individual to perform this function for all clients of the CMHC, or it may divide this duty between several individuals, assigning specific clients to specific individuals. While we believe that CMHCs already actively work to coordinate client assessment, care planning, and care implementation, we also believe that designating specific individuals to perform this function may be new to CMHCs. We estimate that, on average, designated CMHC staff will spend 20 to 30 minutes per client per week (76 to 114 hours annually) overall to fulfill this requirement. The annual cost per CMHC associated with this requirement is $3,572 to $5,358 for a psychiatric registered nurse, $2,356 to $3,534 for a mental health counselor, or $2,660 to $3,990 for a clinical social worker. The aggregate annual cost for all CMHCs is $357,200 to $535,800 if a psychiatric registered nurse is used; $235,600 to $353,400 if a mental health counselor is used, or $266,000 to $399,000, if a clinical social worker is used. This estimated burden is shown in Table 5 below.

Finally, paragraph (a)(4) of this standard requires a CMHC that has more than one interdisciplinary treatment team to designate a single team that is responsible for establishing policies and procedures governing the day-to-day provision of CMHC care and services. We believe that using multiple disciplines to establish client care policies and procedures is standard practice and does not pose a burden.

The active treatment plan standard and its content sets forth the requirements for each client's active treatment plan. The written active treatment plan will be established by the client and interdisciplinary treatment team. It will address the client's needs as they were identified in the initial evaluation and subsequent comprehensive assessment. We estimate that establishing the first comprehensive active treatment plan requires 35 minutes of the interdisciplinary treatment team's time. We estimate that compliance with the requirements at § 485.916(c) requires a licensed professional member of the

interdisciplinary team (for this burden estimate, we used the nurse) a total of 35 minutes per client, for a total of 132 hours per CMHC. Based on the nurses' hourly rate, the total cost will be $6,204 per CMHC.

The standard for review of the active treatment plan requires the interdisciplinary treatment team to review and revise the active treatment plan as necessary, but no less frequently than every 30 calendar days. We estimate that updating the content of the active treatment plan requires 10 minutes of the interdisciplinary treatment team's time. Therefore, we estimate that compliance with the requirements at § 485.916(d) requires a licensed professional member of the interdisciplinary team (for this burden estimate we used the nurse) a total of 10 minutes per client, for a total of 38 hours per CMHC. Based on the nurse's hourly rate, the total cost will be $1,786 per CMHC.

In addition, the coordination of services standard requires a CMHC to have and maintain a system of communication, in accordance with its own policies and procedures, to ensure the integration of its services and systems. We believe that active communication within health care providers, including CMHCs, is standard practice; therefore, this requirement does not impose a burden.

Table 5 below shows the annual estimated CMHC burden associated with the standards for the treatment team, active treatment plan, and coordination of services CoP.

TABLE 5—TREATMENT TEAM, ACTIVE TREATMENT PLAN, AND COORDINATION OF SERVICES BURDEN ASSESSMENT

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Psychiatric Registered Nurse ..	76 to 114 Average: 95	7,600 to 11,400 Average: 9,500	$3,572 to $5,358 Average: $4,465	$357,200 to $535,800 Average: $446,500
Mental Health Counselor	76 to 114 Average: 95	7,600 to 11,400 Average: 9,500	$2,356 to $3,534 Average: $2,945	$235,600 to $353,400 Average: $294,500
Clinical Social Worker	76 to 114 Average: 95	7,600 to 11,400 Average: 9,500	$2,660 to $3,990 Average: $3,325	$266,000 to $399,000 Average: $332,500
**Total Average (for all disciplines)	76 to 114 Total Average: 95	Total Average Range: 7,600–11,400 Total Average: 9,500	Total Average Range: $2,862–$4,294 Total Average: $3,578	Total Average Range: $286,200–$429,400 Total Average: $357,800
Development of the Active Treatment Plan	132	13,200	$6,204	$620,400
Review and Update of the Active Treatment Plan	38	3,800	$1,786	$178,600
Total	265	26,500	$11,568	$1,156,800

* **Note:** CMHC will choose one of the providers in table 5 to coordinate each client care.
** **Note:** The Total columns represent an average of all 3 provider type.

Quality Assessment and Performance Improvement (§ 485.917)

The proposed rule provided guidance to the CMHC on how to establish a quality assessment and performance improvement program. It is estimated that a CMHC will spend approximately 20 hours a year to implement a quality assessment and performance improvement program. Many providers are already using comprehensive quality assessment and performance improvement programs for accreditation or independent improvement purposes. For those providers who choose to develop their own quality assessment and performance improvement program, we estimate that it will take 9 hours to create a program. We also estimate that CMHCs will spend 4 hours a year collecting and analyzing data. In addition, we estimate that a CMHC will spend 3 hours a year training their staff and 4 hours a year implementing performance improvement activities. Both the program development and implementation will most likely be managed by that CMHC's administration. Based on an administrator's hourly rate, the total cost of the quality assessment and performance improvement condition of participation is $1,320 per CMHC.

$66 per hour × 20 hours = $1,320

Table 6 below shows the annual estimated CMHC burden associated with the standards for the quality assessment and performance improvement CoP.

TABLE 6—QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN ASSESSMENT

Standard	Time per CMHC (hours)	Total time (hours)	Cost per CMHC	Total cost
QAPI development	9	900	$594	$59,400
QAPI implementation	11	1,100	726	72,600
Total annually	20	2,000	1,320	132,000

Organization, Governance, Administration of Services, and Partial Hospitalization Services (§ 485.918)

Under the CoP for organization, governance, administration of services, and partial hospitalization services, we assessed the potential impact of the following standards on CMHCs: Governing body and administration, provision of services, professional management responsibility, staff training, and physical environment. The governing body and administration standard requires a CMHC to have a designated governing body that assumes

full legal responsibility for management of the CMHC. This standard will also require the CMHC governing body to appoint an administrator, in accordance with its own education and experience requirements, who is responsible for the day-to-day operations of the CMHC. Having a governing body and a designated administrator are standard business practices; therefore, this requirement does not impose a burden.

The provision of services standard sets forth a comprehensive list of services that CMHCs are currently required by statute and regulation to furnish, requires the CMHC and all individuals furnishing services on its behalf to meet applicable State licensing and certification requirements, and requires the CMHC to provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act.

In addition, the professional management responsibility standard requires that, if a CMHC chooses to provide certain services under agreement, it must ensure that the agreement is written. This standard will also require the CMHC to retain full professional management responsibility for the services provided under arrangement on its behalf. Full professional management responsibility will include paying for the arranged services and ensuring that the services are furnished in a safe and effective manner. Having a written agreement and retaining professional management of all care and services provided is standard practice in the health care industry. Therefore, this requirement does not impose a burden.

Further, the staff training standard requires a CMHC to educate all staff who have contact with clients and families about CMHC care and services. It also requires a CMHC to provide an initial orientation for each staff member that addresses his or her specific job duties. Educating staff about the nature of CMHC care and their particular job duties are standard practices that would not impose a burden upon CMHCs.

This standard also requires a CMHC to assess the skills and competency of all individuals furnishing client and family care in accordance with its own written policies and procedures.

Finally, this standard requires a CMHC to provide and document its in-service training program. This standard does not prescribe the content or format of the CMHC's assessment and in-service training programs. Rather, it allows CMHCs to establish their own policies and procedures to meet their individual needs and goals. For example, this can be done by in-servicing on a need recognized through the QAPI program. We believe these requirements reflect standard practice in the industry and present no additional burden.

The physical environment standard requires CMHCs to furnish services in a safe, comfortable, and private environment that meets all Federal, State, and local health and safety requirements and occupancy rules. We believe that this requirement does not impose a burden on CMHCs as it is considered standard practice to provide services in a physical location that is both safe and conducive to meeting the needs of CMHC clients.

This standard also requires a CMHC to have an infection control program. While basic precautions such as thorough hand washing and proper disposal of medical waste are standard practice, developing a comprehensive infection control program may impose a burden on CMHCs. We estimate that an administrator will spend 8 hours on a one-time basis developing infection control policies and procedures and 2 hours per month conducting follow up efforts. The estimated cost associated with this provision is $528 to develop the infection control program and $1,584 annually to follow-up on infection control issues in the CMHC. We believe that staff education regarding infection control will be incorporated into the CMHC's in-service training program, described above and therefore doesn't impose additional burden.

Table 7 below shows the initial year (one-time) and annual estimated CMHC burden, respectively, associated with the standards for the organization, governance, administration of services, and partial hospitalization services CoP.

TABLE 7—ORGANIZATION, GOVERNANCE, ADMINISTRATION OF SERVICES, AND PARTIAL HOSPITALIZATION SERVICES BURDEN ASSESSMENT

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Infection control policies and procedures *	8	800	$528	$52,800
Infection control follow-up	24	2,400	1,584	158,400
Total 1st Year	32	3,200	2,112	211,200
Total Annually	24	2,400	1,584	158,400

* Initial year (one-time) burden items.

We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all CMHC clients.

1. Estimated Effects of CoPs for CMHCs on Other Providers

We do not expect the CoPs for CMHCs included in this rule to affect any other providers.

2. Estimated Effects of CoPs for CMHCs on the Medicare and Medicaid Programs

The budget impacts to the Medicare and Medicaid programs resulting from implementation of the CoPs for CMHCs included in this rule are negligible. Even though there is likely to be an increase in CMS activities, such as on-site surveys, as a result of this final rule, CMS will likely be compelled by budgetary constraints to accommodate these activities into its existing budget. We note, however, that the rule-induced activities have an opportunity cost equal to the value of activities that would have been done in the rule's absence.

C. Alternatives Considered

CMHC providers have been operating without federally-issued health and safety requirements since the 1990 inception of Medicare coverage of partial hospitalization services in CMHCs. In place of Federal standards, we have relied upon State certification and licensure requirements to ensure the health and safety of CMHC clients.

However, CMS has learned that most States either do not have certification or licensure requirements for CMHCs or that States do not apply such certification or licensure requirements to CMHCs that are for-profit, privately owned, and/or not receiving State funds. Due to the possibility of significant gaps in State requirements, to ensure the health and safety of CMHC clients, we chose to propose and are finalizing a core set of health and safety requirements that will apply to all CMHCs receiving Medicare funds, regardless of the State in which the CMHC is located. These requirements ensure a basic level of services provided by qualified staff.

We also considered proposing a more comprehensive set of CoPs for CMHCs. Such a comprehensive set of CoPs would go beyond the requirements in this rule to address other areas of CMHC services and operations, such as a clinical records requirement that would outline the specific contents of a clinical record. While we believe that these areas are important and may warrant additional consideration in future rulemaking, we do not believe that it is appropriate to begin with an expansive set of CoPs at this time. Furthermore, a comprehensive set of CoPs may be difficult for CMHCs to manage, considering that many CMHCs are not currently required to meet any health and safety standards. As a result, we chose to focus on a core set of requirements and allow for the option of additional CoPs in the future.

Additionally, we considered proposing fewer CoPs. However, all of the CoPs included in this regulation are intended to act as a cohesive system. For example eliminating the assessment requirement would most likely cause issues with the formation of the interdisciplinary team and the client's active treatment plan. We believe that the CoPs build on each other, and that eliminating one or more would introduce vulnerabilities in patient safety.

D. Conclusion

We estimate that this final rule will cost CMHCs approximately $3 million in the first year of implementation and approximately $2.2 million annually thereafter. We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all CMHC clients.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 1. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395 (hh)).

■ 2. Add and reserve subpart I, and add a new subpart J to part 485 to read as follows:

Subpart I—[Reserved]

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

Sec.

485.900 Basis and scope.
485.902 Definitions.
485.904 Condition of participation: Personnel qualifications.
485.910 Condition of participation: Client rights.
485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.
485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.
485.917 Condition of participation: Quality assessment and performance improvement.
485.918 Condition of participation: Organization, governance, administration of services, and partial hospitalization services.

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

§ 485.900 Basis and scope.

(a) *Basis.* This subpart is based on the following sections of the Social Security Act:

(1) Section 1832(a)(2)(J) of the Act specifies that payments may be made under Medicare Part B for partial hospitalization services furnished by a community mental health center (CMHC) as described in section 1861(ff)(3)(B) of the Act.

(2) Section 1861(ff) of the Act describes the items and services that are covered under Medicare Part B as ''partial hospitalization services'' and the conditions under which the items and services must be provided. In addition, section 1861(ff) of the Act specifies that the entities authorized to provide partial hospitalization services under Medicare Part B include CMHCs and defines that term.

(3) Section 1866(e)(2) of the Act specifies that a provider of services for purposes of provider agreement requirements includes a CMHC as defined in section 1861(ff)(3)(B) of the Act, but only with respect to providing partial hospitalization services.

(b) *Scope.* The provisions of this subpart serve as the basis of survey activities for the purpose of determining whether a CMHC meets the specified requirements that are considered necessary to ensure the health and safety of clients; and for the purpose of determining whether a CMHC qualifies for a provider agreement under Medicare.

§ 485.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Active treatment plan means an individualized client plan that focuses on the provision of care and treatment services that address the client's physical, psychological, psychosocial, emotional, and therapeutic needs and goals as identified in the comprehensive assessment.

Community mental health center (CMHC) means an entity as defined in § 410.2 of this chapter.

Comprehensive assessment means a thorough evaluation of the client's physical, psychological, psychosocial, emotional, and therapeutic needs related to the diagnosis under which care is being furnished by the CMHC.

Employee of a CMHC means an individual—

(1) Who works for the CMHC and for whom the CMHC is required to issue a W–2 form on his or her behalf; or

(2) For whom an agency or organization issues a W–2 form, and who is assigned to such CMHC if the CMHC is a subdivision of an agency or organization.

Initial evaluation means an immediate care and support assessment of the client's physical, psychosocial (including a screen for harm to self or others), and therapeutic needs related to the psychiatric illness and related conditions for which care is being furnished by the CMHC.

Representative means an individual who has the authority under State law to authorize or terminate medical care on behalf of a client who is mentally or physically incapacitated. This includes a legal guardian.

Restraint means—

(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces

the ability of a client to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a client for the purpose of conducting routine physical examinations or tests, or to protect the client from falling out of bed, or to permit the client to participate in activities without the risk of physical harm (this does not include a client being physically escorted); or

(2) A drug or medication when it is used as a restriction to manage the client's behavior or restrict the client's freedom of movement, and which is not a standard treatment or dosage for the client's condition.

Seclusion means the involuntary confinement of a client alone in a room or an area from which the client is physically prevented from leaving.

Volunteer means an individual who is an unpaid worker of the CMHC; or if the CMHC is a subdivision of an agency or organization, is an unpaid worker of the agency or organization and is assigned to the CMHC. All volunteers must meet the standard training requirements under § 485.918(d).

§ 485.904 Condition of participation: Personnel qualifications.

(a) *Standard: General qualification requirements.* All professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of their State licenses, certifications, or registrations. All personnel qualifications must be kept current at all times.

(b) *Standard: Personnel qualifications for certain disciplines.* The following qualifications must be met:

(1) *Administrator of a CMHC.* A CMHC employee who meets the education and experience requirements established by the CMHC's governing body for that position and who is responsible for the day-to-day operation of the CMHC.

(2) *Clinical psychologist.* An individual who meets the qualifications at § 410.71(d) of this chapter.

(3) *Clinical Social worker.* An individual who meets the qualifications at § 410.73 of this chapter.

(4) *Social worker.* An individual who—

(i) Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education, or a baccalaureate degree in psychology or sociology, and is supervised by a clinical social worker, as described in paragraph (b)(3) of this section; and

(ii) Has 1 year of social work experience in a psychiatric healthcare setting.

(5) *Mental health counselor.* A professional counselor who is certified and/or licensed by the State in which he or she practices, and has the skills and knowledge to provide a range of behavioral health services to clients. The mental health counselor conducts assessments and provides services in areas such as psychotherapy, substance abuse, crisis management, psychoeducation, and prevention programs.

(6) *Occupational therapist.* A person who meets the requirements for the definition of ''occupational therapist'' at § 484.4 of this chapter.

(7) *Physician.* An individual who meets the qualifications and conditions as defined in section 1861(r) of the Act, and provides the services at § 410.20 of this chapter, and has experience providing mental health services to clients.

(8) *Physician assistant.* An individual who meets the qualifications and conditions as defined in section 1861(s)(2)(K)(i) of the Act and provides the services, in accordance with State law, at § 410.74 of this chapter.

(9) *Advanced practice nurse.* An individual who meets the following qualifications:

(i) Is a nurse practitioner who meets the qualifications at § 410.75 of this chapter; or

(ii) Is a clinical nurse specialist who meets the qualifications at § 410.76 of this chapter.

(10) *Psychiatric registered nurse.* A registered nurse, who is a graduate of an approved school of professional nursing, is licensed as a registered nurse by the State in which he or she is practicing, and has at least 1 year of education and/or training in psychiatric nursing.

(11) *Psychiatrist.* An individual who specializes in assessing and treating persons having psychiatric disorders; is board certified, or is eligible to be board certified by the American Board of Psychiatry and Neurology, or has documented equivalent education, training or experience, and is fully licensed to practice medicine in the State in which he or she practices.

§ 485.910 Condition of participation: Client rights.

The client has the right to be informed of his or her rights. The CMHC must protect and promote the exercise of these client rights.

(a) *Standard: Notice of rights and responsibilities.* (1) During the initial evaluation, the CMHC must provide the client, the client's representative (if appropriate) or surrogate with verbal and written notice of the client's rights and responsibilities. The verbal notice must be in a language and manner that the client or client's representative or surrogate understands. Written notice must be understandable to persons who have limited English proficiency.

(2) During the initial evaluation, the CMHC must inform and distribute written information to the client concerning its policies on filing a grievance.

(3) The CMHC must obtain the client's and/or the client representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) *Standard: Exercise of rights and respect for property and person.* (1) The client has the right to—

(i) Exercise his or her rights as a client of the CMHC.

(ii) Have his or her property and person treated with respect.

(iii) Voice grievances and understand the CMHC grievance process; including but not limited to grievances regarding mistreatment and treatment or care that is (or fails to be) furnished.

(iv) Not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a client has been adjudged incompetent under State law by a court of proper jurisdiction, the rights of the client are exercised by the person appointed in accordance with State law to act on the client's behalf.

(3) If a State court has not adjudged a client incompetent, any legal representative designated by the client in accordance with State law may exercise the client's rights to the extent allowed under State law.

(c) *Standard: Rights of the client.* The client has a right to—

(1) Be involved in developing his or her active treatment plan.

(2) Refuse care or treatment.

(3) Have a confidential clinical record. Access to or release of client information and the clinical record client information is permitted only in accordance with 45 CFR parts 160 and 164.

(4) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property.

(5) Receive information about specific limitations on services that he or she will be furnished.

(6) Not be compelled to perform services for the CMHC, and to be compensated by the CMHC for any work performed for the CMHC at prevailing wages and commensurate with the client's abilities.

(d) *Standard: Addressing violations of client rights.* The CMHC must adhere to the following requirements:

(1) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property by anyone, including those furnishing services on behalf of the CMHC, are reported immediately to the CMHC's administrator by CMHC employees, volunteers and contracted staff.

(2) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the CMHC and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and documentation of all alleged violations must be conducted in accordance with procedures established by the CMHC.

(3) Take appropriate corrective action in accordance with State law if the alleged violation is investigated by the CMHC's administration or verified by an outside entity having jurisdiction, such as the State survey and certification agency or the local law enforcement agency; and

(4) Ensure that, within 5 working days of becoming aware of the violation, all violations are reported to the State survey and certification agency, and verified violations are reported to State and local entities having jurisdiction.

(e) *Standard: Restraint and seclusion.* (1) All clients have the right to be free from physical or mental abuse, and corporal punishment. All clients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion, defined in § 485.902, may only be imposed to ensure the immediate physical safety of the client, staff, or other individuals.

(2) The use of restraint or seclusion must be in accordance with the written order of a physician or other licensed independent practitioner who is authorized to order restraint or seclusion in accordance with State law and must not exceed one 1-hour duration per order.

(3) The CMHC must obtain a corresponding order for the client's immediate transfer to a hospital when restraint or seclusion is ordered.

(4) Orders for the use of restraint or seclusion must never be written as a standing order or on an as-needed basis.

(5) When a client becomes an immediate threat to the physical safety of himself or herself, staff or other individuals, the CMHC must adhere to the following requirements:

(i) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the client or other individuals from harm.

(ii) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the client or other individuals from harm.

(iii) The use of restraint or seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by State law.

(iv) The condition of the client who is restrained or secluded must be continuously monitored by a physician or by trained staff who have completed the training criteria specified in paragraph (f) of this section.

(v) When restraint or seclusion is used, there must be documentation in the client's clinical record of the following:

(A) A description of the client's behavior and the intervention used.

(B) Alternatives or other less restrictive interventions attempted (as applicable).

(C) The client's condition or symptom(s) that warranted the use of the restraint or seclusion.

(D) The client's response to the intervention(s) used, including the rationale for continued use of the intervention.

(E) The name of the hospital to which the client was transferred.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The client has the right to safe implementation of restraint or seclusion by trained staff. Application of restraint or seclusion in a CMHC must only be imposed when a client becomes an immediate physical threat to himself or herself, staff or other individuals and only in facilities where restraint and seclusion are permitted.

(1) *Training intervals.* In facilities where restraint and seclusion are permitted, all appropriate client care staff working in the CMHC must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion and use of alternative methods to restraint and seclusion. In facilities where restraint and seclusion are not permitted, appropriate client care staff working in CMHC must be trained in the use of alternative methods to restraint and seclusion. Training will occur as follows:

(i) Before performing any of the actions specified in this paragraph (f).

(ii) As part of orientation.

(iii) Subsequently on a periodic basis, consistent with the CMHC's policy.

(2) *Training content.* The CMHC must require all appropriate staff caring for clients to have appropriate education, training, and demonstrated knowledge based on the specific needs of the client population in at least the following:

(i) Techniques to identify staff and client behaviors, events, and environmental factors that may trigger circumstances that could require the use of restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) In facilities where restraint and seclusion are permitted, choosing the least restrictive intervention based on an individualized assessment of the client's medical and behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion that are permitted in the CMHC, including training in how to recognize and respond to signs of physical and psychological distress.

(v) In facilities where restraint and seclusion are permitted, clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) In facilities where restraint and seclusion are permitted, monitoring the physical and psychological well-being of the client who is restrained or secluded, including, but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by the CMHC's policy.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address clients' behaviors.

(4) *Training documentation.* The CMHC must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) *Standard: Death reporting requirements.* The CMHC must report deaths associated with the use of seclusion or restraint.

(1) The CMHC must report to CMS each death that occurs while a client is in restraint or seclusion awaiting transfer to a hospital.

(2) Each death referenced in paragraph (g)(1) of this section must be

reported to the CMS Regional Office by telephone no later than the close of business the next business day following knowledge of the client's death.

(3) Staff must document in the client's clinical record the date and time the death was reported to CMS.

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

The CMHC must ensure that all clients admitted into its program are appropriate for the services the CMHC furnishes in its facility.

(a) *Standard: Admission.* (1) The CMHC must determine that each client is appropriate for the services it provides as specified in § 410.2 of this chapter.

(2) For clients assessed and admitted to receive partial hospitalization services, the CMHC must also meet separate requirements as specified in § 485.918(f).

(b) *Standard: Initial evaluation.* (1) A licensed mental health professional employed by the CMHC and acting within his or her state scope of practice requirements must complete the initial evaluation within 24 hours of the client's admission to the CMHC.

(2) The initial evaluation, at a minimum, must include the following:

(i) The admitting diagnosis as well as other diagnoses.

(ii) The source of referral.

(iii) The reason for admission as stated by the client or other individuals who are significantly involved.

(iv) Identification of the client's immediate clinical care needs related to the psychiatric diagnosis.

(v) A list of current prescriptions and over-the-counter medications, as well as other substances that the client may be taking.

(vi) For partial hospitalization services only, include an explanation as to why the client would be at risk for hospitalization if the partial hospitalization services were not provided.

(3) Based on the findings of the initial evaluation, the CMHC must determine the appropriate members of each client's interdisciplinary treatment team.

(c) *Standard: Comprehensive assessment.* (1) The comprehensive assessment must be completed by licensed mental health professionals who are members of the interdisciplinary treatment team, performing within their State's scope of practice.

(2) The comprehensive assessment must be completed in a timely manner, consistent with the client's immediate needs, but no later than 4 working days after admission to the CMHC.

(3) The comprehensive assessment must identify the physical, psychological, psychosocial, emotional, therapeutic, and other needs related to the client's psychiatric illness. The CMHC's interdisciplinary treatment team must ensure that the active treatment plan is consistent with the findings of the comprehensive assessment.

(4) The comprehensive assessment, at a minimum, must include the following:

(i) The reasons for the admission.

(ii) A psychiatric evaluation, completed by a psychiatrist, non-physician practitioner or psychologist practicing within the scope of State licensure that includes the medical history and severity of symptoms. Information may be gathered from the client's primary health care provider (if any), contingent upon the client's consent.

(iii) Information concerning previous and current mental status, including but not limited to, previous therapeutic interventions and hospitalizations.

(iv) Information regarding the onset of symptoms of the illness and circumstances leading to the admission.

(v) A description of attitudes and behaviors, including cultural and environmental factors that may affect the client's treatment plan.

(vi) An assessment of intellectual functioning, memory functioning, and orientation.

(vii) Complications and risk factors that may affect the care planning.

(viii) Functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals.

(ix) Factors affecting client safety or the safety of others, including behavioral and physical factors, as well as suicide risk factors.

(x) A drug profile that includes a review of all of the client's prescription and over-the-counter medications; herbal remedies; and other alternative treatments or substances that could affect drug therapy.

(xi) The need for referrals and further evaluation by appropriate health care professionals, including the client's primary health care provider (if any), when warranted.

(xii) Factors to be considered in discharge planning.

(xiii) Identification of the client's current social and health care support systems.

(xiv) For pediatric clients, the CMHC must assess the social service needs of the client, and make referrals to social services and child welfare agencies as appropriate.

(d) *Standard: Update of the comprehensive assessment.* (1) The CMHC must update the comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred.

(2) The assessment must be updated no less frequently than every 30 days.

(3) The update must include information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals.

(e) *Standard: Discharge or transfer of the client.* (1) If the client is transferred to another entity, the CMHC must, within 2 working days, forward to the entity, a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(2) If a client refuses the services of a CMHC, or is discharged from a CMHC due to noncompliance with the treatment plan, the CMHC must forward to the primary health care provider (if any) a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(3) The CMHC discharge summary must include—

(i) A summary of the services provided, including the client's symptoms, treatment and recovery goals and preferences, treatments, and therapies.

(ii) The client's current active treatment plan at time of discharge.

(iii) The client's most recent physician orders.

(iv) Any other documentation that will assist in post-discharge continuity of care.

(4) The CMHC must adhere to all Federal and State-related requirements pertaining to the medical privacy and the release of client information.

§ 485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.

The CMHC must designate an interdisciplinary treatment team that is responsible, with the client, for directing, coordinating, and managing the care and services furnished for each client. The interdisciplinary treatment team is composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and therapeutic needs of CMHC clients.

(a) *Standard: Delivery of services.* (1) An interdisciplinary treatment team, led by a physician, NP, PA, CNS, clinical psychologist, or clinical social worker, must provide the care and services offered by the CMHC.

(2) Based on the findings of the comprehensive assessment, the CMHC must determine the appropriate licensed mental health professional, who is a member of the client's interdisciplinary treatment team, to coordinate care and treatment decisions with each client, to ensure that each client's needs are assessed, and to ensure that the active treatment plan is implemented as indicated.

(3) The interdisciplinary treatment team may include:

(i) A doctor of medicine, osteopathy or psychiatry (who is an employee of or under contract with the CMHC).

(ii) A psychiatric registered nurse.

(iii) A clinical social worker.

(iv) A clinical psychologist.

(v) An occupational therapist.

(vi) Other licensed mental health professionals, as necessary.

(vii) Other CMHC staff or volunteers, as necessary.

(4) If the CMHC has more than one interdisciplinary team, it must designate the treatment team responsible for establishing policies and procedures governing the coordination of services and the day-to-day provision of CMHC care and services.

(b) *Standard: Person-centered active treatment plan.* All CMHC care and services furnished to clients must be consistent with an individualized, written, active treatment plan that is established by the CMHC interdisciplinary treatment team, the client, and the client's primary caregiver(s), in accordance with the client's recovery goals and preferences, within 7 working days of admission to the CMHC. The CMHC must ensure that each client and the client's primary caregiver(s), as applicable, receive education and training provided by the CMHC that are consistent with the client's and caregiver's responsibilities as identified in the active treatment plan.

(c) *Standard: Content of the person-centered active treatment plan.* The CMHC must develop a person-centered individualized active treatment plan for each client. The active treatment plan must take into consideration client recovery goals and the issues identified in the comprehensive assessment. The active treatment plan must include all services necessary to assist the client in meeting his or her recovery goals, including the following:

(1) Client diagnoses.

(2) Treatment goals.

(3) Interventions.

(4) A detailed statement of the type, duration, and frequency of services, including social work, psychiatric nursing, counseling, and therapy services, necessary to meet the client's specific needs.

(5) Drugs, treatments, and individual and/or group therapies.

(6) Family psychotherapy with the primary focus on treatment of the client's conditions.

(7) The interdisciplinary treatment team's documentation of the client's or representative's and primary caregiver's (if any) understanding, involvement, and agreement with the plan of care, in accordance with the CMHC's policies.

(d) *Standard: Review of the person-centered active treatment plan.* The CMHC interdisciplinary treatment team must review, revise, and document the individualized active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. The CMHC must also meet partial hospitalization program requirements specified under § 424.24(e) of this chapter if such services are included in the active treatment plan.

(e) *Standard: Coordination of services.* The CMHC must develop and maintain a system of communication that assures the integration of services in accordance with its policies and procedures and, at a minimum, would do the following:

(1) Ensure that the interdisciplinary treatment team maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that care and services are provided in accordance with the active treatment plan.

(3) Ensure that the care and services provided are based on all assessments of the client.

(4) Provide for and ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services are provided by employees or those under contract with the CMHC.

(5) Provide for ongoing sharing of information with other health care and non-medical providers, including the primary health care provider, furnishing services to a client for conditions unrelated to the psychiatric condition for which the client has been admitted, and non-medical supports addressing environmental factors such as housing and employment.

§ 485.917 Condition of participation: Quality assessment and performance improvement.

The CMHC must develop, implement, and maintain an effective, ongoing, CMHC-wide data-driven quality assessment and performance improvement program (QAPI). The CMHC's governing body must ensure that the program reflects the complexity of its organization and services, involves all CMHC services (including those services furnished under contract or arrangement), focuses on indicators related to improved behavioral health or other healthcare outcomes, and takes actions to demonstrate improvement in CMHC performance. The CMHC must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The CMHC program must be able to demonstrate measurable improvement in indicators related to improving behavioral health outcomes and CMHC services.

(2) The CMHC must measure, analyze, and track quality indicators; adverse client events, including the use of restraint and seclusion; and other aspects of performance that enable the CMHC to assess processes of care, CMHC services, and operations.

(b) *Standard: Program data.* (1) The program must use quality indicator data, including client care, and other relevant data, in the design of its program.

(2) The CMHC must use the data collected to do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved by the CMHC's governing body.

(c) *Standard: Program activities.* (1) The CMHC's performance improvement activities must:

(i) Focus on high risk, high volume, or problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems.

(iii) Give priority to improvements that affect behavioral outcomes, client safety, and person-centered quality of care.

(2) Performance improvement activities must track adverse client events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the CMHC.

(3) The CMHC must take actions aimed at performance improvement and, after implementing those actions, the CMHC must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* CMHCs must develop, implement and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the CMHC's population and internal organizational needs, must reflect the scope, complexity, and past performance of the CMHC's services and operations.

(2) The CMHC must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The CMHC's governing body is responsible for ensuring the following:

(1) That an ongoing QAPI program for quality improvement and client safety is defined, implemented, maintained, and evaluated annually.

(2) That the CMHC-wide quality assessment and performance improvement efforts address priorities for improved quality of care and client safety, and that all improvement actions are evaluated for effectiveness.

(3) That one or more individual(s) who are responsible for operating the QAPI program are designated.

§ 485.918 Condition of participation: Organization, governance, administration of services, and partial hospitalization services.

The CMHC must organize, manage, and administer its resources to provide CMHC services, including specialized services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from an inpatient mental health facility.

(a) *Standard: Governing body and administrator.* (1) A CMHC must have a designated governing body made up of two or more designated persons, one of which may be the administrator, that assumes full legal authority and responsibility for the management of the CMHC, the services it furnishes, its fiscal operations, and continuous quality improvement. One member of the governing body must possess knowledge and experience as a mental health clinician.

(2) The CMHC's governing body must appoint an administrator who reports to the governing body and is responsible for the day-to-day operation of the CMHC. The administrator must be a CMHC employee and meet the education and experience requirements established by the CMHC's governing body.

(b) *Standard: Provision of services.* (1) A CMHC must be primarily engaged in providing the following care and services to all clients served by the CMHC regardless of payer type, and must do so in a manner that is consistent with the following accepted standards of practice:

(i) Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from inpatient mental health facilities.

(ii) Provides 24-hour-a-day emergency care services.

(iii) Provides day treatment, partial hospitalization services other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

(iv) Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such services, unless otherwise directed by State law.

(v) Provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act, as measured by the total number of CMHC clients treated by the CMHC for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC for each 12-month period of enrollment.

(A) A CMHC is required to submit to CMS a certification statement provided by an independent entity that certifies that the CMHC's client population meets the 40 percent requirement specified at this paragraph (b)(1)(v).

(B) The certification statement described in paragraph (b)(1)(v)(A) of this section is required upon initial application to enroll in Medicare, and as a part of revalidation, including any off cycle revalidation, thereafter carried out pursuant to § 424.530 of this chapter. Medicare enrollment will be denied or revoked in instances where the CMHC fails to provide the certification statement as required. Medicare enrollment will also be denied or revoked if the 40 percent requirement as specified in this paragraph (b)(1)(v) is not met.

(vi) Provides individual and group psychotherapy utilizing a psychiatrist, psychologist, or other licensed mental health counselor, to the extent authorized under State law.

(vii) Provides physician services.

(viii) Provides psychiatric nursing services.

(ix) Provides clinical social work services.

(x) Provides family counseling services, with the primary purpose of treating the individual's condition.

(xi) Provides occupational therapy services.

(xii) Provides services of other staff trained to work with psychiatric clients.

(xiii) Provides drugs and biologicals furnished for therapeutic purposes that cannot be self-administered.

(xiv) Provides client training and education as related to the individual's care and active treatment.

(xv) Provides individualized therapeutic activity services that are not primarily recreational or diversionary.

(xvi) Provides diagnostic services.

(2) The CMHC and individuals furnishing services on its behalf must meet applicable State licensing and certification requirements.

(c) *Standard: Professional management responsibility.* A CMHC that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management and oversight of staff and services for all arranged services. As part of retaining financial management responsibility, the CMHC must retain all payment responsibility for services furnished under arrangement on its behalf. Arranged services must be supported by a written agreement which requires that all services be as follows:

(1) Authorized by the CMHC.

(2) Furnished in a safe and effective manner.

(3) Delivered in accordance with established professional standards, the policies of the CMHC, and the client's active treatment plan.

(d) *Standard: Staff training.* (1) A CMHC must provide education about CMHC care and services, and person-centered care to all employees, volunteers, and staff under contract who have contact with clients and their families.

(2) A CMHC must provide an initial orientation for each individual furnishing services that addresses the specific duties of his or her job.

(3) A CMHC must assess the skills and competence of all individuals furnishing care and, as necessary, provide in-service training and education programs where indicated. The CMHC must have written policies and procedures describing its method(s)

of assessing competency and must maintain a written description of the in-service training provided during the previous 12 months.

(e) *Standard: Physical environment.* (1) *Environmental conditions.* The CMHC must provide a safe, functional, sanitary, and comfortable environment for clients and staff that is conducive to the provision of services that are identified in paragraph (b) of this section.

(2) *Building.* The CMHC services must be provided in a location that meets Federal, State, and local health and safety standards and State health care occupancy regulations.

(3) *Infection control.* There must be policies, procedures, and monitoring for the prevention, control, and investigation of infection and communicable diseases with the goal of avoiding sources and transmission of infection.

(4) *Therapy sessions.* The CMHC must ensure that individual or group therapy sessions are conducted in a manner that maintains client privacy and ensures client dignity.

(f) *Standard: Partial hospitalization services.* A CMHC providing partial hospitalization services must—

(1) Provide services as defined in § 410.2 of this chapter.

(2) Provide the services and meet the requirements specified in § 410.43 of this chapter.

(3) Meet the requirements for coverage as described in § 410.110 of this chapter.

(4) Meet the content of certification and plan of treatment requirements as described in § 424.24(e) of this chapter.

(g) *Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients.* The CMHC and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of clients. If State or local law provides for licensing of CMHCs, the CMHC must be licensed. The CMHC staff must follow the CMHC's policies and procedures.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 19, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 24, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–24056 Filed 10–28–13; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 78 Tuesday,

No. 209 October 29, 2013

Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Determination of Endangered Species Status for 15 Species on Hawaii Island; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2012–0070; 4500030113]

RIN 1018–AY09

Endangered and Threatened Wildlife and Plants; Determination of Endangered Species Status for 15 Species on Hawaii Island

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine endangered species status under the Endangered Species Act of 1973 (Act), as amended, for 15 species on the island of Hawaii. In addition, we are recognizing a taxonomic change for one Hawaiian plant currently listed as an endangered species and revising the List of Endangered and Threatened Plants accordingly. The effect of this regulation is to conserve these species under the Act.

DATES: This rule is effective on November 29, 2013.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* and *http://www.fws.gov/pacificislands.* Comments and materials received, as well as supporting documentation used in preparing this final rule, are available for public inspection, by appointment, during normal business hours, at U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850; by telephone at 808–792–9400; or by facsimile at 808–792–9581.

FOR FURTHER INFORMATION CONTACT: Loyal Mehrhoff, Field Supervisor, U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850; by telephone at 808–792–9400; or by facsimile at 808–792–9581. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. This is a final rule to list 15 species (13 plants, 1 insect (picture-wing fly), and 1 crustacean (anchialine pool shrimp)) from the island of Hawaii, in the State of Hawaii, as endangered species. In addition, in this final rule, we also recognize a taxonomic change for one endangered plant species, and revise the List of Endangered and Threatened Plants accordingly.

The basis for our action. Under the Act, we determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the 15 Hawaii Island species are currently in danger of extinction throughout all their ranges as the result of ongoing threats that include the destruction and modification of habitat from nonnative feral ungulates (e.g., pigs, goats); competition with nonnative plant and animal species; agricultural and urban development; wildfire, erosion, drought, and hurricanes; climate change; predation and herbivory; the inadequacy of existing regulatory mechanisms; human dumping of nonnative fish and trash; small numbers of individuals and populations; hybridization; the lack of reproduction in the wild; loss of host plants; and competition with nonnative tipulid flies (large crane flies). We fully considered comments from the public, including comments we received during a public hearing, and comments we received from peer reviewers, on the proposed rule.

Peer reviewers support our methods. We obtained opinions from 11 knowledgeable individuals with scientific expertise to review our technical assumptions, to review our analysis, and to determine whether or not we used the best available information. Nine (2 plant reviewers, 2 picture-wing fly reviewers, and 5 of the 7 anchialine pool shrimp reviewers) of these 11 peer reviewers generally concurred with our methods and provided additional information, clarifications, and suggestions to improve this final rule. One shrimp peer reviewer recommended further surveys for the anchialine pool shrimp, and a second shrimp reviewer commented that we should proceed with caution regarding listing the shrimp due to the lack of biological information. A response to all peer review comments is provided elsewhere in this final rule.

The final critical habitat designation for *Bidens micrantha* ssp. *ctenophylla, Isodendrion pyrifolium,* and *Mezoneuron kavaiense,* as proposed in the **Federal Register** (77 FR 63928; October 17, 2012), is still under development and undergoing agency review. It will publish in the near future in the **Federal Register** under Docket No. FWS–R1–ES–2013–0028.

Previous Federal Actions

Federal actions for these species prior to October 17, 2012, are outlined in our proposed rule (77 FR 63928), which was published on that date. Publication of the proposed rule opened a 60-day comment period, which closed on December 17, 2012. In addition, we published a public notice of the proposed rule on October 20, 2012, in the local Honolulu Star Advertiser, West Hawaii Today, and the Hawaii Tribune Herald newspapers. On April 30, 2013, we published in the **Federal Register** a document (78 FR 25243) that made available and requested public comments on the draft economic analysis for the October 17, 2012, proposed critical habitat designation (77 FR 63928); announced a public information meeting and hearing to be held in Kailua-Kona, Hawaii Island, on May 15, 2013; and reopened the comment period on the October 17, 2012, proposed rule for an additional 30 days. This second comment period closed on May 30, 2013. In total, we accepted public comments on the October 17, 2012, proposed rule for 90 days.

Background

Hawaii Island Species Addressed in This Final Rule

The table below (Table 1) provides the scientific name, common name, and listing status for the species that are the subjects of this final rule.

TABLE 1—THE HAWAII ISLAND SPECIES ADDRESSED IN THIS FINAL RULE

[Note that many of the species share the same common name]

Scientific name	Common name(s)	Listing status
Plants:		
Bidens hillebrandiana ssp. *hillebrandiana*	kookoolau	Endangered.
Bidens micrantha ssp. *ctenophylla*	kookoolau	Endangered.
Cyanea marksii	haha	Endangered.
Cyanea tritomantha	aku	Endangered.
Cyrtandra nanawaleensis	haiwale	Endangered.
Cyrtandra wagneri	haiwale	Endangered.
Mezoneuron kavaiense (taxonomic change accepted) (Formerly listed as *Caesalpinia kavaiense*).	uhiuhi	Endangered—Listed in 1986.
Phyllostegia floribunda	NCN [1]	Endangered.
Pittosporum hawaiiense	hoawa, haawa	Endangered.
Platydesma remyi	NCN	Endangered.
Pritchardia lanigera	loulu	Endangered.
Schiedea diffusa ssp. *macraei*	NCN	Endangered.
Schiedea hawaiiensis	NCN	Endangered.
Stenogyne cranwelliae	NCN	Endangered.
Animals:		
Drosophila digressa	picture-wing fly	Endangered.
Vetericaris chaceorum	anchialine pool shrimp	Endangered

[1] NCN = no common name.

Taxonomic Change Since Listing for One Plant Species

We listed *Mezoneuron kavaiense* as an endangered species in 1986 (51 FR 24672; July 8, 1986), based on the taxonomic treatment of Hillebrand (1888, pp. 110–111). Following the reduction of *Mezoneuron* to *Caesalpinia* by Hattink (1974, p. 5), Geesink *et al.* (1990, pp. 646–647) changed the name to *Caesalpinia kavaiensis.* In 1989, the List of Endangered and Threatened Plants (List) was revised to identify the listed entity as *Caesalpinia kavaiense,* although the specific epithet was misspelled in the List (at that time the correct spelling for this entity was *Caesalpinia kavaiensis*). Recent phylogenetic studies support separation of *Mezoneuron* from *Caesalpinia* (Bruneau *et al.* 2008, p. 710). The recognized scientific name for this species is *Mezoneuron kavaiense* (Wagner *et al.* 2012, p. 37). The range of the species between the time of listing and now has not changed. Therefore, we recognize the listed species as *Mezoneuron kavaiense.* We are amending the List to reflect this taxonomic change, but this amendment does not in any way change the listed entity or its protections under the Act (16 U.S.C. 1531 *et seq.*).

An Ecosystem-Based Approach to Listing 15 Species on Hawaii Island

On the island of Hawaii, as on most of the Hawaiian Islands, native species that occur in the same habitat types (ecosystems) depend on many of the same biological features and the successful functioning of that ecosystem to survive. We have therefore organized the species addressed in this final rule by common ecosystem. Although the listing determination for each species is analyzed separately, we have organized the individual analysis for each species within the context of the broader ecosystem in which it occurs to avoid redundancy. In addition, native species that share ecosystems often face a suite of common factors that may be a threat to them, and ameliorating or eliminating these threats for each individual species often requires the exact same management actions in the exact same areas. Effective management of these threats often requires implementation of conservation actions at the ecosystem scale to enhance or restore critical ecological processes and provide for long-term viability of those species in their native environment. Thus, by taking this approach, we hope not only to organize this final rule efficiently, but also to more effectively focus conservation management efforts on the common threats that occur across these ecosystems. Those efforts would facilitate restoration of ecosystem functionality for the recovery of each species, and provide conservation benefits for associated native species, thereby potentially precluding the need to list other species under the Act that occur in these shared ecosystems. In addition, this approach is in accord with the primary stated purpose of the Act (see section 2(b)): ''to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved.''

We are listing the plants *Bidens hillebrandiana* ssp. *hillebrandiana, Bidens micrantha* ssp. *ctenophylla, Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Platydesma remyi, Pritchardia lanigera, Schiedea diffusa* ssp. *macraei, Schidea hawaiiensis,* and *Stenogyne cranwelliae;* and the animals *Drosophila digressa* and *Vetericaris chaceorum,* from Hawaii Island as endangered species. These 15 species (13 plants, 1 anchialine pool shrimp, and 1 picture-wing fly) are found in 10 ecosystem types: anchialine pool, coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff (Table 2).

TABLE 2—THE 15 HAWAII ISLAND SPECIES AND THE ECOSYSTEMS UPON WHICH THEY DEPEND

Ecosystem	Species	
	Plants	Animals
Anchialine Pool		*Vetericaris chaceorum.*

TABLE 2—THE 15 HAWAII ISLAND SPECIES AND THE ECOSYSTEMS UPON WHICH THEY DEPEND—Continued

Ecosystem	Species	
	Plants	Animals
Coastal	*Bidens hillebrandiana* ssp. *hillebrandiana*.	
Lowland Dry	*Bidens micrantha* ssp. *ctenophylla*.	
Lowland Mesic	*Pittosporum hawaiiense*	*Drosophila digressa*.
	Pritchardia lanigera.	
Lowland Wet	*Cyanea marksii*.	
	Cyanea tritomantha.	
	Cyrtandra nanawaleensis.	
	Cyrtandra wagneri.	
	Phyllostegia floribunda.	
	Platydesma remyi.	
	Pritchardia lanigera.	
Montane Dry	*Schiedea hawaiiensis*.	
Montane Mesic	*Phyllostegia floribunda*	*Drosophila digressa*.
	Pittosporum hawaiiense.	
Montane Wet	*Cyanea marksii*	*Drosophila digressa*.
	Cyanea tritomantha.	
	Phyllostegia floribunda.	
	Pittosporum hawaiiense.	
	Platydesma remyi.	
	Pritchardia lanigera.	
	Schiedea diffusa ssp. *macraei*.	
	Stenogyne cranwelliae.	
Dry Cliff	*Bidens hillebrandiana* ssp. *hillebrandiana*.	
Wet Cliff	*Cyanea tritomantha*.	
	Pritchardia lanigera.	
	Stenogyne cranwelliae.	

For each species, we identified and evaluated those factors that adversely impact the species and that may be common to all of the species at the ecosystem level. For example, the degradation of habitat by nonnative ungulates is considered a threat to all 15 species, and is likely a threat to many, if not most or all, of the native species within a given ecosystem. We consider such a threat factor to be an ''ecosystem-level threat,'' as each individual species within that ecosystem faces a threat that is essentially identical in terms of the nature of the impact, its severity, its timing, and its scope. Beyond ecosystem-level threats, we further identified and evaluated threat factors that may be unique to certain species and that do not apply to all species under consideration within the same ecosystem. For example, the threat of predation by nonnative wasps is unique to the picture-wing fly *Drosophila digressa,* and is not applicable to any of the other 14 species. We have identified such threat factors, which apply only to certain species within the ecosystems addressed here, as ''species-specific threats.''

Please refer to the proposed rule (77 FR 63928; October 17, 2012) for a description of the island of Hawaii and associated map, and for a description of the 10 ecosystems on Hawaii Island that support the 15 species. We have made minor revisions to our description of the anchialine pool ecosystem described in the proposed rule (77 FR 63928; October 17, 2012); therefore, we have included the revised version in its entirety in this final rule (see *Hawaii Island Ecosystems,* below).

Hawaii Island Ecosystems

There are 12 different ecosystems (anchialine pool, coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, subalpine, alpine, dry cliff, and wet cliff) recognized on the island of Hawaii. The 15 species addressed in this final rule occur in 10 of these 12 ecosystems (none of the 15 species are reported in subalpine and alpine ecosystems). The 10 Hawaii Island ecosystems that support the 15 species are described in the proposed rule (77 FR 63928; October 17, 2012), with the exception of a revised description of the anchialine pool ecosystem below; see Table 2 (above) for a list of the species that occur in each ecosystem type.

Anchialine Pools

Anchialine pools are land-locked bodies of water that have indirect underground connections to the sea, contain varying levels of salinity, and show tidal fluctuations in water level. Anchialine pool habitats can be distinguished from similar systems (i.e., tidal pools) in that they are land-locked with no surface connections to water sources either saline or fresh, but have subterranean hydrologic connections to both fresh and ocean water where water flows through cracks and crevices, and remain tidally influenced (Holthuis 1973, p. 3; Stock 1986, p. 91). Anchialine habitats are ecologically distinct and unique, and while widely distributed throughout the world, they only occur in the United States in the Hawaiian Islands (Brock 2004, pp. i, 2, and 12). In Hawaii, the anchialine pool ecosystem has been reported from Oahu, Molokai, Maui, Kahoolawe, and Hawaii Island. In the Hawaiian Islands, there are estimated to be 600 to 700 anchialine pools, with the majority occurring on the island of Hawaii (Brock 2004, p. i). Over 80 percent of the State's anchialine pools are found on the island of Hawaii, with a total of approximately 520 to 560 pools distributed over 130 sites along all but the island's northernmost and steeper northeastern shorelines. Characteristic animal species include crustaceans (e.g., shrimps, prawns, amphipods, isopods, etc.), several fish species, mollusks, and other invertebrates adapted to the pools' surface and subterranean habitats (Brock 2004, p. i; The Nature Conservancy (TNC) 2009, pp. 1–3). Generally, vegetation within the anchialine pools consists of various types of algal forms (blue-green, green, red, and golden-brown). The majority of Hawaii's anchialine pools occur in bare or

sparsely vegetated lava fields, although some pools occur in areas with various groundcover, shrub, and tree species (Chai *et al.* 1989, pp. 2–24; Brock 2004, p. 35). The anchialine pool shrimp in this final rule, *Vetericaris chaceorum,* occurs in this ecosystem (Kensley and Williams 1986, pp. 417–437).

Description of the 15 Species

Below is a brief description of each of the 15 species, presented in alphabetical order by genus. Plants are presented first, followed by animals.

Plants

In order to avoid confusion regarding the number of locations of each species (a location does not necessarily represent a viable population, as in some cases there may only be one or a very few representatives of the species present), we use the word ''occurrence'' instead of ''population.'' Each occurrence is composed only of wild (i.e., not propagated and outplanted) individuals.

Bidens hillebrandiana ssp. *hillebrandiana* (kookoolau), a perennial herb in the sunflower family (Asteraceae), occurs only on the island of Hawaii (Ganders and Nagata 1999, pp. 275–276). Historically, *B. hillebrandiana* ssp. *hillebrandiana* was known from two locations along the windward Kohala coastline, in the coastal and dry cliff ecosystems, often along rocks just above the ocean (Degener and Wiebke 1926, in litt.; Flynn 1988, in litt.). Currently, there are two known occurrences of *B. hillebrandiana* ssp. *hillebrandiana* totaling 40 or fewer individuals along the windward Kohala coast, in the coastal and dry cliff ecosystems. There are 30 individuals on the Pololu seacliffs, and 5 to 10 individuals on the seacliffs between Pololu and Honokane Nui (Perlman 1998, in litt.; Perlman 2006, in litt.). Biologists speculate that this species may total as many as 100 individuals with further surveys of potential habitat along the Kohala coast (Mitchell *et al.* 2005b; PEPP 2006, p. 3).

Bidens micrantha ssp. *ctenophylla* (kookoolau), a perennial herb in the sunflower family (Asteraceae), occurs only on the island of Hawaii (Ganders and Nagata 1999, pp. 271, 273). Historically, *B. micrantha* ssp. *ctenophylla* was known from the north Kona district, in the lowland dry ecosystem (HBMP 2010b). Currently, this subspecies is restricted to an area of less than 10 square miles (sq mi) (26 square kilometers (sq km)) on the leeward slopes of Hualalai volcano, in the lowland dry ecosystem in 6 occurrences totaling fewer than 1,000 individuals. The largest occurrence is found off Hina Lani Road with over 475 individuals widely dispersed throughout the area (Zimpfer 2011, in litt.). Another occurrence at Kealakehe was reported to have been abundant and common in 1992, but by 2010 had declined to low numbers (Whister 2007, pp. 1–18; Bio 2008, in litt.; HBMP 2010b; Whister 2008, pp. 1–11). In addition, there are three naturally occurring individuals in Kaloko–Honokohau National Historical Park (NHP) (Beavers 2010, in litt.), and three occurrences within close proximity to each other to the northeast of the park: Five individuals in an exclosure at Puuwaawaa Wildlife Sanctuary (HBMP 2010b); a few scattered individuals at Kaupulehu; and a few individuals on private land at Palani Ranch (Whistler 2007, pp. 1–18; Whistler 2008, pp. 1–11). *Bidens micrantha* ssp. *ctenophylla* has also been outplanted within Kaloko–Honokohau NHP (49 individuals), Koaia Tree Sanctuary (1 individual), and Puuwaawaa (5 individuals) (Boston 2008, in litt.; HBMP 2010b; Billings 2012, in litt.).

Cyanea marksii (haha), a shrub in the bellflower family (Campanulaceae), is found only on the island of Hawaii. Historically, *C. marksii* was known from the Kona district, in the lowland wet and montane wet ecosystems (Lammers 1999, p. 457; HBMP 2010e). Currently, there are 27 individuals distributed among 3 occurrences in south Kona, in the lowland wet and montane wet ecosystems (PEPP 2007, p. 61). There is an adult and 20 to 30 juveniles (each approximately 1 inch (in) (2.54 centimeters (cm) tall)) in a lava tube in the Kona unit of the Hakalau National Wildlife Refuge (NWR) (PEPP 2007, p. 61), 3 adult individuals and 6 seedlings in the Kaohe pit crater in the South Kona FR (Perry 2012, in litt.), and 25 individuals on private land in south Kona (PEPP 2007, p. 61; Bio 2011, pers. comm.). Fruit has been collected from the individuals on private land, and 11 plants have been successfully propagated at the Volcano Rare Plant Facility (VRPF) (PEPP 2007, p. 61; Bio 2011, pers. comm.).

Cyanea tritomantha (aku), a palmlike shrub in the bellflower family (Campanulaceae), is known only from the island of Hawaii (Pratt and Abbott 1997, p. 13; Lammers 2004, p. 89). Historically, this species was known from the windward slopes of Mauna Kea, Mauna Loa, Kilauea, and the Kohala Mountains, in the lowland wet, montane wet, and wet cliff ecosystems (Pratt and Abbott 1997, p. 13). Currently, there are 16 occurrences of *Cyanea tritomantha* totaling fewer than 400 individuals in the lowland wet, montane wet, and wet cliff ecosystems: 10 occurrences (totaling fewer than 240 individuals) in the Kohala Mountains (Perlman 1993, in litt.; Perlman 1995a, in litt.; Perlman and Wood 1996, pp. 1–14; HBMP 2010f; PEPP 2010, p. 60); 2 occurrences (totaling fewer than 75 individuals) in the Laupahoehoe Natural Area Reserve (NAR) (HBMP 2010f; Bio 2011, pers. comm.); 1 occurrence (20 adults and 30 juveniles) at Puu Makaala NAR (Perlman and Bio 2008, in litt.; Agorastos 2010, in litt.; HBMP 2010f; Bio 2011, pers. comm.); 1 occurrence with 10 to 20 individuals off Tom's Trail in the Upper Waiakea Forest Reserve FR (Perlman and Bio 2008, in litt.; Perry 2012, in litt.); and 2 occurrences (totaling fewer than 11 individuals) in Olaa Tract in Hawaii Volcanoes National Park HVNP (Pratt 2007a, in litt.; Pratt 2008a, in litt.; Orlando 2012, in litt.). In 2003, over 75 individuals were outplanted in HVNP's Olaa Tract and Small Tract; however, by 2010, less than one third of these individuals remained (Pratt 2011a, in litt.). In addition, a few individuals have been outplanted at Puu Makaala NAR and Upper Waiakea FR (Hawaii Department of Land and Natural Resources (HDLNR) 2006; Belfield 2007, in litt.; Agorastos 2010, in litt.). *Cyanea tritomantha* produces few seeds, and their viability tends to be low (Moriyasu 2009, in litt.)

Cyrtandra nanawaleensis (haiwale), a shrub or small tree in the African violet family (Gesneriaceae), is known only from the island of Hawaii (Wagner and Herbst 2003, p. 29; Wagner *et al.* 2005a—*Flora of the Hawaiian Islands database*). Historically, *C. nanawaleensis* was known only from the Nanawale FR and the adjacent Malama Ki FR in the Puna district, in the lowland wet ecosystem (St. John 1987, p. 500; Wagner *et al.* 1988, in litt.; HBMP 2010g; Pratt 2011b, in litt.). Currently, *C. nanawaleensis* is known from 5 occurrences with approximately 160 individuals in the lowland wet ecosystem: 2 occurrences in Malama Ki FR totaling 70 individuals (Lau 2011, pers. comm.); 1 occurrence in Keauohana FR (with 56 individuals) (Magnacca 2011a, in litt.); 2 occurrences in the Halepuaa section of Nanawale FR (one with 28 mature and 65 immature plants at 200 feet (ft) (61 meters (m)) elevation, and a second occurrence with 9 mature and 57 immature plants at 270 ft (82 m)) (Johansen 2012, in litt.; Kobsa 2012, in litt.; Perry 2012, in litt.); and 1 occurrence with an unknown number of individuals on private lands in lower Puna (Perry 2012, in litt.). A total of

approximately 56 individuals have been outplanted in Halepuaa and Keauhana (Perry 2012, in litt.).

Cyrtandra wagneri (haiwale), a shrub or small tree in the African violet family (Gesneriaceae), occurs only on the island of Hawaii (Lorence and Perlman 2007, p. 357). Historically, *C. wagneri* was known from a few individuals along the steep banks of the Kaiwilahilahi Stream in the Laupahoehoe NAR, in the lowland wet ecosystem (Perlman *et al.* 1998, in litt.). In 2002, there were 2 known occurrences totaling fewer than 175 individuals in the Laupahoehoe NAR: One occurrence (totaling 150 individuals (50 adults and 100 juveniles)) along the steep banks of the Kilau Stream (Lorence *et al.* 2002, in litt.; Perlman and Perry 2003, in litt.; Lorence and Perlman 2007, p. 359), and a second occurrence (with approximately 10 sterile individuals) along the slopes of the Kaiwilahilahi stream banks (Lorence and Perlman 2007, p. 359). Currently, there are no individuals remaining at Kaiwilahilahi Stream, and the individuals at Kilau Stream appear to be hybridizing with the endangered *Cyrtandra tintinnabula.* Biologists have identified only eight individuals at Kilau Stream that express the true phenotype of *Cyrtandra wagneri,* and only three of these individuals are reproducing successfully (PEPP 2010, p. 102; Bio 2011, pers. comm.).

Phyllostegia floribunda (NCN), a perennial herb in the mint family (Lamiaceae), is found only on the island of Hawaii (Wagner 1999, p. 268; Wagner *et al.* 1999b, p. 815). Historically, *P. floribunda* was reported in the lowland wet, montane mesic, and montane wet ecosystems at scattered sites along the slopes of the Kohala Mountains; southeast through Hamakua, Laupahoehoe NAR, Waiakea FR, and Upper Waiakea FR; and southward into Hilo, HVNP, and Puna. One report exists of the species occurring from north Kona and a few occurrences in south Kona (Cuddihy *et al.* 1982, in litt.; Wagner *et al.* 2005b—*Flora of the Hawaiian Islands database;* Perlman *et al.* 2008, in litt.; HBMP 2010h; Bishop Museum 2011—*Herbarium Database*). Currently, there are 12 known occurrences of *P. floribunda* totaling fewer than 100 individuals, in the lowland wet, montane mesic, and montane wet ecosystems (Bruegmann 1998, in litt.; Giffin 2009, in litt.; HBMP 2010h): 2 occurrences within HVNP, at Kamoamoa (1 individual) (HBMP 2010h) and near Napau Crater (4 individuals) (Pratt 2005, in litt.; Pratt 2007b, in litt.; HBMP 2010h); 1 occurrence behind the Volcano solid waste transfer station (10 to 50 individuals) (Flynn 1984, in litt.; Perlman and Wood 1993—*Hawaii Plant Conservation Maps database;* Pratt 2007b, in litt.; HBMP 2010h); 1 occurrence (with an unknown number individuals) in the Wao Kele O Puna NAR (HBMP 2010h); 1 occurrence with 20 individuals in a fenced exclosure in the Upper Waiakea FR (Perry 2012, in litt.); at least 1 occurrence each (with a few individuals each) in the Puu Makaala NAR, Waiakea FR, and TNC's Kona Hema Preserve (PR) (Perry 2006, in litt.; Perlman 2007, in litt.; Giffin 2009, in litt.; PEPP 2008, pp. 106–107; Perlman *et al.* 2008, in litt.; Pratt 2008a, in litt.; Pratt 2008b, in litt.; Agorastos 2010, in litt.); 2 occurrences (each with an unknown number of individuals) from the South Kona FR; 1 occurrence (one individual) in the Kipahoehoe NAR; and 1 occurrence (with an unknown number of individuals) in the Lapauhoehoe NAR (Moriyasu 2009, in litt.; HBMP 2010h; Agorastos 2010, in litt.). Since 2003, over 400 individuals have been outplanted at HVNP, Waiakea FR, Puu Makaala NAR, Honomalino in TNC's Kona Hema PR, and Kipahoehoe NAR (Bruegmann 2006, in litt.; HDLNR 2006, p. 38; Tangalin 2006, in litt.; Belfield 2007, in litt.; Pratt 2007b, in litt.; VRPF 2008, in litt.; VRPF 2010, in litt.; Bio 2008, in litt.; Agorastos 2010, in litt.). However, for reasons unknown, approximately 90 percent of the outplantings experience high seedling mortality (Pratt 2007b, in litt.; Van DeMark *et al.* 2010, pp. 24–43).

Pittosporum hawaiiense (hoawa, haawa), a small tree in the pittosporum family (Pittosporaceae), is known only from the island of Hawaii (Wagner *et al.* 1999c, p. 1,044). Historically, *P. hawaiiense* was known from the leeward side of the island, from the Kohala Mountains south to Kau, in the lowland mesic, montane mesic, and montane wet ecosystems (Wagner *et al.* 1999c, p. 1,044). Currently, there are 14 known occurrences totaling fewer than 175 individuals, from HVNP to Puu O Umi NAR, and south Kona, in the lowland mesic, montane mesic, and montane wet ecosystems: 1 occurrence in Puu O Umi NAR (several scattered individuals) (Perlman 1995b, in litt.); 1 occurrence (with a least one individual) in TNC's Kona Hema PR (Oppenheimer *et al.* 1998, in litt.); 1 occurrence with 50 to 100 individuals at Kukuiopae in the South Kona FR (Perlman and Perry 2002, in litt.; Perry 2012, in litt.); 1 occurrence (with a few individuals) in the Manuka NAR (Perry 2011, in litt.); 8 occurrences (totaling fewer than 58 individuals) scattered within the Kahuku unit of HVNP; 1 occurrence in the Olaa FR (at least one individual), just adjacent to the Olaa Tract in HVNP; and 1 occurrence (with fewer than 6 individuals) at the Volcano solid waste transfer station (Wood and Perlman 1991, in litt.; McDaniel 2011a, in litt.; McDaniel 2011b, in litt.; Pratt 2011d, in litt.). Biologists have observed very low regeneration in these occurrences, which is believed to be caused, in part, by rat predation on the seeds (Bio 2011, pers. comm.).

Platydesma remyi (NCN), a shrub or shrubby tree in the rue family (Rutaceae), occurs only on the island of Hawaii (Stone *et al.* 1999, p. 1210; USFWS 2010, pp. 4–66—4–67, A–11, A–74). Historically, *P. remyi* was known from a few scattered individuals on the windward slopes of the Kohala Mountains and several small populations on the windward slopes of Mauna Kea, in the lowland wet and montane wet ecosystems (Stone *et al.* 1999, p. 1210; HBMP 2010i). Currently, *P. remyi* is known from 8 occurrences totaling fewer than 40 individuals, all of which are found in the Laupahoehoe NAR or in closely surrounding areas, in the lowland wet and montane wet ecosystems: Along the banks of Kaiwilahilahi Stream in the Laupahoehoe NAR (unknown number of individuals) (Perlman and Perry 2001, in litt.; Bio 2008, in litt.; HBMP 2010i); near the Spencer Hunter Trail in the Laupahoehoe NAR (fewer than 17 individuals) (PEPP 2010, p. 102); in the central part of the Laupahoehoe NAR (5 to 6 scattered individuals) (HBMP 2010i); near Kilau (1 to 3 individuals) and Pahale (1 to 3 individuals) Streams in Laupahoehoe NAR; in the southeastern region of Laupahoehoe NAR (1 individual); in the Hakalau unit of the Hakalau NWR (1 individual) (USFWS 2010, p. 4–74—4–75); and in the Humuula region of the Hilo FR (2 individuals) (Bruegmann 1998, in litt.; Bio 2008, in litt.; PEPP 2008, p. 107; HBMP 2010i). According to field biologists, this species appears to be declining with no regeneration believed to be caused, in part, by rat predation on the seeds (Bio 2011, pers. comm.). In 2009, 29 individuals of *P. remyi* were outplanted in Laupahoehoe NAR (Bio 2008, in litt.). Their current status is unknown.

Pritchardia lanigera (loulu), a medium-sized tree in the palm family (Arecaceae), is found only on the island of Hawaii (Read and Hodel 1999, p. 1,371; Hodel 2007, pp. 10, 24–25). Historically, *P. lanigera* was known from the Kohala Mountains, Hamakua district, windward slopes of Mauna Kea,

and southern slopes of Mauna Loa, in the lowland mesic, lowland wet, montane wet, and wet cliff ecosystems (Read and Hodel 1999, p. 1,371; HBMP 2010c). Currently, *P. lanigera* is known from 8 occurrences totaling fewer than 230 individuals scattered along the windward side of the Kohala Mountains, Kau FR, and TNC Kau Preserve, in the lowland mesic, lowland wet, montane wet, and wet cliff ecosystems. Approximately 100 to 200 individuals are scattered over 1 sq mi (3 sq km) in Waimanu Valley and surrounding areas (Wood 1995, in litt.; Perlman and Wood 1996, p. 6; Wood 1998, in litt.; Perlman *et al.* 2004, in litt.; HBMP 2010c). There are at least five individuals in the back rim of Alakahi Gulch in Waipio Valley (HBMP 2010c), and five individuals in the Kau FR (Perry 2013, in litt.) According to field biologists, pollination rates appear to be low for this species, and the absence of seedlings and juveniles at known locations suggests that regeneration is not occurring, which they believe to be caused, in part, by beetle, rat, and pig predation on the fruits, seeds, and seedlings (Bio 2011, pers. comm.; Crysdale 2013, pers. comm.).

Schiedea diffusa ssp. *macraei* (NCN), a perennial climbing herb in the pink family (Caryophyllaceae), is reported only from the island of Hawaii (Wagner *et al.* 2005c—*Flowering Plants of the Hawaiian Islands database;* Wagner *et al.* 2005d, p. 106). Historically, *S. diffusa* ssp. *macraei* was known from the Kohala Mountains, the windward slopes of Mauna Loa, and the Olaa Tract of HVNP, in the montane wet ecosystem (Perlman *et al.* 2001, in litt.; Wagner *et al.* 2005d, p. 106; HBMP 2010j). Currently, there is one individual of *S. diffusa* ssp. *macraei* on the slopes of Eke in the Kohala Mountains, in the montane wet ecosystem (Wagner *et al.* 2005d, p. 106; Bio 2011, pers. comm.).

Schiedea hawaiiensis (NCN), a perennial herb or subshrub in the pink family (Caryophyllaceae), is known only from the island of Hawaii (Wagner *et al.* 2005d, pp. 92–96). Historically, *S. hawaiiensis* was known from a single collection by Hillebrand (1888, p. 33) from the Waimea region, in the montane dry ecosystem (Wagner *et al.* 2005d, pp. 92–96). Currently, *S. hawaiiensis* is known from 25 to 40 individuals on the U.S. Army's Pohakuloa Training Area (PTA) in the montane dry ecosystem, in the saddle area between Moana Loa and Mauna Kea (Gon III and Tierney 1996 in Wagner *et al.* 2005d, p. 92; Wagner *et al.* 2005d, p. 92; Evans 2011, in litt.). In addition, there are over 150 individuals outplanted at PTA (Kipuka Alala and Kalawamauna), Puu Huluhulu, Puu Waawaa, and Kipuka Oweowe (Evans 2011, in litt.).

Stenogyne cranwelliae (NCN), a vine in the mint family (Lamiaceae), is known only from the island of Hawaii. Historically, *S. cranwelliae* was known from the Kohala Mountains, in the montane wet and wet cliff ecosystems (Weller and Sakai 1999, p. 837). Currently, there are 6 occurrences of *S. cranwelliae* totaling fewer than 160 individuals in the Kohala Mountains, in the montane wet and wet cliff ecosystems: Roughly 1.5 sq mi (2.5 sq km) around the border between the Puu O Umi NAR and Kohala FR, near streams and bogs (ranging from 3 to 100 scattered individuals) (Perlman and Wood 1996, pp. 1–14; HBMP 2010k); Opaeloa, in the Puu O Umi NAR (3 individuals) (Perlman and Wood 1996, pp. 1–14; HBMP 2010k); Puukapu, in the Puu O Umi NAR (6-by-6-ft (2-by-2-m) ''patch'' of individuals) (HBMP 2010k); the rim of Kawainui Gulch (1 individual) (Perlman and Wood 1996, pp. 1–14; HBMP 2010k); along Kohakohau Stream, in the Puu O Umi NAR (a few individuals) (Perlman and Wood 1996, pp. 1–14; HBMP 2010k); and Waimanu Bog Unit in the Puu O Umi NAR (a ''patch'' of individuals) (Agorastos 2010, in litt.)

Animals

Drosophila digressa (picture-wing fly), a member of the family Drosophilidae, was described in 1968 by Hardy and Kaneshiro and is found only on the island of Hawaii (Hardy and Kaneshiro 1968, pp. 180–1882; Carson 1986, p. 3–9). This species is small, with adults ranging in size from 0.15 to 0.19 in (4.0 to 5.0 mm) in length. Adults are brownish yellow in color and have yellow-colored legs and hyaline (shiny-clear) wings with prominent brown spots. Breeding generally occurs year round, but egg laying and larval development increase following the rainy season as the availability of decaying matter, which picture-wing flies feed on, increases in response to heavy rains. In contrast to most continental Drosophilidae, many endemic Hawaiian species are highly host-plant-specific (Magnacca *et al.* 2008, p. 1). *Drosophila digressa* relies on the decaying stems of *Charpentiera* spp. and *Pisonia* spp. for oviposition (to deposit or lay eggs) and larval substrate (Magnacca *et al.* 2008, pp. 11, 13; Magnacca 2013, in litt.). The larvae complete development in the decaying tissue before dropping to the soil to pupate (Montgomery 1975, pp. 65–103; Spieth 1986, p. 105). Pupae develop into adults in approximately 1 month, and adults sexually mature 1 month later. Adults live for 1 to 2 months. The adult flies are generalist microbivores (microbe eating) and feed upon a variety of decomposing plant material. *Drosophila digressa* occurs in elevations ranging from approximately 2,000 to 4,500 ft (610 to 1,370 m), in the lowland mesic, montane mesic, and montane wet ecosystems (Magnacca 2011a, pers. comm.). Historically, *D. digressa* was known from six sites: Moanuiahea pit crater on Hualalai, Papa in South Kona, Manuka FR, Kipuka 9 along Saddle Road, Bird Park in HVNP, and Olaa FR (Montgomery 1975, p. 98; Magnacca 2006, pers. comm.; HBMP 2010d; Magnacca 2011b, in litt.; Kaneshiro 2013, in litt.). Currently, *D. digressa* is known from only two locations, one population in the Manuka NAR within the Manuka FR, in the lowland mesic and montane mesic ecosystems, and a second population in the Olaa FR in the montane wet ecosystem (Magnacca 2011b, in litt.). The current number of individuals at each of these locations is unknown (Magnacca 2011b, in. litt.).

Vetericaris chaceorum (anchialine pool shrimp) is a member of the family Procarididae, and is considered one of the most primitive shrimp species in the world (Kensley and Williams 1986, pp. 428–429). Currently known from only two locations on the island of Hawaii, *V. chaceorum* is one of seven described species of hypogeal (underground) shrimp found in the Hawaiian Islands that occur in anchialine pools (Brock 2004, p. 6). Relatively large in size for a hypogeal shrimp species, adult *Vetericaris chaceorum* measure approximately 2.0 in (5.0 cm) in total body length, excluding the primary antennae, which are approximately the same length as the adult's body length (Kensley and Williams 1986, p. 419). The species lacks large chelapeds (claws) (Kensley and Williams 1986, p. 426), which are a key diagnostic characteristic of all other known shrimp species. *V. chaceorum* is largely devoid of pigment and lacks eyes, although eyestalks are present (Kensley and Williams 1986, p. 419). Observations of *Vetericaris chaceorum* indicate the species is a strong swimmer and propels its body forward in an upright manner with its appendages held in a basket formation below the body. Forward movement is produced by a rhythmic movement of the thoracic and abdominal appendages, and during capture of some specimens, *V. chaceorum* escape tactics included only forward movement and a notable lack of tail flicking, which would allow backward movement and which is common to other shrimp species

(Kensley and Williams 1986, p. 426). No response was observed when the species was exposed to light (Kensley and Williams 1986, p. 418).

The feeding habits of *Vetericaris chaceorum* were unknown for decades with the only published data from Kensley and Williams (1986, p. 426), who reported that the gut contents of a captured specimen included large quantities of an orange-colored oil and fragments of other crustaceans, indicating that the species may be carnivorous upon its associated anchialine pool shrimp species. Sakihara (2012, in litt.) recently confirmed that *V. chaceorum* is carnivorous after observing *V. chaceorum* collected from Manuaka Natural Area Reserve actively feeding on *Halocaridina rubra* in the laboratory. In general, hypogeal shrimp occur within both the illuminated part of their anchialine pool habitat as well as within the cracks and crevices in the water table below the surface (Brock 2004, p. 6). The relative abundance of some Hawaii species is directly tied to food abundance (Brock 2004, p. 10). The lighted environment of anchialine pools offers refugia of high benthic productivity, resulting in higher population levels for the shrimp compared to the surrounding interstitial spaces often occupied by these species, albeit in lower numbers (Brock 2004, p. 10; Wada 2013, pers. comm.).

Although over 400 of the estimated 520 to 560 anchialine pool habitats have been surveyed on the island of Hawaii, *Vetericaris chaceorum* has only been documented from two locations: Lua o Palahemo, which is a submerged lava tube located on the southernmost point of Hawaii Island in an area known as Ka Lae (South Point) (Kensley and Williams 1986, pp. 417–418; Brock 2004, p. 2; HBMP 2010), and at Manuka, where only recently *V. chaceorum* was discovered in a series of pristine shallow anchialine pool complexes within and adjacent to the NAR, approximately 15 mi (25 km) northwest of Lua o Palahemo (Sakihara 2012, in litt.). The Service has concluded that the lack of detection of this species in the several hundred anchialine pools surveyed on the island of Hawaii since the 1970s suggests this species has a very limited range (Holthius 1973, pp. 1–128 cited in Sakihara 2012, pp. 83, 91, and 93; Maciolek and Brock 1974, pp. 1–73; Maciolek 1983, pp. 606–618; Kensley and Williams 1986, pp. 417–426; Maciolek 1987, pp. 1–23; Chai *et al.* 1989, pp. 1–37; Chan 1995, pp. 1–31; Brock and Kam 1997, pp. 1–109; Bozanic 2004, p. 1; Brock 2004, pp. 1–60; Sakihara 2009, pp. 1–35; Sakihara 2012, pp. 83–95; Wada 2012, pers. comm.; Wada *et al.* 2012, pp. 1–2; Sakihara 2013 in litt.). In total, only five individuals have been observed during one survey period in 1985 at Lua o Palahmo, and a total of seven individuals were observed in four pools during surveys conducted between 2009 and 2010 at Manuka. These two locations are described below.

Lua o Palahemo Site: Age estimates for Lua o Palahemo range from as young as 11,780 years to a maximum of age of 25,000 years, based upon radio carbon data and timing of geophysical climatic events (Kensley and Williams 1986, pp. 417–418). Brock (2004, p. 18) states this lava tube is probably the second most important anchialine pool habitat in the State because of its unique connection to the ocean, the vertical size (i.e., depth), and the presence of a total of five different species including *Halocaridina palahemo, H. rubra, Procaris hawaiiana, Calliasmata pholidota,* and *Vetericaris chaceorum*. Lua o Palahemo is a naturally occurring opening (i.e., a surface collapse) into a large lava tube below. The opening measures approximately 33 ft (10 m) in diameter and is exposed to sunlight. Unlike most anchialine pools in the Hawaiian Islands, which have depths less than 4.9 ft (1.5 m) (Brock 2004, p. 3), Lua o Palahemo's deep pool includes a deep shaft with vertical sides extending downward about 46 ft (14 m) into the lava tube below, which branches in two directions, both ending in blockages (Holthuis 1974, p. 11; Kensley and Williams 1986, p. 418). At the subterranean level at the base of the opening, the lava tube runs generally north and south, extending northward for 282 ft (86 m) and southward for 718 ft (219 m), to a depth of 108 ft (33 m) below sea level (Kensley and Williams 1986, p. 418).

Manuka Site: The anchialine pools at Manuka were first surveyed 1972 (Macioleck and Brock 1972, p. iii); however, this survey primarily covered only the southern extremity of the site. A more thorough survey of the Manuka coastline was conducted between 1989 and 1992 (20 pools along the southern coast of Manuka, which included both diurnal and nocturnal observations (Chan 1995, p. 1). These pools were then diurnally surveyed in 2004 (80 pools along the entire Manuka coastline) (Brock 2004, pp. 1–60), and again between 2008 and 2009 (80 pools along the entire Manuka coastline) (Sakihara 2009, pp. 1–35). The most recent and most comprehensive surveys of Manuka were conducted between 2009 and 2010, when Hawaii State biologists surveyed 81 pools at Manuka both day and night, which resulted in the discovery of *Vetericaris chaceorum* in 4 of the pools surveyed. Three of the pools are within Manuka NAR, and one pool is adjacent to the NAR, on unencumbered State land (collectively referred to as Manuka throughout this final rule) (Sakihara 2013, in litt.). This discovery documents the first observation of this species in almost three decades (Sakihara 2012, in litt.). Visual accounts made by the biologists estimate that *V. chaceorum* is established in four anchialine pools along the southern section of the NAR, approximately 15 mi (25 km) from Lua o Palahemo. A total of seven individuals of this species were observed in four pools around Awili Point and Keawaiki (Sakihara 2012, p. 89; Sakihara 2013, in litt.), although estimates of the total number of individuals are undeterminable due to the cryptic nature of this species (Sakihara 2012, in litt.). Sakihara (2012, in litt.) stated that the anchialine habitat at Manuka is considerably different than that of Lua o Palahemo, and is considered to be one of the most biologically valuable habitats of this type (Sakihara 2012, in litt.; Sakihara 2013, in litt.). The Manuka anchialine pools are characterized by shallow (less than 2 ft (0.5 m)) open pools dispersed throughout barren basaltic terrain. This observation expands the known habitat conditions that support *V. chaceorum* (Sakihara 2012, in litt.). According to Sakihara (2013, in litt.), it appears that three of the Manuka pools (the three pools closest to a jeep road) have a subterranean connection, although this has not been confirmed. Although anchialine pools have been surveyed in the Manuka area in the past (Maciolek and Brock 1974, pp. 1–80; Chan 1995, pp. 1–34; Brock 2004, pp. i–iv; Sakihara 2009, pp. 1–35; Sakihara 2012, pp. 83–95; Sakihara 2013 in litt.), the surveys conducted between 2009 and 2010 were the first to document the presence of *V. chaceorum* in this anchialine pool complex. In 1995, an anchialine pool shrimp matching the description of *V. chaceorum* was observed in at least one pool at Manuka NAR, but its identification was never confirmed (Brock 2004, p. 31; Sakihara 2012, p. 89).

Four surveys have been conducted at Lua o Palahemo (Maciolek and Brock 1974, pp. 1–73; Kensley and Williams 1986, pp. 417–426; Bozanic 2004, p. 1–3; Wada 2012, pers. comm.; Wada *et al.* 2012, pp. 1–2), with five individuals observed during one survey in 1985. Five surveys have been conducted at Manuka (Maciolek and Brock 1974, pp.

1–73; Chan 1995, pp. 1–34; Brock 2004, pp. i–iv, 1–60; Sakihara 2009, pp. 1–35; Sakihara 2012, pp. 83–95; Sakihara 2013 in litt.), with seven individuals observed in four pools between 2009 and 2010. Because of the ability of hypogeal shrimp species to inhabit the interstitial and crevicular spaces in the water table bedrock surrounding anchialine pools, it is very difficult to estimate population size of a given species within a given area (Brock 2004, pp. 10–11). We are unable to estimate the population size of either occurrence of *Vetericaris chaceorum* given this behavior.

Summary of Comments and Recommendations

On October 17, 2012, we published a proposed rule to list 15 Hawaii Island species (13 plants, 1 picture-wing fly, and 1 anchialine pool shrimp) as endangered throughout their ranges, and to designate critical habitat for 3 plant species (77 FR 63928). The comment period for the proposal opened on October 17, 2012, for 60 days, ending on December 17, 2012. We requested that all interested parties submit comments or information concerning the proposed rule. We contacted all appropriate State and Federal agencies, county governments, elected officials, scientific organizations, and other interested parties and invited them to comment. In addition, we published a public notice of the proposed rule on October 20, 2012, in the local Honolulu Star Advertiser, West Hawaii Today, and the Hawaii Tribune Herald newspapers, at the beginning of the comment period. We received four requests for public hearings. On April 30, 2013, we published a document (78 FR 25243) reopening the comment period on the October 17, 2012, proposed rule (77 FR 63928), announcing the availability of our draft economic analysis (DEA) on the proposed critical habitat, and requesting comments on both the proposed rule and the DEA. In addition, in that same document (78 FR 25243; April 30, 2013), we announced a public information meeting and hearing, which was held in Kailua-Kona, Hawaii, on May 15, 2013.

During the comment periods, we received 33 comment letters, including the 11 peer review comment letters, on the proposed listing of 15 species, proposed taxonomic change for 1 endangered plant species, and proposed designation of critical habitat. In this final rule, we address only the comments regarding the proposed listing of 15 species and proposed taxonomic change for 1 plant species. Comments addressing the proposed critical habitat designation will be fully addressed in a separate rulemaking action, and published in the **Federal Register** at a later date.

Two commenters were State of Hawaii agencies ((1) Hawaii Department of Business, Economic Development, and Tourism's Hawaii Housing Finance and Development Corporation, and (2) Hawaii Department of Hawaiian Home Lands); one was a county agency (County of Hawaii Planning Department); two were Federal agencies; and 28 were nongovernmental organizations or individuals. During the May 15, 2013, public hearing, no individuals or organizations made comments on the proposed listing.

All substantive information related to the listing of the 15 species or the taxonomic change for 1 species provided during the comment periods has either been incorporated directly into this final determination or is addressed below. Comments received were grouped into general issues specifically relating to the proposed listing status of the 13 plants, or the picture-wing fly or anchialine pool shrimp, or the proposed taxonomic change for 1 plant species, and are addressed in the following summary and incorporated into the final rule as appropriate.

Peer Review

In accordance with our peer review policy published in the **Federal Register** on July 1, 1994 (59 FR 34270), we solicited expert opinions from 14 knowledgeable individuals with scientific expertise on the Hawaii Island plants, picture-wing fly, and anchialine pool shrimp, and their habitats, including familiarity with the species, the geographic region in which these species occur, and conservation biology principles. We received responses from 11 of these peer reviewers. Nine of these 11 peer reviewers generally supported our methodology and conclusions. One peer reviewer expressed concern regarding the lack of more recent survey data for the anchialine pool shrimp at Manuka, and was unaware of the recent surveys (between 2009 and 2010) conducted by Hawaii State biologists. Another commented that we should proceed with caution due to the lack of biological information regarding the shrimp. Three peer reviewers supported the Service's ecosystem-based approach for organizing the rule and for focusing on the actions needed for species conservation and management, and all 11 reviewers provided information on one or more of the Hawaii Island species, which was incorporated into this final rule (see also Summary of Changes from Proposed Rule). We reviewed all comments received from the peer reviewers for substantive issues and new information regarding the listing of 15 species and taxonomic change for 1 plant species. Peer reviewer comments are addressed in the following summary and incorporated into the final rule as appropriate.

Peer Review Comments on Plants

(1) *Comment:* One peer reviewer recommended that we include inundation by high surf and subsequent erosion, and the nonnative plant *Wedelia* [*Sphagneticola*] *trilobata* (wedelia), as threats to the plant *Bidens hillebrandiana* ssp. *hillebrandiana.*

Our Response: We have incorporated this information, as appropriate, into Summary of Changes from Proposed Rule, Table 3, and in the sections ''Nonnative Plants in the Coastal Ecosystem'' and ''Habitat Destruction and Modification Due to Rockfalls, Treefalls, Landslides, Heavy Rain, Inundation by High Surf, Erosion, and Drought'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range* in this final rule (see below).

(2) *Comment:* One peer reviewer recommended that we include vandalism and trash dumping as threats to the plant *Bidens micrantha* ssp. *ctenophylla,* in the Kaloko Makai area.

Our Response: We are aware that vandalism and trash dumping has occurred in the Kaloko Makai area near the individuals of *Bidens micrantha* ssp. *ctenophylla* in the past, although it has not been recently observed (Ball 2013, pers. comm.). We will continue to monitor this potential threat in that area.

(3) *Comment:* One peer reviewer informed us of an act of vandalism where approximately 150 ft (46 m) of fencing was removed from a fenced exclosure in the Upper Waiakea FR where individuals of the plant *Phyllostegia floribunda* are found. The fencing was repaired later in the same month (November 2012), and the plants appeared to suffer no adverse impacts.

Our Response: We agree that vandalism is a potential threat to all fenced species. However, vandalism is not considered an imminent threat at this time because the frequency at which vandalism occurs and the degree of impact cannot be determined in advance of the incident occurring. We will continue to monitor the area and gather information on this potential threat.

(4) *Comment:* One peer reviewer suggested that we identify the nonnative plant *Paederia foetida* (skunk weed) as a threat to the plant *Cyrtandra*

nanawaleensis because it completely covers and smothers understory vegetation and outcompetes low-growing plants and small shrubs for light and space and that we identify *Psidium cattleianum* (strawberry guava) as a threat to *Cyanea tritomantha* because it forms dense stands in which few other plants can grow, displacing native vegetation through competition.

Our Response: We have included this information in this final rule (see Summary of Changes from Proposed Rule, below).

(5) *Comment:* One peer reviewer supported the listing of the plants *Schiedea diffusa* ssp. *macraei, S. hawaiiensis,* and *Stenogyne cranwelliae* as endangered, and stated that we did a very thorough job of outlining the threats for these three species. In addition, this peer reviewer expressed appreciation for our emphasis on the anticipated effects of climate change in the proposed rule.

Our Response: We appreciate the support from this peer reviewer regarding our threats analysis, and our discussion on the anticipated threats from climate change. All 15 species we are listing in this final rule may be especially vulnerable to the effects of climate change due to their small number of populations and individuals, as well as highly restricted ranges. Environmental changes that may affect these species are expected to include habitat loss or alteration and changes in disturbance regimes (e.g., storms, hurricanes, and drought).

(6) *Comment:* One peer reviewer stated that climate change appears to be having especially serious effects on *Schiedea* species occurring in dry habitats due to death of adult plants, presumably through drought, failure to regenerate due to drought, and increased fire frequency. Drought may have a pronounced effect on *Schiedea hawaiiensis.*

Our Response: We agree that drought is a threat to *Schiedea hawaiiensis,* for the reasons mentioned above (see also ''Habitat Destruction and Modification by Fire'' and ''Habitat Destruction and Modification Due to Rockfalls, Treefalls, Landslides, Heavy Rain, Inundation by High Surf, Erosion, and Drought'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* below).

(7) *Comment:* One peer reviewer stated that *Schiedea diffusa* ssp. *macraei* and *S. hawaiiensis* are obligate autogamous species (i.e., reproduces by self-pollination) and facultative autogamous (i.e., reproduces by self- and cross-pollination), respectively. Because both of these species are hermaphroditic and autogamous, they are capable of regenerating from single individuals, and may not be severely hampered by inbreeding depression. Unfortunately, autogamous species of *Schiedea* also appear to be short-lived, emphasizing the importance of appropriate conditions for regeneration.

Our Response: We agree that the obligate and facultative autogamous nature of *Schiedea diffusa* ssp. *macraei* and *S. hawaiiensis,* respectively, in addition to being hermaphroditic, afford these species the ability to regenerate from single individuals and may not be severely hampered by inbreeding depression. However, there are other negative impacts that can result from low number of individuals (e.g., random demographic fluctuations; climate change effects; and localized catastrophes, such as hurricanes, drought, rockfalls, landslides, and disease outbreaks (Pimm *et al.* 1988, p. 757; Mangel and Tier 1994, p. 607). Any of these stressors represent threats that can lessen the chances of survival for these species in the wild. We agree that the short-lived nature of these species increases the importance for appropriate conditions for regeneration, and have added this information to our files.

(8) *Comment:* One peer reviewer pointed out that it was incorrect to state, in our proposed rule (77 FR 63928; October 17, 2012) on page 63931, that *Mezoneuron* was listed in error as *Caesalpinia kavaiense* in 50 CFR 17.12, because at the time of the listing (51 FR 24672; July 8, 1986), this was the accepted name applied to the taxon. The peer reviewer stated that it is important to emphasize that names of taxa typically may change during the course of standard taxonomic investigations, and these changes do not affect the validity of conservation concerns for the taxon in question.

Our Response: We wish to clarify the error described in the October 17, 2012 (77 FR 63928), proposed rule regarding *Mezoneuron kavaiense.* The error described in the proposed rule refers to the entry in the 1989 List of Endangered and Threatened Plants (50 CFR 17.12), where this taxon was revised and the specific epithet was misspelled as *Caesalpinia kavaiense* (instead of *Caesalpinia kavaiensis*). Subsequent taxonomic revision resulted in the currently recognized scientific name for the listed entity, *Mezoneuron kavaiense,* which we accept in this final rule.

(9) *Comment:* One peer reviewer pointed out that under our description of the lowland dry ecosystem, we incorrectly wrote ''high rates of diversity and endemism'' when technically it should read ''high levels of diversity and endemism,'' as rate is a process occurring over time.

Our Response: We agree with the peer reviewer.

Peer Review Comments on the Picture-Wing Fly

(10) *Comment:* One peer reviewer provided additional information regarding the host plants for *Drosophila digressa.* Although *D. digressa* has only been reared from *Charpentiera* spp., at Manuka, *D. digressa* was found in a *Pisonia sandwicensis* treefall with a considerable number of rotten branches. A large number of individuals of *D. digressa* were found in a small area, indicating a local breeding group rather than vagrant individuals. The only *Charpentiera* spp. in this area are a few trees in a pit crater, over 0.62 mi (1 km) from the known location of *D. digressa* on *Pisonia sandwicensis.* This reviewer further stated that many native *Drosophila* species that breed in either *Charpentiera* spp. or *Pisonia* spp. are also able to use both plants. According to the reviewer, while this ability of *D. digressa* to use both tree species as host plants expands its potential habitat slightly, it does not do so by a great deal, as *Pisonia sandwicensis* and *P. brunoniana* [two of the three species of *Pisonia* on Hawaii Island] are only found on Hawaii Island at the sites where *D. digressa* is already known (Olaa and Manuka), or where the forest is currently too open and dry to support this species of picture-wing fly (Kipuka Pualulu and Puu Waawaa cone). *Pisonia umbellifera* can be found at lower elevations on the windward side of the island, such as gulches on the east slopes of Kohala and Mauna Kea below 1,500 ft (457) m, but *D. digressa* has never been recorded from these areas or elevation. Species of *Pisonia* face most of the same threats as species of *Charpentiera* (i.e., goat and cattle browsing of leaves and seedlings, pig rooting of seedlings, and desiccation of habitat from drought and subsequent fires at Manuka). The reviewer concludes that even if *Pisonia* spp. at Manuka survive the [ongoing] drought, the habitat will likely be too dry to support *D. digressa.*

Our Response: We appreciate this information regarding *Drosophila digressa* and have incorporated this new information, as appropriate, in this final rule (see above, Description of the 15 Species; see below, Summary of Changes from Proposed Rule, ''Habitat Destruction and Modification by Introduced Ungulates'' (*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range*), ''Predation and Herbivory''

(*Factor C. Disease or Predation*), and ''Loss of Host Plants'' (*Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence*)).

(11) *Comment:* One peer reviewer stated that the drought-associated ohia [*Metrosideros polymorpha*] dieback occurring at Manuka adversely affects *Drosophila digressa* by allowing more sunlight into the understory, increasing the temperature and lowering humidity. This increases the stress on the picture-wing flies and their host plants, as well as increasing opportunities for invasive plants to become established. The extraordinary amount of dead wood accumulation at Manuka means that any fire that occurs there likely would be extremely damaging. A fire resulting from a similar scenario at Kealakekua Ranch a year or two ago produced smoke that covered most of the island and burned for weeks because it is nearly impossible to fight fire in such dense brush.

Our Response: We appreciate the additional information provided regarding the drought-associated ohia dieback at Manuka and *Drosophila digressa,* and we have included this new information in our final rule, as appropriate, in ''Habitat Destruction and Modification Due to Rockfalls, Treefalls, Landslides, Heavy Rain, Inundation by High Surf, Erosion, and Drought'' (*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range*) in this final rule (see below).

Peer Review Comments on the Anchialine Pool Shrimp

(12) *Comment:* One peer reviewer commented that the field surveys cited in our proposed rule are not adequate, and that more surveys should be conducted at other sites such as Manuka, Hawaii. The peer reviewer also recommended that the analysis of listing *Vetericaris chaceorum* as endangered should be based on the number of field surveys conducted, the number of pools surveyed, the number of locations surveyed, trapping surveys, day and night surveys, and seasonal surveys.

Our Response: We are required to make listing determinations solely on the basis of the best scientific and commercial data available, and, for the reasons described here, we have concluded that the number and locations of surveys are adequate to determine that *Vetericaris chaceorum* appears to be restricted to a limited number of pools in the southern portion of the island of Hawaii, and that *V. chaceorum* faces threats from habitat degradation and destruction and from predation such that it is in danger of extinction throughout its range. There are between 600 and 700 anchialine pools in the Hawaiian Islands and approximately 80 percent (approximately 520 to 560) occur on Hawaii Island. Over 400 pools have been surveyed on Hawaii Island alone since the 1970s, and *V. chaceorum* has only been documented from two locations: Lua o Palahemo and Manuka, where *V. chaceorum* was recently (between 2009 and 2010) discovered in a series of pristine shallow anchialine pool complexes within and adjacent to Manuka NAR (Holthius 1973, pp. 1–128 cited in Sakihara 2012, pp. 83, 91, and 93; Maciolek and Brock 1974, pp. 1–73; Maciolek 1983, pp. 606–618; Maciolek 1987, pp. 1–23; Chai *et al.* 1989, pp. 1–37; Chan 1995, pp. 1–31; Brock and Kam 1997, pp. 1–109; Brock 2004, pp. 1–60; Sakihara 2009, pp. 1–35; Sakihara 2012, pp. 83–95; Wada *et al.* 2012, pp. 1–2). This reviewer was apparently unaware that Hawaii State biologists conducted surveys at Manuka between 2008 and 2009, and again between 2009 and 2010 (Sakihara 2009, pp. 1–35; Sakihara 2012, pp. 83–95). Several other peer reviewers stated that the Service used the best available scientific and commercial data to document the presence or absence of *V. chaceorum* in anchialine pools around Hawaii Island.

Under the Act, we determine whether a species is an endangered species or a threatened species because of any of five factors (see Summary of Factors Affecting the 15 Species, below), and we are required to make listing determinations solely on the basis of the best scientific and commercial data available, pursuant to section 4(b)(1)(A) of the Act. Based on the best available information we determined that *V. chaceorum* faces threats from habitat destruction and modification by feral goats and cattle at Lua o Palahemo; dumping of trash and introduction of nonnative fish at Lua o Palahemo; and introduction of nonnative fish at the pools at Manuka (see Summary of Factors Affecting the 15 Species, below).

(13) *Comment:* One peer reviewer questioned the importance of flushing to the functioning of the anchialine pool ecosystem and its relationship to the effects of excessive siltation and sedimentation on the population of *Vetericaris chaceorum* and its associated species and the anchialine pool ecosystem at Lua o Palahemo. The commenter referenced the occurrence of large numbers of individuals of *Halocaridina rubra, Procaris hawaiiana,* and *V. chaceorum* during the 1985 survey (Kensley and Williams 1985, pp. 417–426) despite a reduction in visibility (few centimeters) as a result of the disturbance of ceiling sediments caused by exhalation bubbles during an exit phase of a dive. The commenter also stated that ''there is no reason to discount the opposite idea that increased flushing has mobilized the sediment, allowed the movement of native predators and competitors into the system, and resulted in the decline or perhaps extirpation of *Vetericaris.''* The commenter then suggested that the thick sediment cone just below the opening was not a problem for the dense populations of native species detected directly beneath the surface of the pool during the 1985 surveys.

Our Response: We acknowledge the peer reviewer's statement that *Vetericaris chaceorum* and other native species may be able to coexist with a certain level sedimentation in the anchialine pool ecosystem at Lua o Palahemo. However, the water clarity has declined since earlier surveys (Kensley and Williams 1986, pp. 417–437; Bozanic 2004, pp. 1–3; Wada 2010, in litt.; Wada et al. 2012, in litt.; Wada 2012, pers. comm.; Wada 2013, in litt.), which took place in the 1970s and 1980s, despite the presence of silt in the system at that time. Further, we disagree that the reduced visibility created by a diver's exhalation bubbles or similar human-initiated disturbance during those early surveys is comparable to the low visibility levels apparent in recent surveys before surveyors even enter the water. Flushing is necessary for the successful functioning of an anchialine pool ecosystem (Brock 2004, pp. 11, 35–36). We have concluded that continued excessive siltation into and additional collapse of the lava tube system at Lua o Palahemo is causing degradation of the anchialine pool ecosystem. These factors, combined with the system's diminished ability to flush, have resulted in the degradation of water quality, which has also led to the drastic decline in two of the other hypogeal shrimp species within the pool (i.e., *Procaris hawaiiana* numbered in the thousands, and *Halocaridina* numbered in the tens of thousands (Kensley and Williams 1986, p. 418), and the most recent survey counted 7 *Procaris hawaiiana* and zero *Halocaridina* (Wada *et al.* 2012, in litt.; Wada 2013, pers. comm.)). These shrimp are considered food sources for *V. chaceorum,* and their decline may affect the survival of *V. chaceorum.*

(14) *Comment:* One peer reviewer requested that the discussion of Lua o Palahemo clarify land ownership and the attitude of the landowner toward the anchialine pool and its fauna.

Our Response: Lua o Palahemo is located on land owned by the State of

Hawaii Department of Hawaiian Homelands (DHHL). We hope to work with DHHL to address the threats to *Vetericaris chaceorum* and the anchialine pool ecosystem at Lua o Palahemo from ungulates, recreational vehicles, dumping of trash, the intentional introduction of nonnative fish, and sedimentation, as identified in this final rule.

(15) *Comment:* One peer reviewer suggested that additional data on phylogenetic or biogeographical relationships on the ancestor(s) to *Vetericaris chaceorum* could have very important implications about the spatial extent of potential habitat, specific features of the habitat that may be critical to the species, and other possible sites where the species may occur. However, the peer reviewer also stated that this information is not currently available.

Our Response: We agree that such information would provide additional insights on the species' distribution and range, as well as the physical and biological habitat features required for the conservation of *Vetericaris chaceorum.* However, as the peer reviewer noted, such information is not currently available. The documented observation of *V. chaceorum* less than 19 mi (25 km) from Lua o Palahemo in the shallow water pools at Manuka, Hawaii, may be explained by Maciolek's (1983, p. 615) hypothesis that habitats may be colonized from long-existing subterranean populations.

(16) *Comment:* One peer reviewer suggested that we add nonnative plants (e.g., *Prosopis pallida* (kiawe)) as a threat to the anchialine pool shrimp *Vetericaris chaceorum,* as any nonnative canopy or peripheral vegetation may result in changes in anchialine habitat conditions such as increased senescence, changes in water quality, and potential increases in nutrient availability that may alter primary production and the community structure of the algae. This peer reviewer further stated that these impacts may primarily affect the predominant endemic faunal species *Halocaridina rubra,* which is considered to be a key species in maintaining the ecological integrity of the anchialine pools, and that this may ultimately lead to an overall degradation of the anchialine pool ecosystem, and therefore impact *V. chaceorum.* However, this peer reviewer also noted that both Lua o Palahemo and Manuka are either very sparse or entirely free of peripheral vegetation, but that this does not preclude the possibility of *P. pallida* or any other type of nonnative vegetation from establishing itself within these areas.

Our Response: The Act and our regulations direct us to consider the ''present'' or ''threatened'' destruction, modification, or curtailment of the species' habitat or range. At this time, there are insufficient data to determine the impacts on *Vetericaris chaceorum* from nonnative plants such as *Prosopis pallida.* Therefore, we cannot address nonnative plants as threats to *V. chaceorum* (i.e., we cannot identify a future condition that may or may not occur as a threat) in this final rule. We will consider the need to address nonnative plants in our future recovery planning efforts for this species, should new information become available indicating nonnative plants are a threat to *V. chaceorum* at Lua o Palahemo or Manuka.

(17) *Comment:* Two peer reviewers suggested that we add native marine fish species (e.g., aholehole (*Kuhlia* sp.) or papio (*Caranx* sp.)) not normally found in anchialine pools as a threat to *Vetericaris chaceorum,* from either natural events (e.g., high surf and storm surges) or deliberate introduction by people to the Lua o Palahemo anchialine pool ecosystem. According to these reviewers, the introduction of native marine fish in anchialine pools could result in the same deleterious impacts to *V. chaceorum* and its pool habitat as the intentional introduction of nonnative fish (see ''Dumping of Trash and Introduction of Nonnative Fish'' under *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence,* below). One peer reviewer later suggested that it was possible, although unlikely, that native marine fish would be intentionally introduced to the four pools at Manuka.

Our Response: We agree that the introduction of native marine species, normally isolated from the anchialine pool environment, into the anchialine pool at Lua o Palahemo that supports *Vetericaris chaceorum* may be possible. For the reasons described below, we believe it is unlikely that natural events such as high surf and storm surges will introduce native marine fish to either location (Lua o Palahemo or Manuka) of *V. chaceorum,* although one peer reviewer suggested that the 2005 earthquake on Hawaii Island may have reopened or improved the connection between the ocean and Lua o Palahemo, thus allowing natural recruitment of native marine fish into and out of the pool (Kinzie 2012, in litt.). The intentional introduction of native marine fish is possible at its two known locations.

Nonnative fish have been intentionally introduced to Lua o Palahemo in the past (see ''Dumping of Trash and Introduction of Nonnative Fish'' under *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence,* below), and it is not unreasonable to assume that native marine fish may be deliberately introduced to the pool. In our 2012 snorkel survey of this pool, we observed a tropical marine goby in the pool (Wada *et al.* 2012, in litt.). However, it is unclear how this fish gained access to the pool. The accidental introduction or natural recruitment of native marine fish due to natural events such as storm surge and high surf is unlikely at Lua o Palahemo due to its elevation above the coast (approximately 25 ft (8 m)) and its distance from the coast (490 ft (150 m)) (Kensley and Williams 1986, p. 418). Although a massive landslide or earthquake may trigger a local tsunami that generates waves that may sweep over and deposit native marine fish in the pool, these events are purely speculative.

The intentional introduction of native marine fish is possible at the Manuka pools that support *V. chaceorum* because there is evidence that at least one pool in this area harbors nonnative freshwater poeciliids (see Factors Affecting the 15 Species, below) and marine fish, likely introduced by fishermen. This pool is located near a popular coastal fishing spot. Three of the four pools that support *V. chaceorum* at Manuka are located between 10 and 33 ft (3 and 10 m) from a jeep road that provides access to coastal fishing and recreational locations frequented by the public (Sakihara 2013, in litt.). The fourth pool is approximately 60 ft (18 m) from the jeep road (Sakihara 2013, in litt.). However, the accidental introduction or natural recruitment of native marine fish, due to natural events such as storm surge and high surf, is unlikely at the four pools that support *V. chaceorum* at Manuka because these pools are located at least 98 ft (30 m) from the coast (Sakihara 2013, in litt.), and storm surge and high surf that would cover this distance is improbable. Although a massive landslide or earthquake may trigger a tsunami that generates waves that may sweep over and deposit native marine fish in the pools, these events are purely speculative.

On Maui, both aholehole and papio have been found in the larger anchialine pools closest to the ocean at Ahihi Kinau NAR, where high surf and storm waves appear to wash those and other native marine fish into the pools (Wada 2013, in litt.). However, these pools are

subject to coastal influences due to natural events such as storm surge and high surf due to their proximity to the ocean. We are unaware of any data documenting the impacts of native marine fish that may be swept into the pools at Ahihi Kinau NAR on native anchialine pool shrimp.

Native marine fish species have a purely marine (pelagic) larval stage, so a population of native fishes in an anchialine pool is likely to be individuals that are introduced to pools post larvae-stage (Sakihara 2013, in litt.). According to Brock (2004, p. 9), native marine fish are typically found in pools in close proximity to the ocean and it is believed that the biological status of these pools changes with successful colonization or mortality of marine fishes in these pools. The presence of native fish in Hawaiian anchialine pools usually signals the lack of hypogeal shrimp (Brock 2004, p. 9). Brock (2004, p. 29) also states that native marine fish are not able to complete their life cycles in anchialine pools, so the impacts to hypogeal shrimp are temporary (i.e., only as long as the fish occupy the pool) and that hypogeal shrimp may successfully hide in crevices from predatory fish and thus possibly recolonize a pool after the fish die off. Therefore, although *V. chaceorum* is a hypogeal shrimp and three species upon which it is known to feed in Lua o Palahemo are hypogeal shrimp, we are unable to determine the impact of marine fish on *V. chaceorum* at this time.

(18) *Comment:* Two peer reviewers mentioned the presence of aggressive biting isopods and an eel at Lua o Palahemo, and the possibility of the eel, specifically, as a predator of *Vetericaris chaceorum.*

Our Response: We are aware that eels have been seen periodically in other anchialine pools, including pools at Manuka NAR on Hawaii Island and Ahihi Kinau on Maui. At this time, however, there are insufficient data to determine the impacts on *Vetericaris chaceorum* from biting isopods and an unidentified eel at Lua o Palahemo. Therefore, we are unable to address these animals as threats to *V. chaceorum* in this final rule. We will consider the need to address biting isopods and eels in our future recovery planning efforts for this species, should new information become available indicating these animals are threats to *V. chaceorum.*

(19) *Comment:* Two peer reviewers suggested that earthquakes and subsequent landslides and rockfalls are threats to *Vetericaris chaceorum,* due to destruction or degradation of its pool habitat. This peer reviewer believes that given a large enough earthquake, the Lua o Palahemo anchialine pool could potentially lose its connection to the ocean by boulder ''chokes'' that block off movement of ocean water to and from the pool, or by a complete or partial collapse of the tube itself. This peer reviewer then added that we would need an engineer to make a more definitive assessment regarding the pool's vulnerability to collapse.

Our Response: We agree that earthquakes and subsequent landslides and rockfalls are potential threats to *Vetericaris chaceorum* and its habitat. We also agree that an engineer or other professional with the necessary skills is needed to assess the vulnerability of the lava tubes within the Lua o Palahemo anchialine pool to the threat of earthquakes. We do not have enough data to include earthquakes as a threat at this time.

(20) *Comment:* Two peer reviewers commented that our analysis of the threats to *Vetericaris chaceorum* seemed too focused on the surface of the anchialine pool rather than on the depths within Lua o Palahemo (where *V. chaceorum* is reported to occur). One of the peer reviewers questioned the relevance of threats at the opening when the species is so far below the surface, while the other peer reviewer stated that any impacts at the surface of the pool may lead to degradation of the habitat within the recesses of the lava tube by causing shifts in water quality, physical conditions, and flushing, and therefore causing shifts in biological characteristics (i.e., benthic algae and primary consumer abundance and assemblage). As such, these threats may extend beyond the immediately impacted areas at Lua o Palahemo.

Our Response: Based on the best scientific and commercial data available, we believe *Vetericaris chaceorum* faces threats from habitat loss or degradation from sedimentation in Lua o Palahemo due to degradation of the immediate area surrounding the pool. Feral goats and cattle trample and forage on both native and nonnative plants around and near the pool opening (Magnacca 2012, in litt.; Richardson 2012, in litt.), increasing erosion resulting in sediment entering the pool (see ''Habitat Destruction and Modification by Introduced Ungulates'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* below). In addition, *V. chaceorum* faces threats from the intentional dumping of trash (at Lua o Palahemo) and introduction of nonnative fish (at Lua o Palahemo and Manuka NAR), activities which originate at the pool openings and result in impacts to *V. chaceorum* (within the deep recesses of Lua o Palahemo and within the shallower pools at Manuka NAR) (see ''Dumping of Trash and Introduction of Nonnative Fish'' under *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence,* below).

(21) *Comment:* One peer reviewer commented that the proposed rule presents a good summary of potential threats to the shrimp and its habitat, and it clearly makes the point that the population at Lua o Palahemo is exceedingly small and probably declining, if not extinct.

Our Response: We appreciate this reviewer's concurrence and have considered that the shrimp may no longer be extant at Lua o Palahemo; however, since anchialine pool shrimp are known to spend much of their time within the crevices of pools, we believe the species may still be present in the pool, but in very low numbers.

(22) *Comment:* One peer reviewer commented that they had observed items that humans dumped into Lua o Palahemo, including a bicycle, boom box, and large cement block, but that they were uncertain whether or not these items had a deleterious or observable effect on *V. chaceorum.*

Our Response: The impact of human dumping of trash into an anchialine pool is directly related to the proportion between the size of the pool and the amount and type of trash dumped. For example, a large trash bag in a small, shallow anchialine pool will negatively impact habitat quality, whereas the negative effect from same trash bag in a larger, deeper anchialine pool will not reach the same magnitude of effect. In addition, if the boom box had decaying batteries in it, contaminants such as lead, mercury and cadmium could have leached into the pool (Center for Disease Control—Agency for Toxic Substances and Disease Registry (CDC–ATSDR) 2011—*Toxic Substance Database*). In addition, there is risk from exposure to general electronic waste contaminants, which contain various hazardous materials and are harmful to the environment (e.g., polyvinyl chloride, polychlorinated biphenyls, and chromium) (CDC–ATSDR 2011—*Toxic Substance Database*). These toxins produce varying effects on biological organisms that include, but are not limited to, deoxyribose nucleic acid (DNA) damage, mucous membrane damage, cancer, and organ failure (CDC–ATSDR 2011—*Toxic Substance Database*).

(23) *Comment:* Five peer reviewers commented on the likelihood of

whether or not *Vetericaris chaceorum* has a niched habitat deep within the darkness of the lava tube at Lua o Palahemo where it was observed in 1985, or whether it has a broader habitat that extends throughout the matrix of the lava tube of Lua o Palahemo. The first of these peer reviewers commented that, due to insufficient data and the challenging conditions of assessing the particular habitat(s) of Lua o Palahemo, it would be difficult to determine whether this species would likely occur throughout Lua o Palahemo or only be limited to the area where it was originally collected from within the lava tube. The second peer reviewer commented that literature suggested that *Vetericaris chaceorum* did not have a uniform distribution throughout Lua o Palahemo when it was first observed and collected, so that would suggest that it does have a limited niche and that it is highly likely that it would be still limited to the area where it was originally collected within the lava tube. The third of these peer reviewers commented that it has been confirmed that the range of *Vetericaris chaceorum* extends beyond Lua o Palahemo, although only approximately 25 km away. Therefore, it is plausible that its distribution within Lua o Palahemo also extends beyond where it was originally collected. Furthermore, the habitat in which *Vetericaris chaceorum* was found at Manuka is considerably different than that of Lua o Palahemo, which was characterized by shallow (less than 0.5 m deep), open pools dispersed throughout barren basaltic terrain. Accordingly, its range does not seem to be limited to the deep recesses of the anchialine habitat, but may also roam freely throughout shallow exposed areas. The fourth peer reviewer commented that *Vetericaris chaceorum* likely has a wider lateral distribution in the Lua o Palahemo lava tube and that it is likely found in adjacent hypogeal habitat. The fourth peer reviewer also commented that it is unclear if *Vetericaris chaceorum* venture into the lighted, mixohaline portion of Lua o Palahemo. The fifth peer reviewer commented that there is no reason to believe that the shrimp's range did not extend, at least, to the ends of that lava tube, and possibly into other openings connecting to it. As the boundaries of Lua o Palahemo were not defined in the proposed rule, an answer to the question about ''throughout Lua o Palahemo'' is not clear.

Our Response: We agree and are aware that it is difficult to know exactly where this species occurs within Lua o Palahemo, and whether or not it favors the depth at which it was observed or if it utilizes the greater part of the lava tube. The newly discovered occurrence in the shallow pools at Manuka suggests that the habitat is not limited to the area it was originally collected from deep within the lava tube at Lua o Palahemo, and that it is likely *Vetericaris chaceorum* occupies areas along the matrices of Lua o Palahemo at varying depths. Because hypogeal shrimp often spend much of their time in crevices, and it is possible that *V. chaceorum* can occur throughout the lava tube, we retain the status of extant for the population of *V. chaceorum* at this location, despite the fact that *V. chaceorum* was not observed in recent surveys. Regarding the boundaries of Lua o Palahemo, we do not currently have any data that lay out the entire matrix of the lava tube, nor are we aware that such data exist.

(24) *Comment:* Three peer reviewers commented that the threats to the habitat of Lua o Palahemo expand throughout the entire lava tube matrix. One of these three peer reviewers also said that the historical differences documented for Lua o Palahemo, primarily in water clarity and quality, and the absence of other shrimp species that were common (such as *Halocaridina*) suggests the habitat has undergone serious degradation in the last 30 to 40 years that is likely to get worse if actions are not taken.

Our Response: We agree that the threats to the species' habitat at Lua o Palahemo are not limited to any particular area and span the scope of the entire lava tube matrix. We also agree that more surveys and monitoring efforts are needed to determine how best to recover this habitat. The Service has conducted surveys in 2010 and 2012 (Wada 2012, pers. comm.; Wada et al. 2012, in litt.), and will continue to monitor and research this habitat in the future, in addition to conservation methodologies to recover *Vetericaris chaceorum* at this site.

(25) *Comment:* One peer reviewer commented that it is unclear that the best available scientific data and methodologies currently available can determine rarity vs. human accessibility to the *Vetericaris chaceorum.* This commenter also stated that a dark-adapted organism could potentially be found anywhere within the hypogeal environment of the Hawaiian Islands, and that the Service may be drawing its listing conclusion of this species based on lack of biological knowledge. In addition, this reviewer commented that the lack of information may not enable practical management decisions.

Our Response: We agree that it is difficult to determine the entire range that is occupied by *Vetericaris chaceorum* on Hawaii Island or elsewhere in the Hawaiian Islands. We have based our determination on the number of estimated pools throughout the Hawaiian Islands and the percentage of these pools that have been surveyed. Despite surveys throughout the islands, *Vetericaris chaceorum* has only been observed in two pool complexes on Hawaii Island: Lua o Palahemo and Manuka. In addition, the fact that these two habitats are so different informs us that *Vetericaris chaceorum* is not solely a dark-adapted organism, but that it is has a range of suitable habitat that also includes shallow pools in full sunlight. This increase in suitable habitat types, the number of surveys throughout the Hawaiian Islands, and the fact that in total only 12 shrimp (5 at Lua o Palahemo and 7 at Manuka) have ever been observed suggest that *Vetericaris chaceorum* is not occurring in high numbers. We do not currently have methodologies that afford us the opportunity to search cracks and crevices within the anchialine pool environment; however, if this type of survey technology equipment becomes available, it will certainly enhance our understanding of the population dynamics of hypogeal shrimp, including *Vetericaris chaceorum.* The Service agrees that additional information will benefit management decisions.

(26) *Comment:* Two peer reviewers commented on the connection of Lua o Palahemo to the marine environment. One of these reviewers commented that the further collapse of the lava tube and increased siltation may have the effect of decreasing the slight flow of colder water into the depth of the lava tube, and that the further collapse may actually have a beneficial effect, such as isolation from human access. The second peer reviewer commented that the lava tube may be connected to a deep water marine habitat and associated fauna.

Our Response: Kensley and Williams (1986, p. 435) state that it is probable that neither temperature nor salinity imposes a barrier to the dispersal of hypogeal shrimp. They reported a surface temperature of 24 degrees Celsius, but they did not report the temperature at the depth they observed *Vetericaris chaceorum* (Kensley and Williams 1986, p. 418). During the surveys conducted by the Service in 2012, the temperature of the water at a depth of 7.5 m from the surface ranged from 23.8 degrees Celsius at noon to 26.4 Celsius at 4:50 a.m. (Wada *et al.* 2012, in litt.). The data suggest

temperature is not currently a determining factor in the presence or absence of *Vetericaris chaceorum* at Lua o Palahemo.

The definition of an anchialine pool includes being tidally influenced due to a subterranean connection to the ocean, so we agree that the lava tube is connected to a marine habitat and fauna, although to what extent and what depth is not known at this time. The size (i.e., a smaller cracks versus a wide diameter lava tube) of the connection to the marine environment will determine to some extent the species present in a given anchialine pool; the better the connection to the sea, the more likely a pool will have marine organisms (Brock 2004, p. 9). For example, the unusual ecotypic variant of the moray eel (*Gymnothorax pictus,* puhi) is often found in pools with better connections to the sea (Brock 2004, p. 9). Regarding relationship between a further collapse of the lava tube and human access, we have no data to support or deny a benefit from limiting human access to the depths of Lua o Palahemo.

(27) *Comment:* One peer reviewer commented that since so little is known about *Vetericaris chaceorum,* most considerations of threats are conjectural, and that because no apparent observations have been made of this species in the upper reaches of Lua o Palahemo, purported threats to other anchialine species may not be a limiting factor or relevant to life in the lightless marine environment.

Our Response: As described earlier, *Vetericaris chaceorum* was initially discovered in 1985, in complete darkness within one of the lava tubes at Lua o Palahemo, at a location 180 m (590 ft) from the opening, at a depth of 30 m (98 ft). We agree that there is still much to be learned about *V. chaceorum's* life history and biology. It was recently confirmed that the species is not confined to the dark depths of Lua o Palahemo. In addition, Sakihara (2013, in litt.) observed *V. chaceorum* feeding on other anchialine pool shrimp species. Considering the new information, threats to other anchialine pool shrimp at varying depths are directly relevant to the survival of *V. chaceorum.* If the food supply of *V. chaceorum* is declining or diminished, it will have a direct impact on the health and survival of *V. chaceorum.* Further, the threats of dumping nonnative fish and trash can directly negatively impact the ecosystem at either Lua o Palahemo or Manuka; this is confirmed by observations at other anchialine pools around the Hawaiian Islands where nonnative fish and trash have caused the degradation of pools (Brock 2004, pp. 12–15).

(28) *Comment:* One peer reviewer questioned the value of comparing *Vetericaris chaceorum* with the anchialine pool shrimp *Halocaridina rubra.* This peer reviewer commented that *Vetericaris chaceorum* is likely much more specialized and that its lack of eyes, limited swimming option, and, as far as is known, very limited distribution makes comparisons between the two species uninformative for the most part. This peer reviewer further stated that the observations on the behavior of *V. chaceorum* suggests it may prey on smaller organisms by capturing them in the basket formed by its pereiopods as it swims in the dark; if this is true, the species would require large volumes of open water. The reviewer further elaborates that Kensley and Williams (1986) note the species is a strong swimmer and apparently stays in midwater, avoiding the solid walls, consistent with the filter-basket feeding hypothesis. If true, this makes this species somewhat different from other anchialine shrimp, which are generally associated with the substratum, although Maciolek observed *H. rubra* feeding in midwater ''presumably grazing only on phytoplankton.'' Similarly *V. chaceorum* does not appear to be very similar to the more well-studied anchialine shrimp. Its troglobitic (more correctly stygobitic) habit, large size, possibly its specialized trophic role and potentially unique evolutionary history should make comparisons with other anchialine shrimp suspect.

Our Response: We appreciate this reviewer's comments regarding the value of comparing *Vetericaris chaceorum* and *Halocaridina rubra.* We agree that these two shrimp are not exactly the same; however, *H. rubra* is the most well-studied anchialine pool shrimp in the Hawaiian Islands, and, therefore, we used it as a surrogate species in some examples for *V. chaceorum* in regards to the negative impacts associated with human dumping of nonnative fish and trash, in addition to recognizing it as a potential food source for *V. chaceorum.* The newly discovered population of *V. chaceorum* in the four shallow pools at Manuka has broadened our understanding of the range and habitat for this species, debunking the thoughts that this species is niched to the dark depths of Lua o Palahemo. Further, this challenges the above hypothesis that this species may require large volumes of open water. As stated in the comments above, we have much to learn about *V. chaceorum,* and we base our action in this rule on the fact that the habitat is threatened by sedimentation, recreational off-road vehicles, human dumping of nonnative fish, and human dumping of trash.

(29) *Comment:* One peer reviewer commented that poeciliids are not only introduced illegally in Hawaii, State agencies introduce mosquito fish to freshwater and anchialine habitats as mosquito control. While perhaps legal, the effects are just as detrimental. However, the peer reviewer did not think that mosquito control is a concern for a site like Lua o Palahemo.

Our Response: We agree that mosquito control is not a concern at Lua o Palahemo, and we have no information that would indicate that State agencies are introducing nonnative fish at Manuka for mosquito control.

(30) *Comment:* The proposed rule states that reduced flushing in the pool portion of Lua o Palahemo may allow an accumulation of sediment and detritus in the pool, reducing food productivity and the ability of *Vetericaris chaceorum* to move between the pool and water table. One peer reviewer commented there is no reason to discount the opposite idea that increased flushing has mobilized the sediment, allowed the movement of native predators and competitors into the system, and resulted in the decline or perhaps extirpation of *V. chaceorum.* In support of this is the statement in the October 17, 2012, proposed rule at 77 FR 63939: ''During those dives, researchers made five observations of *Vetericaris chaceorum* in total darkness at a depth of 108 ft (33 m) and 590 ft (180 m) from the opening, collecting two specimens. Kensley and Williams (1986, p. 418) noted, however, that the area surveyed directly beneath the surface of the pool contained the highest density of animals (e.g., shrimps and crustaceans).'' This suggests the very thick sediment cone just below the opening was not a problem for the dense populations of native species. All this just shows that there is an exceedingly limited understanding of how the system functions, and specifically what physical, chemical, and hydrologic aspects of the system promote sustaining *V.* chaceorum and its associated species. This commenter suggested that a high level of sediment is not, per se, deleterious to the shrimp, other anchialine pool species, and, by inference, the entire pool.

Our Response: We agree it is possible that increased flushing allowed the movement of native predators and competitors into the system, resulting in the decline or perhaps extirpation of *Vetericaris chaceorum* at Lua o

Palahemo; however, we are unaware of any data to support this hypothesis. Recent surveys by the Service and State (Wada 2012, pers. comm.; Wada *et al.* 2012, in litt.) have found the degradation of habitat of Lua o Palahemo is a result of excessive siltation and sedimentation of the anchialine pool system, combined with the diminished ability of the system to flush, which Brock (2004, pp. 11, 35–36) described as necessary for a functioning anchialine pool system. Long-term sedimentation accumulation leads to the senescence of anchialine pools (Ramsey 2013, in litt.). Suspended sediment within the water column of Lua o Palahemo likely reduces the capacity of the pool to produce adequate cyanobacteria and algae to support some of the pool's herbivorous hypogeal species. A decreased food supply (i.e., a reduction in cyanobacteria and algae) would likely lead to a lower abundance of herbivorous hypogeal shrimp species, as well as a lower abundance of the known carnivorous species (i.e., *Vetericaris chaceorum*). Because lower numbers of the herbivorous hypogeal shrimp have been observed over time, the data indicate this is a contributing to, but not necessarily the sole factor in, the lack of detection of *Vetericaris chaceorum* at Lua o Palahemo.

(31) *Comment:* One peer reviewer commented that Lua o Palahemo should not be treated as a typical anchialine pool. Rather it is a singular system, or perhaps somewhat like Lake Kauhako. Extrapolating from the little we know about typical anchialine systems will probably not be productive.

Our Response: Anchialine pools are land-locked bodies of water that have indirect underground connections to the sea, contain varying levels of salinity, and show tidal fluctuations in water level. Lua o Palahemo meets this definition. Further, Lua o Palahemo has floral and faunal characteristics of an anchialine pool ecosystem (see *Hawaii Island Ecosystems* and Description of the 15 Species, above). Lake Kauhako is situated in the crater of an extinct, late Pleistocene volcano on the north shore of Molokai, Hawaii, and reportedly not tidally influenced, although early data suggested it may have been at one time and anchialine pool shrimp were observed here in 1982 (Maciolek 1982, p. 12; Donachie *et al.* 1999, p. 93). Lake Kauhako is considered one of the deepest lakes in the United States with a depth of 814 ft (248 m) (Donachie *et al.* 1999, p. 93). Lake Kauhako is also meromictic (has layers of water that do not intermix) and anoxic (lacking dissolved oxygen) below 6 ft (2 m); Lua o Palahemo has not been classified as meromictic and is not noted as anoxic until a depth of 98 ft (30 m) and a distance of 180 m into one of the branches of the lava tube from the base of the surface opening (Kensley and Williams 1986, pp. 417–20). Both Lake Kauhako and Lua o Palahemo do have comparable surface dissolved oxygen and salinity and temperature gradients; however, the shape and depth of each water body, in addition to the presence or absence of tidal influence and meromictic properties, provide some distinction for these two bodies of water.

(32) *Comment:* One peer reviewer commented that the reproductive mode of *Vetericaris chaceorum* would play an important role in determining if populations could recolonize neighboring habitats after a local extirpation. Maciolek postulates that these habitats are colonized from long-existing subterranean populations, and Kensley and Williams (1986) state: ''Given the relative youth of the Lua o Palahemo lava tube, the above-mentioned and unexplained absences and occurrences, and the presence of some of these shrimps in modern wells and quarries, Maciolek's postulate (1983: 615) that these habitats are colonized from long-existing subterranean populations, must be strengthened.'' If this is true, the main habitat of *V. chaceorum* may be completely different from what we know about Lua o Palahemo.

Our Response: We agree it would be beneficial to know the reproductive mode for *Vetericaris chaceorum;* however, the complete life history for this species is not known at this time. Hypogeal shrimp by definition occupy subterranean habitat. The fact that *V. chaceorum* is described as a primitive species, combined with the depth within Lua o Palahemo in which *V. chaceorum* was observed and the recent discovery of *V. chaceorum* in very different habitat at Manuka, together appear to support Maciolek's hypothesis that hypogeal shrimp colonized anchialine pool habitats from long-existing subterranean populations, but this is only conjecture at this time. The newly discovered population at Manuka supports the thought that the main habitat of *V. chaceorum* at Lua o Palahemo is likely different from what we previously thought.

Comments From the State of Hawaii

(33) *Comment:* The Hawaii Department of Business, Economic Development, and Tourism's Hawaii Housing Finance and Development Corporation challenged our proposal to list *Bidens micrantha* ssp. *ctenophylla* as an endangered species, stating that the lowland dry ecosystem covers a very large area on Hawaii Island and that the Service did not have enough studies regarding the absence or abundance of this species within this ecosystem. According to this agency, without knowing the absence or prevalence of this species, it cannot be determined whether or not this species should be designated as endangered, and the Service's findings are premature with no foundation.

Our Response: We disagree that there is a lack of information regarding the presence or abundance of *Bidens micrantha* ssp. *ctenophylla* in the lowland dry ecosystem on the island of Hawaii and that our determination to list this species as an endangered species is premature and without foundation. Lowland dry ecosystems in the Hawaiian Islands have undergone sweeping changes over the last 100 years due to development, agriculture, and nonnative plants and animals that have resulted in the loss of over 90 percent of Hawaii's dry forests (Bruegmann 1996, pp. 26–27; Cabin *et al.* 2000, pp. 439–453; Sakai *et al.* 2002, pp. 276–302; Cordell *et al.* 2008, pp. 279–284); however, the actual extent of native dry forest cover may be as low as 1 percent (Pau 2011, in litt.). Forty-five percent of Hawaii's dry forest plant species are at risk of endangerment (Pau *et al.* 2009, p. 3,167). Twenty-five percent of the endangered plant species in the Hawaiian Islands are dry forest species, and approximately 20 percent of Hawaii's dry land plant species are believed to be extinct (Cabin *et al.* 2000, pp. 439–453; Sakai *et al.* 2002, pp. 276–302). One of the last remaining areas of lowland dry forest in the Hawaiian Islands is in the north Kona region of Hawaii Island, where only patches or scattered individuals of native plants remain amidst a sea of the highly flammable, nonnative fountain grass (*Pennisetum setaceum*), where over 200,000 ac (80,939 ha) of land are covered with fountain grass (HISC 2013, in litt.). North Kona is also a rapidly growing, urban area with a steady flow of new housing, roads, commercial, and industrial developments. Surveys and observations conducted over the last 90 years have detected *Bidens micrantha* ssp. *ctenophylla* from only six locations, totaling fewer than 1,000 individuals in north Kona (see Description of the 15 Species, above) (Sherff 1920, p. 97; Degener and Wiebke 1926, in litt.; Scottsberg 1926, in litt.; Borges and Degener 1929, in litt.; Degener and Iwasaki 1930, in litt.; Nishina 1931, in litt.; Krajina 1961, in litt.; Gillett 1965,

in litt.; Nagata and Ganders 1983, pp. 1–16; Pratt and Abbott 1996, p. 26; Ganders and Nagata 1999, pp. 271, 273; TNC 2007–*Ecosystem Database of ArcMap Shapefiles,* unpublished; Whistler 2007, pp. 1–18; Bio 2008, in litt.; Whistler 2008, pp. 1–11; Hawaii Forest Institute 2009, in litt.; Beavers 2010, in litt.; Faucette 2010, pp. 1–27; HBMP 2010b; Giffin 2011, pers. comm.; Pau 2011, in litt.; Wagner 2011, in litt.; Zimpfer 2011, in litt.; Kaahahui O Ka Nahelehele 2013, in litt.).

Under the Act, we determine whether a species is an endangered species or a threatened species because of any of five factors (see Summary of Factors Affecting the 15 Species, below), and we are required to make listing determinations solely on the basis of the best available scientific and commercial data *available* [emphasis ours] (sections 4(a)(1) and 4(b)(1)(A)). The threats to *B. micrantha* ssp. *ctenophylla,* as well as those that impact lowland dry ecosystems in the Hawaiian Islands, are well documented. This plant species faces threats from habitat degradation from development and nonnative ungulates (feral pigs and goats), predation by nonnative ungulates (feral pigs and goats) and rats, competition with nonnative plants, fire, drought, hurricanes, and hybridization; it also faces threats from the synergistic effects that may arise from any combination of these threats (see Summary of Factors Affecting the 15 Species, below). Therefore, in this final rule, we have made our determination to list *Bidens micrantha* ssp. *ctenophylla* as an endangered species based on the best scientific and commercial data available.

Comments From Federal Agencies

All of the comments we received from Federal agencies have been incorporated, as appropriate, in the Description of the 15 Species, above, and Summary of Changes from Proposed Rule, below.

Public Comments on the Proposed Listing of 15 Species

(34) *Comment:* One commenter, representing Laiopua 2020, stated that none of the 15 species proposed for listing occurs on parcels proposed for development of the Laiopua Community Center (Tax Map Key parcels 3–7–4–021:002, 003, and 023). The commenter provided a 2008 botanical survey report (Gerrish and Leonard Bisel Associates, LLC, 2008, entire) to confirm the absence of the 15 species on the three parcels.

Our Response: We appreciate the information provided by the commenter and have taken it into consideration in this final listing determination. The botanical survey published by Gerrish and Leonard Bisel Associates, LLC, in 2008 was one of multiple surveys and botanical expert reports used by the Service to determine the range of *Bidens micrantha* ssp. *ctenophylla* in North Kona. Since *Bidens micrantha* ssp. *ctenophylla* is known to occur in the area of Laiopua, the Service considered this area as habitat for this species. In addition, there is likely a seed bank in the soil of the surrounding area that, if given the opportunity, can contribute toward the recovery of this species.

Summary of Changes From Proposed Rule

In preparing this final rule, we reviewed and fully considered comments from the peer reviewers and public on the proposed listing for 15 species. This final rule incorporates the following substantive changes to our proposed listing, based on the comments we received:

(1) We added inundation by high surf as a threat to the newly listed plant *Bidens hillebrandiana* ssp. *hillebrandiana* in the following locations in this final rule: Table 3 (below) and ''Habitat Destruction and Modification Due to Rockfalls, Treefalls, Landslides, Heavy Rain, Inundation by High Surf, Erosion, and Drought'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range* (below), based on a peer review comment.

(2) We added the nonnative understory plant species *Sphagneticola trilobata* [*Wedelia trilobata*] (wedelia) as a threat to the plant *Bidens hillebrandiana* ssp. *hillebrandiana* in the coastal and dry cliff ecosystem, and to ''Specific Nonnative Plant Species Impacts'' (below), based on a peer review comment.

(3) We added the nonnative vine *Paederia foetida* (skunk weed) as a threat to the newly listed plant *Cyrtandra nanawaleensis* in the lowland wet ecosystem and to ''Specific Nonnative Plant Species Impacts'' (below), based on a peer review comment.

(4) We added the nonnative canopy plant species *Psidium cattleianum* (strawberry guava) as a threat to *Cyanea tritomantha* in the wet cliff ecosystem, based on a peer review comment that we include this nonnative plant species as a threat to this species in its known locations, in this final rule.

(5) We added *Pisonia* spp. as a host plant for the picture-wing fly *Drosophila digressa,* in the following locations in this final rule: Description of the 15 Species (above); ''Habitat Destruction and Modification by Introduced Ungulates'' and ''Habitat Destruction and Modification Due to Rockfalls, Treefalls, Landslides, Heavy Rain, Inundation by High Surf, Erosion, and Drought'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range* (below); ''Predation and Herbivory'' under *Factor C. Disease or Predation* (below); and ''Loss of Host Plants'' under *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence* (below), based on a peer review comment.

(6) Hawaii State biologists discovered a population of *Vetericaris chaceorum* at Manuka NAR between 2009 and 2010. We solicited public comments on the new location in the **Federal Register** in our April 30, 2013, document announcing the availability of the draft economic analysis and reopening the comment period on the proposed rule (78 FR 25243). The new location information has been incorporated in the following sections in this final rule: Description of the 15 Species (above), ''Habitat Destruction and Modification by Sedimentation'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range* (below), and ''Dumping of Trash and Introduction of Nonnative Fish'' (below) under *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence,* and we reassessed whether listing was warranted for *V. chaceorum* based on this additional information.

(7) We revised the statement that incorrectly indicated that the outplanted individuals of *Bidens micrantha* ssp. *ctenophylla* within KHNHP are fenced in Description of the 15 Species, above, based on a comment we received.

Summary of Factors Affecting the 15 Species

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued

existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

If we determine that the level of threat posed to a species by one or more of the five listing factors is such that the species meets the definition of either endangered or threatened under section 3 of the Act, that species may then be listed as endangered or threatened. The Act defines an endangered species as ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The threats to each of the individual 15 species are summarized in Table 3, and discussed in detail below.

TABLE 3–SUMMARY OF PRIMARY THREATS IDENTIFIED FOR EACH OF THE 15 HAWAII ISLAND SPECIES

Species	Ecosystem	Factor A						Factor B	Factor C				Factor D	Factor E
		Agriculture and urban development	Ungulates	Non native plants	Fire	Stochastic events	Climate change	Over-utilization	Disease	Predation/ herbivory by ungulates	Predation/ herbivory by other NN vertebrates	Predation/ herbivory by NN invertebrates	Inadequate existing regulatory mechanisms	Other species-specific threats
Plants:														
Bidens hillebrandiana ssp. *hillebrandiana*.	CO, DC		P, G	X		H, RF, L, HS, E.	Pt			P, G	R		X	LN
Bidens micrantha ssp. *ctenophylla*.	LD	X	P, G	X	X	H, DR	Pt			P, G	R		X	HY
Cyanea marksii	LW, MW		P, C, M	X		H, RF, L	Pt			P, C, M	R	S	X	LN
Cyanea tritomantha	LW, MW, WC		P, C	X		H, TF	Pt			P, C	R	S	X	NR
Cyrtandra nanawaleensis	LW		P	X		H	Pt			P	R	S	X	HY
Cyrtandra wagneri	LW		P	X		H, HR, E	Pt			P	R	S	X	LN, HY
Phyllostegia floribunda	LW, MM, MW		P	X	X	H	Pt			P			X	
Pittosporum hawaiiense	LM, MM, MW		P, C, M	X		H	Pt			P, C, M	R		X	NR
Platydesma remyi	LW, MW		P	X		H	Pt			P			X	LN, NR
Pritchardia lanigera	LM, LW, MW, WC.		P, G, M, C	X		H	Pt	X		P, G, M	R	LH, B	X	NR
Schiedea diffusa ssp. *macraei*.	MW		P, C	X		H	Pt			P, C	R		X	LN
Schiedea hawaiiensis	MD		P, G, SH, M.	X	X	H, DR	Pt			P, G, SH, M	R		X	LN
Stenogyne cranwelliae	MW, WC		P	X		H	Pt			P	R	S	X	
Animals														
Drosophila digressa (Picture-wing fly).	LM, MM, MW		P, G, C, M	X	X	H, DR	Pt					W, A	X	LN, LOH, F
Vetericaris chaceorum (Anchialine pool shrimp).	AP		G, C				Pt						X	REC, SD, D

Factor A = Habitat Modification
Factor B = Overutilization
Factor C = Disease or Predation
Factor D = Inadequacy of Regulatory Mechanisms
Factor E = Other Species-Specific Threats
AP = Anchialine Pools
CO = Coastal
LD = Lowland Dry
LM = Lowland Mesic
LW = Lowland Wet
MD = Montane Dry
MM = Montane Mesic
MW = Montane Wet
DC = Dry Cliff
WC = Wet Cliff
P = Pigs
G = Goats
C = Cattle
SH = Sheep
M = Mouflon
R = Rats
S = Slugs
W = Wasps
A = Ants
LH = Leafhopper
B = Beetles
H = Hurricane
DR = Drought
RF = Rockfalls
L = Landslides
HR = Heavy Rain
HS = High Surf
E = Erosion
TF = Tree Fall
D = Dumping (i.e., Human dumping of nonnative fish and trash)
LN = Limited Numbers
HY = Hybridization
NR = No Regeneration
F = Flies
LOH = Loss of Host
REC = Recreational vehicles
SD = Sedimentation
Pt = Potential
X = Threat
Blank = Not a Threat

The following constitutes a list of ecosystem-scale threats that affect the species in this final rule in one or more of the 10 described ecosystems on Hawaii Island:

(1) Foraging and trampling of native plants by feral pigs (*Sus scrofa*), goats (*Capra hircus*), cattle (*Bos taurus*), sheep (*Ovis aries*), or mouflon sheep (*Ovis gmelini musimon*), which results in severe erosion of watersheds because these mammals inhabit terrain that is often steep and remote (Cuddihy and Stone 1990, p. 63). Foraging and trampling events destabilize soils that support native plant communities, bury or damage native plants, and have adverse water quality effects due to runoff over exposed soils.

(2) Ungulate destruction of seeds and seedlings of native plant species via foraging and trampling (Cuddihy and Stone 1990, pp. 63, 65) facilitates the conversion of disturbed areas from native to nonnative vegetative communities.

(3) Disturbance of soils by feral pigs from rooting can create fertile seedbeds for alien plants (Cuddihy and Stone 1990, p. 65), some of them spread by ingestion and excretion by pigs.

(4) Increased nutrient availability as a result of pigs rooting in nitrogen-poor soils, which facilitates establishment of alien weeds. Introduced vertebrates are known to enhance the germination of alien plants through seed scarification in digestive tracts or through rooting and fertilization with feces of potential seedbeds (Stone 1985, p, 253). In addition, alien weeds are more adapted to nutrient-rich soils than native plants (Cuddihy and Stone 1990, p. 65), and rooting activity creates open areas in forests allowing alien species to completely replace native stands.

(5) Rodent damage to plant propagules, seedlings, or native trees, which changes forest composition and structure (Cuddihy and Stone 1990, p. 67).

(6) Feeding or defoliation of native plants from alien insects, which reduces geographic ranges of some species because of damage (Cuddihy and Stone 1990, p. 71).

(7) Alien insect predation on native insects, which affects pollination of native plant species (Cuddihy and Stone 1990, p. 71).

(8) Significant changes in nutrient cycling processes because of large numbers of alien invertebrates, such as earthworms, ants, slugs, isopods, millipedes, and snails, resulting in changes to the composition and structure of plant communities (Cuddihy and Stone 1990, p. 73).

Each of the above threats is discussed in more detail below, and summarized in Table 3.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range

The Hawaiian Islands are located over 2,000 mi (3,200 km) from the nearest continent. This isolation has allowed the few plants and animals that arrived in the Hawaiian Islands to evolve into many highly varied and endemic species (species that occur nowhere else in the world). The only native terrestrial mammals in the Hawaiian Islands are two bat taxa, the extant Hawaiian hoary bat (*Lasiurus cinereus semotus*) and an extinct, unnamed, insectivorous bat (Ziegler 2002, p. 245). The native plants of the Hawaiian Islands, therefore, evolved in the absence of mammalian predators, browsers, or grazers. As a result, many of the native species have lost unneeded defenses against threats such as mammalian predation and competition with aggressive, weedy plant species that are typical of continental environments (Loope 1992, p. 11; Gagne and Cuddihy 1999, p. 45; Wagner *et al.* 1999d, pp. 3–6). For example, Carlquist (in Carlquist and Cole 1974, p. 29) notes that ''Hawaiian plants are notably free from many characteristics thought to be deterrents to herbivores (toxins, oils, resins, stinging hairs, coarse texture).''

Native Hawaiian plants are therefore highly vulnerable to the impacts of introduced mammals and alien plants. In addition, species restricted and adapted to highly specialized locations (e.g., *Bidens hillebrandiana* ssp. *hillebrandiana*) are particularly vulnerable to changes (e.g., nonnative species, hurricanes, fire, and climate change) in their habitat (Carlquist and Cole 1974, pp. 28–29; Loope 1992, pp. 3–6; Stone 1992, pp. 88–102).

Habitat Destruction and Modification by Agriculture and Urban Development

The consequences of past land use practices, such as agricultural or urban development, have resulted in little or no native vegetation below 2,000 ft (600 m) throughout the Hawaiian Islands (TNC 2007–*Ecosystem Database of ArcMap Shapefiles,* unpublished), largely impacting the coastal, lowland dry, lowland mesic, and lowland wet ecosystems. Although agriculture has been declining in importance, large tracts of former agricultural lands are being converted into residential areas or left fallow (TNC 2007–*Ecosystem Database of ArcMap Shapefiles,* unpublished). In addition, Hawaii's population has increased almost 7 percent in the past 10 years, further increasing demands on limited land and water resources in the islands (Hawaii Department of Business, Economic Development, and Tourism (HDBEDT) 2010).

Development and urbanization of the lowland dry ecosystem on Hawaii Island is a threat to one species in this rule, *Bidens micrantha* ssp. *ctenophylla. Bidens micrantha* ssp. *ctenophylla* is currently found in an area less than 10 sq mi (26 sq km) on the leeward slopes of Hualalai volcano in the lowland dry ecosystem. This area encompasses the increasingly urbanized region of north Kona, where there is very little undisturbed habitat (Pratt and Abbott 1997, p. 25). Approximately 25 percent (119 individuals of 475) of the largest of the 6 occurrences of this species is in the right-of-way of the Ane Keohokalole Highway Project (USFWS 2010, in litt.) and Kaloko Makai Development, although 154 ac (62 ha) will be set aside as a lowland dry forest preserve (Kaloko Makai Dryland Forest Preserve) to compensate for the loss of these individuals as a result of highway construction and prior to the Kaloko Makai Development. Individuals of *Bidens micrantha* ssp. *ctenophylla* also occur in areas where the development of the Villages of Laiopua at Kealakehe and of the Keahuolu affordable housing project (Whistler 2007, pp. 1–18; DHHL 2009, p. 15) is a threat to the species.

Habitat Destruction and Modification by Introduced Ungulates

Introduced mammals have greatly impacted the native vegetation, as well as the native fauna, of the Hawaiian Islands. The presence of introduced alien mammals is considered one of the primary factors underlying the alteration and degradation of native plant communities and habitats on the island of Hawaii. The destruction or degradation of habitat due to nonnative ungulates (hoofed mammals), including pigs, goats, cattle, sheep, and mouflon, is currently a threat to the 10 ecosystems (lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, coastal, anchialine pool, dry cliff, and wet cliff) on Hawaii Island and their associated species. Habitat degradation or destruction by ungulates is also a threat to all 13 plant species and the picture-wing fly in this final rule (Table 3). Habitat degradation or destruction by ungulates is a threat to the anchialine pool shrimp at Lua o Palahemo, but is not reported to pose a threat to the four pools that support this species at Manuka.

The destruction or degradation of habitat due to pigs is currently a threat to nine of the Hawaii Island ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) and their associated species. In Hawaii, pigs have been described as the most pervasive and disruptive nonnative influence on the unique native forests of the Hawaiian Islands, and are widely recognized as one of the greatest current threats to forest ecosystems (Aplet *et al.* 1991, p. 56; Anderson and Stone 1993, p. 195).

These feral animals are extremely destructive and have both direct and indirect impacts on native plant communities. While rooting in the earth in search of invertebrates and plant material, pigs directly impact native plants by disturbing and destroying vegetative cover, and by trampling plants and seedlings. It has been estimated that at a conservative rooting rate of 2 sq yards (yd) (1.7 sq m) per minute, with only 4 hours of foraging a day, a single pig could disturb over 1,600 sq yd (1,340 sq m) (or approximately 0.3 ac, or 0.12 ha) of groundcover per week (Anderson *et al.* 2007, p. 2).

Pigs reduce or eliminate plant regeneration by damaging or eating seeds and seedlings (further discussion of predation by nonnative ungulates is provided under *Factor C. Disease or Predation,* below). Pigs are a major vector for the establishment and spread of competing invasive, nonnative plant species by dispersing plant seeds on their hooves and fur, and in their feces (Diong 1982, pp. 169–170), which also serves to fertilize disturbed soil (Matson 1990, p. 245; Siemann *et al.* 2009, p. 547). Pigs feed on the fruits of many nonnative plants, such as *Passiflora tarminiana* (banana poke) and *Psidium cattleianum* (strawberry guava), spreading the seeds of these invasive species through their feces as they travel in search of food. Pigs also feed on native plants, such as Hawaiian tree ferns that they root up to eat the core of the trunk (Baker 1975, p. 79). In addition, rooting pigs contribute to erosion by clearing vegetation and creating large areas of disturbed soil, especially on slopes (Smith 1985, pp. 190, 192, 196, 200, 204, 230–231; Stone 1985, pp. 254–255, 262–264; Medeiros *et al.* 1986, pp. 27–28; Scott *et al.* 1986, pp. 360–361; Tomich 1986, pp. 120–126; Cuddihy and Stone 1990, pp. 64–65; Aplet *et al.* 1991, p. 56; Loope *et al.* 1991, pp. 1–21; Gagne and Cuddihy 1999, p. 52; Nogueira-Filho *et al.* 2009, pp. 3,677–3,682; Dunkell *et al.* 2011, pp. 175–177). Erosion impacts native plant communities by watershed degradation and alteration of plant nutrient status due to associated outcomes such as sediment build up in waterways and top soil run off, respectively, as well as damage to individual plants from landslides (Vitousek *et al.* 2009, pp. 3074–3086; Chan-Halbrendt *et al.* 2010, p. 252).

Pigs have been cited as one of the greatest threats to the public and private lands within the Olaa Kilauea Partnership (an area of land that includes approximately 32,000 ac (12,950 ha) in the upper sections of the Olaa and Waiakea forests above Volcano village) that comprise the lowland mesic, lowland wet, montane mesic, and montane wet ecosystems that support individuals of three of the plant species in this final rule (*Cyanea tritomantha, Phyllostegia floribunda,* and *Pittosporum hawaiiense*) (Olaa Kilauea Partnership Area Feral Animal Monitoring Report 2005, pp. 1–4; Perlman 2007, in litt.; Pratt 2007a, in litt.; Pratt 2007b, in litt.; Benitez *et al.* 2008, p. 58; HBMP 2010f; HBMP 2010h; PEPP 2010, p. 60, TNC 2012, in litt.). Impacts from feral pigs are also a threat to the coastal, lowland mesic, lowland wet, montane wet, dry cliff, and wet cliff ecosystems in the northern Kohala Mountains and adjacent coastline. These ecosystems support occurrences of seven of the plant species in this final rule (*Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea tritomantha, Cyrtandra wagneri, Platydesma remyi, Pritchardia lanigera, Schiedea diffusa* ssp. *macraei,* and *Stenogyne cranwelliae*) (Wood 1995, in litt.; Wood 1998, in litt.; Perlman *et al.* 2001, in litt.; Wagner *et al.* 2005d, pp. 31–33; Kohala Mountain Watershed Partnership (KMWP) 2007, pp. 54–56; Lorence and Perlman 2007, pp. 357–361; HBMP 2010a; HBMP 2010c; HBMP 2010f; HBMP 2010i; HBMP 2010j; HBMP 2010k; PEPP 2010, pp. 63, 101, 106; Bio 2011, pers. comm.). In addition, feral pigs are a threat to the lowland wet and montane wet ecosystems in south Kona, Kau, and Puna districts that support the plants *Cyanea marksii, Cyrtandra nanawaleensis,* and *Pritchardia lanigera* (Bio 2011, pers. comm.; Magnacca 2011b, pers. comm.; Maui Forest Bird Recovery Project 2011, in litt.; Crysdale 2013, pers. comm.). Feral pigs have also been reported in the lowland dry ecosystem that supports the plant *Bidens micrantha* ssp. *ctenophylla* (Bio 2011, pers. comm.) and the montane dry ecosystem that supports habitat for the only known occurrence of the plant *Schiedea hawaiiensis* (Mitchell *et al.* 2005c; U.S. Army Garrison 2006, pp. 27, 34, 95–97, 100–107, 112). Although we do not have direct evidence of feral pigs threatening the particular species on Hawaii Island that are in this final rule, those threats have been documented on other islands where pigs have been introduced (Mitchell *et al.* 2005c; U.S. Army Garrison 2006, pp. 27, 34, 95–97, 100–107, 112). We find it is reasonable to infer that feral pig threats to these species that have been observed on other Hawaiian islands would act in a similar manner on Hawaii Island, where those species interact.

Many of the most important host plants of Hawaiian picture-wing flies (*Charpentiera, Pisonia, Pleomele, Reynoldsia, Tetraplasandra, Urera,* and the lobelioids (e.g., *Cyanea* spp.)) are also among the most susceptible to damage from feral ungulates, such as pigs (Foote and Carson 1995, p. 370; Kaneshiro and Kaneshiro 1995, pp. 8, 39; Magnacca *et al.* 2008, p. 32; Magnacca 2013, in litt.). Feral pig browsing alters the essential microclimate in picture-wing fly (*Drosophila digressa*) habitat by opening up the canopy, leading to increased desiccation of soil and host plants (*Charpentiera* spp. and *Pisonia* ssp.), which disrupts the host plants' life cycle and decay processes, resulting in disruption of the picture-wing fly's life cycle, particularly oviposition and larvae substrate (Magnacca *et al.* 2008, pp. 1, 32). Foote and Carson (1995, p. 369) have experimentally demonstrated the above detrimental effects of feral pigs on *Drosophila* spp. in wet forest habitat on the island of Hawaii. In addition, Montgomery (2005, in litt.; 2007, in litt.) and Foote (2005, pers. comm.) have observed feral pig damage to host plants (e.g., *Charpentiera* sp., *Cheirodendron* sp., *Pleomele* sp., *Tetraplasandra* sp., *Urera kaalae*) of Hawaiian picture-wing flies on the island of Hawaii (Foote 2005, pers. comm.) and throughout the main Hawaiian Islands (Montgomery 2005, in litt.; 2007, in litt.). Magnacca (2012, pers. comm.) has observed the lack of regeneration of picture-wing fly host plants due to destruction of seedlings caused by pig rooting and herbivory.

The destruction or degradation of habitat due to goats is currently a threat to all 10 of the described ecosystems on Hawaii Island (anchialine pool, coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) and their associated species. Goats occupy a wide variety of habitats on Hawaii Island, where they consume native vegetation, trample roots and seedlings, accelerate erosion, and promote the invasion of alien plants

(van Riper and van Riper 1982, pp. 34–35; Stone 1985, p. 261; Kessler 2011, pers. comm.). Goats are able to access, and forage in, extremely rugged terrain, and they have a high reproductive capacity (Clarke and Cuddihy 1980, pp. C–19, C–20; Culliney 1988, p. 336; Cuddihy and Stone 1990, p. 64). Because of these factors, goats have completely eliminated some plant species from islands (Atkinson and Atkinson 2000, p. 21).

Goats are be highly destructive to native vegetation, and contribute to erosion by eating young trees and young shoots of plants before they can become established, creating trails that damage native vegetative cover, promoting erosion by destabilizing substrate and creating gullies that convey water, and dislodging stones from ledges that can cause rockfalls and landslides and damage vegetation below (Cuddihy and Stone 1990, pp. 63–64). A recent study by Chynoweth *et al.* (2011, in litt.), which deployed GPS (global positioning system) satellite collars on 12 feral goats to track movement patterns every 2 hours for 1 year in Pohakuloa Training Area, found that goats prefer native-dominated shrublands in the montane dry ecosystem during the day and barren lava at night. Pohakuloa Training Area supports one of the few montane dry forest ecosystems on Hawaii Island that supports native plants in the montane dry ecosystem, including the only occurrence of the plant *Schiedea hawaiiensis* (U.S. Army Garrison 2006, pp. 27, 34; Evans 2011, in litt.). In addition, one of the two occurrences of the plant *Pritchardia lanigera* is known from an unfenced area of the Kohala Mountains, where herds of wild goats and other ungulates occur (Maly and Maly 2004 *in* KMWP 2007, p. 55; KMWP 2007, pp. 54–55; Warshauer *et al.* 2009, pp. 10, 24; Laws *et al.* 2010, in litt.; Ikagawa 2011, in litt.). Maly and Maly (2004 *in* KMWP 2007, p. 55) report that ''herds of wild goats roam throughout this region, trampling, grubbing, and rending, grinding the bark of old trees and eat the young ones . . . which will destroy the beauty and alter the climate of the mountainous region of Hawaii.'' There are direct observations that goats are also altering the coastal ecosystem along the Kohala Mountains, the location of the only known wild individuals of the plant *Bidens hillebrandiana* ssp. *hillebrandiana* (Warshauer *et al.* 2009, p. 24; Bio 2011, pers. comm.). Goats are also found in North Kona and have been observed browsing in the lowland dry ecosystem that supports the plant *B. micrantha* ssp. *ctenophylla* (Bio 2011, pers. comm.; Knoche 2011, in litt.). Fresh seedlings from native plants attract goats to the dry and rough lava (Bio 2011, pers. comm.). Further, the host plants (*Charpentiera* spp. and *Pisonia* spp.) of the picture-wing fly in this final rule appear to be decreasing throughout their ranges due to impacts from browsing goats (Foote and Carson 1995, p. 369; Science Panel 2005, pp. 1–23; Magnacca *et al.* 2008, p. 32; Magnacca 2013, in litt.). Feral goat browsing alters the picture-wing fly's (*Drosophila digressa*) essential microclimate by opening up the canopy, leading to increased desiccation of soil and host plants, which disrupts the host plants' life cycle and decay processes, resulting in the disruption of the picture-wing fly's life cycle, particularly oviposition and larvae substrate (Magnacca *et al.* 2008, pp. 1, 32). Based on observations of goats and their scat (Magnacca 2012, pers. comm.) within the Ka Lae region where the Lua o Palahemo anchialine pool is located, the Service concludes that goats contribute to the degradation of the anchialine pool habitat and, thus, are a threat to the anchialine pool shrimp *Vetericaris chaceorum.* Feral goats trample and forage on both native and nonnative plants around and near the pool opening at Lua o Palahemo, and increase erosion around the pool and sediment entering the pool.

The destruction or degradation of habitat due to cattle is currently a threat to five of the described ecosystems (anchialine pool, lowland mesic, lowland wet, montane mesic, and montane wet) on Hawaii Island and their associated species. Feral cattle eat native vegetation, trample roots and seedlings, cause erosion, create disturbed areas into which alien plants invade, and spread seeds of alien plants in their feces and on their bodies. The forest in areas grazed by cattle degrades to grassland pasture, and plant cover is reduced for many years following removal of cattle from an area. In addition, several alien grasses and legumes purposely introduced for cattle forage have become noxious weeds (Tomich 1986, pp. 140–150; Cuddihy and Stone 1990, p. 29).

The wet forests of Kohala Mountain are reported to have a feral cattle population of at least 100 individuals that are causing forest degradation by trampling and browsing, which leads to subsequent increased nitrogen availability through deposition of feces (Stone 1985, p. 253), all of which contribute to the influx of nonnative plant and animal species (KMWP 2007, pp. 54–55; Laws 2010, in litt.). Feral cattle are reported from remote regions on Hawaii Island, including the back of both Pololu and Waipio Valleys (KMWP 2007, p. 55). Feral cattle are a threat to the lowland wet and montane wet ecosystems on Kohala Mountain where individuals of *Cyanea tritomantha, Pittosporum hawaiiense,* and *Pritchardia lanigera,* and the last wild individual of *Schiedea diffusa* ssp. *macraei,* are reported (PEPP 2010, pp. 59–60; Bio 2011, pers. comm.). According to a 2010 Service report (USFWS 2010, pp. 3–15, 4–86), a herd of 200 to 300 feral cattle roams the Kona unit of the Hakalau Forest NWR, where individuals of *Cyanea marksii* are reported (USFWS 2010, pp. 3–15, 4–86). Field biologists have observed cattle-induced habitat degradation at all elevations in this refuge unit, including within the montane wet ecosystem that supports individuals of *Cyanea marksii* (PEPP 2007, p. 61; USFWS 2010, pp. 1–15, 2–13, 4–10, 4–58–4–59, 4–82, 4–86; Bio 2011, pers. comm.; Krauss 2012, pers. comm.). In addition, the host plants (*Charpentiera* spp. and *Pisonia* spp.) of the picture-wing fly *Drosophila digressa* have decreased throughout their ranges due to impacts from cattle browsing in the lowland mesic and montane mesic ecosystems (Science Panel 2005, pp. 1–23; Magnacca 2011b, in litt.; Magnacca 2013, in litt.). Feral cattle browsing alters the picture-wing fly's essential microclimate by opening up the canopy, leading to increased desiccation of soil and host plants, which disrupts the host plants' life cycle and decay processes, resulting in the disruption of the picture-wing fly's life cycle, particularly oviposition and larvae substrate (Magnacca *et al.* 2008, pp. 1, 32). According to Palikapu Dedman with the Pele Defense Fund, observations of feral cattle in the Ka Lae region where the Lua o Palahemo anchialine pool is located contribute to the degradation of the anchialine pool habitat (Richarson 2012, in litt.). Feral cattle trample and forage on both native and nonnative plants around and near the pool opening at Lua o Palahemo, and increase erosion around the pool and sediment entering the pool. We therefore conclude that feral cattle are a threat to the anchialine pool shrimp *Vetericaris chaceorum* (Richardson 2012, in litt., pp. 1–2). Further, cattle carcasses have been observed within the pool at Lua o Palahemo (Kinzie 2012, in litt.). Due to the steep sides of the pool, animals may fall into the water, and if they die there, their decomposing bodies could have a negative impact on the ability of the pool habitat to support *V. chaceorum* (Kinzie 2012, in litt.).

The destruction or degradation of habitat due to feral sheep is currently a

threat to the montane dry ecosystem on Hawaii Island and its associated species. Feral sheep browse and trample native vegetation, and have decimated large areas of native forest and shrubland on Hawaii Island (Tomich 1986, pp. 156–163; Cuddihy and Stone 1990, pp. 65–66). Browsing erodes top soil, which alters moisture regimes and micro-environments, and results in the loss of native plant and animal taxa (Tomich 1986, pp. 156–163; Cuddihy and Stone 1990, pp. 65–66). In addition, nonnative opportunistic plant seeds get dispersed to disturbed forest sites by adhering to sheep wool coats (Hawaii Division of Forestry and Wildlife (HDOFAW) 2002, p. 3).

In 1962, game hunters intentionally crossbred feral sheep with mouflon sheep and released them on Mauna Kea (Tomich 1986, pp. 156–163). In *Palila* v. *Hawaii Department of Land and Natural Resources* (471 F. Supp. 985 (Haw. 1979)), the Federal court ordered complete removal of feral sheep from Mauna Kea in 1979, because they were harming the endangered palila (*Loxioides bailleui*) by degrading and destroying palila habitat in the montane dry ecosystem. Throughout the past 30 years, attempts to protect the vegetation of Mauna Kea and the saddle from sheep have only been sporadically effective (Scowcroft and Conrad 1992, p. 628). Currently, a large feral population surrounds Mauna Kea and extends into the saddle and northern part of Mauna Loa, including the State forest reserves, where they trample and browse endangered plants (Hess 2008, p. 1). At the U.S. Army's Pohakuloa Training Area, located in the saddle area of the island, biologists have reported that feral sheep are a threat to the last occurrence of the plant species *Schiedea hawaiiensis,* which occurs in the montane dry ecosystem (Mitchell *et al.* 2005a; U.S. Army Garrison 2006, pp. 27, 34).

Five of the described ecosystems (lowland mesic, lowland wet, montane dry, montane mesic, and montane wet) on Hawaii Island, and their associated species are currently threatened by the destruction or degradation of habitat due to mouflon sheep. The mouflon sheep (mouflon), native to Asia Minor, was introduced to the islands of Lanai and Hawaii in the 1950s, as a managed game species, and has become widely established on these islands (Tomich 1986, pp. 163–168; Cuddihy and Stone 1990, p. 66; Hess 2008, p. 1). In 1968, mouflon were introduced to Kahuku Ranch (now a unit of HVNP) on Mauna Loa for trophy hunting. By 2008, mouflon ranged over the southern part of Mauna Loa in the Kahuku area on adjacent public and private lands (Hess 2008, p. 1). According to Ikagawa (2011, in litt.), mouflon are found on the slopes of both Mauna Loa and Mauna Kea. Ikagawa (2011, in litt.) also notes that mouflon and mouflon-sheep hybrids are found from sea level to over 3,280 ft (1,000 m) elevation. Mouflon have high reproduction rates; for example, the original population of 11 individuals on the island of Hawaii has increased to more than 2,500 in 36 years, even though mouflon are hunted as a game animal (Hess 2008, p. 3). Mouflon only gather in herds when breeding, thus limiting control techniques and hunting efficiency (Hess 2008, p. 3; Ikagawa 2011, in litt.). Mouflon are both grazers and browsers, and have decimated vast areas of native forest and shrubland through browsing and bark stripping (Stone 1985, p. 271; Cuddihy and Stone 1990, pp. 63, 66; Hess 2008, p. 3). Mouflon also create trails and pathways through thick vegetation, leading to increased runoff and erosion through soil compaction. In some areas, the interaction of browsing and soil compaction has led to a change from native rainforest to grassy scrublands (Hess 2008, p. 3). Field biologists have observed habitat degradation in five of the described ecosystems (lowland mesic, lowland wet, montane dry, montane mesic, and montane wet) that support four plants (*Cyanea marksii, Pittosporum hawaiiense, Pritchardia lanigera,* and *Schiedea hawaiiensis*) (Bio 2011, pers. comm.; Ikagawa 2011, in litt.; Pratt 2011d, in litt.), and the picture-wing fly (*Drosophila digressa*) (Magnacca 2011b, pers. comm.), in this final rule. Many of the current and proposed fenced exclosures on Hawaii Island are only 4 ft (1.3 m) in height, as they are designed to exclude feral pigs, goats, and sheep. However, a fence height of at least 6 ft (2 m) is required to exclude mouflon sheep, as they can easily jump a 4-ft (1.3-m) fence (Ikagawa 2011, in litt.). Both the increased range of mouflon, as well as the lack of adequately protected habitat, increase the threat of mouflon sheep to additional ecosystems on Hawaii Island.

Between 2010 and 2011, an unauthorized introduction of axis deer (*Axis axis*) occurred on Hawaii, for purposes of big game hunting (Kessler 2011, in litt.; Aila 2012a, in litt.). Axis deer are primarily grazers, but also browse numerous palatable plant species, including those grown as commercial crops (Waring 1996, in litt., p. 3; Simpson 2001, in litt.). They prefer the lower, more openly vegetated areas for browsing and grazing; however, during episodes of drought (e.g., from 1998–2001 on Maui (Medeiros 2010, pers. comm.)), axis deer move into urban and forested areas in search of food (Waring 1996, in litt., p. 5; Nishibayashi 2001, in litt.). Like goats, axis deer are highly destructive to native vegetation and contribute to erosion by eating young trees and young shoots of plants before they can become established, creating trails that can damage native vegetative cover, promoting erosion by destabilizing substrate and creating gullies that convey water, and by dislodging stones from ledges that cause rockfalls and landslides and damage vegetation below (Cuddihy and Stone 1990, pp. 63–64). The unauthorized introduction of axis deer on Hawaii Island is a concern due to the devastating impacts of habitat destruction by axis deer in nine ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) on the islands of Kahoolawe, Lanai, and Maui (Mehrhoff 1993, p. 11; Anderson 2002, poster; Swedberg and Walker 1978, cited in Anderson 2003, pp. 124–125; Perlman 2009, in litt., pp. 4–5; Hess 2008, p. 3; Hess 2010, pers. comm.; Kessler 2010, pers. comm.; Medeiros 2010, pers. comm.). As reported on the islands of Kahoolawe, Lanai, and Maui, the spread of axis deer into nine of the described ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) on Hawaii Island will lead to similar habitat degradation and destruction if the deer are not controlled. The results from the studies above, in addition to the confirmed sightings of axis deer on Hawaii Island, suggest that axis deer will significantly alter these ecosystems and directly damage or destroy native plants if they become established. Although habitat degradation due to axis deer has not yet been observed on Hawaii Island, we believe it is reasonable to assume similar habitat effects on this island. Based on the prevailing evidence of the documented impacts to native ecosystems and individual plants on the other islands, we determine that the expanding population of axis deer on the Island of Hawaii, while not currently resulting in population-level effects to native plants, is expected to do so in the future if the deer are not managed or controlled. See Factor D for further information regarding State efforts to eradicate this species.

In summary, the 15 species dependent upon the 10 ecosystems identified in this final rule (anchialine pool, coastal, lowland dry, lowland mesic, lowland

wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) are exposed to the ongoing threat of feral ungulates (pigs, goats, cattle, sheep, and mouflon sheep). Additionally, if not adequately managed or controlled, impacts from axis deer may also become a threat to these ecosystems in the future. These negative impacts result in the destruction and degradation of habitat for these 15 native species on Hawaii Island. The effects of these nonnative animals include the destruction of vegetative cover; trampling of plants and seedlings; direct consumption of native vegetation; soil disturbance and sedimentation; dispersal of alien plant seeds on hooves and coats, and through the spread of seeds in feces; alteration of soil nitrogen availability; and creation of open, disturbed areas conducive to further invasion by nonnative pest plant species. All of these impacts lead to the subsequent conversion of a plant community dominated by native species to one dominated by nonnative species (see ''Habitat Destruction and Modification by Nonnative Plants,'' below). In addition, because these mammals inhabit terrain that is often steep and remote (Cuddihy and Stone 1990, p. 59), foraging and trampling contributes to severe erosion of watersheds and degradation of streams (Dunkell *et al.* 2011, pp. 175–194). As early as 1900, there was increasing concern expressed about the integrity of island watersheds, due to effects of ungulates and other factors, leading to the establishment of a professional forestry program emphasizing soil and water conservation (Nelson 1989, p. 3).

Habitat Destruction and Modification by Nonnative Plants

Native vegetation on all of the main Hawaiian Islands has undergone extreme alteration because of past and present land management practices, including ranching, the deliberate introduction of nonnative plants and animals, and agricultural development (Cuddihy and Stone 1990, pp. 27, 58). The original native flora of Hawaii (species that were present before humans arrived) consisted of about 1,000 taxa, 89 percent of which were endemic (species that occur only in the Hawaiian Islands). Over 800 plant taxa have been introduced from elsewhere, and nearly 100 of these have become pests (e.g., injurious plants) in Hawaii (Smith 1985, p. 180; Cuddihy and Stone 1990, p. 73; Gagne and Cuddihy 1999, p. 45). Of these 100 nonnative pest plant species, over 35 species have altered the habitat of 14 of the 15 species in this final rule (only the anchialine pool shrimp is not directly impacted by nonnative plants (see Table 3)).

The most-often cited effects of nonnative plants on native plant species are competition and displacement. Competition may be for water, light, or nutrients, or it may involve allelopathy (chemical inhibition of other plants). Alien plants displace native species of plants by preventing their reproduction, usually by shading and taking up available sites for seedling establishment. Alien plant invasions alter entire ecosystems by forming monotypic stands, changing fire characteristics of native communities, altering soil-water regimes, changing nutrient cycling, or encouraging other nonnative organisms (Smith 1989, pp. 61–69; Vitousek *et al.* 1987, pp. 224–227).

Nonnative plants pose serious and ongoing threats to 14 of the 15 species (not the anchialine pool shrimp) in this final rule throughout their ranges by destroying and modifying habitat. They can adversely impact microhabitat by modifying the availability of light and nutrient cycling processes, and by altering soil-water regimes. They can also alter fire regimes affecting native plant habitat, leading to incursions of fire-tolerant nonnative plant species into native habitat. Alteration of fire regimes clearly represents an ecosystem-level change caused by the invasion of nonnative grasses (D'Antonio and Vitousek 1992, p. 73). The grass lifeform supports standing dead material that burns readily, and grass tissues have large surface-to-volume ratios and can dry out quickly (D'Antonio and Vitousek 1992, p. 73). The flammability of biological materials is determined primarily by their surface-to-volume ratio and moisture content, and secondarily by mineral content and tissue chemistry (D'Antonio and Vitousek 1992, p. 73). The finest size classes of material (mainly grasses) ignite and spread fires under a broader range of conditions than do woody fuels or even surface litter (D'Antonio and Vitousek 1992, p. 73). The grass life form allows rapid recovery following fire; there is little above-ground structural tissue, so almost all new tissue fixes carbon and contributes to growth (D'Antonio and Vitousek 1992, p. 73). Grass canopies also support a microclimate in which surface temperatures are hotter, vapor pressure deficits are larger, and the drying of tissues more rapid than in forests or woodlands (D'Antonio and Vitousek 1992, p. 73). Thus, conditions that favor fire are much more frequent in grasslands (D'Antonio and Vitousek 1992, p. 73).

Nonnative plants outcompete native plants by growing faster, and some may release chemicals that inhibit the growth of other plants. Nonnative plants may also displace native species by preventing their reproduction, usually by shading and taking up available sites for seedling establishment (Vitousek *et al.* 1987, pp. 224–227). These competitive advantages allow nonnative plants to convert native-dominated plant communities to nonnative plant communities (Cuddihy and Stone 1990, p. 74; Vitousek 1992, pp. 33–35).

In summary, nonnative plants adversely impact native habitat in Hawaii, including 9 of the described Hawaii Island ecosystems that support 14 of the 15 species (not the anchialine pool shrimp), and directly adversely impact the 13 plant species, by: (1) Modifying the availability of light through alterations of the canopy structure; (2) altering soil-water regimes; (3) modifying nutrient cycling; (4) altering the fire regime affecting native plant communities (e.g., successive fires that burn farther and farther into native habitat, destroying native plants and removing habitat for native species by altering microclimatic conditions to favor alien species); and (5) ultimately converting native-dominated plant communities to nonnative plant communities (Smith 1985, pp. 180–181; Cuddihy and Stone, 1990, p. 74; D'Antonio and Vitousek 1992, p. 73; Vitousek *et al.* 1997, p. 6).

A summary of the specific impacts of nonnative plant species is included below. Please refer to the proposed rule (77 FR 63928; October 17, 2012) for a list of nonnative plants organized by their ecosystems, a detailed discussion of their specific negative effects on the 14 affected Hawaii Island species, and the literature cited for each nonnative plant species. In particular, we note that we provide discussions of nonnative plants in coastal, lowland wet, dry cliff, and wet cliff ecosystems in this rule (below), but the discussions for nonnative plants in the lowland dry, lowland mesic, montane dry, montane mesic, and montane wet ecosystems can be found in the October 17, 2012, proposed rule (77 FR 63928). Based on comments we received on the proposed rule, we have also added information below regarding the nonnative plants wedelia, strawberry guava, and skunk weed that pose threats to three plants, *Bidens hillebrandiana* ssp. *hillebrandiana* (threats from wedelia), *Cyanea tritomantha* (threats from strawberry guava), and *Cyrtandra nanawaleensis* (threats from skunk weed), in this final rule.

• *Andropogon virginicus* may release allelopathic substances that dramatically decrease native plant reestablishment, and has become dominant in areas subjected to natural or human-induced fires.

• *Anemone hupehensis* var. *japonica* has wind-distributed seeds, and resists grazing because of toxic chemicals that induce vomiting when ingested.

• *Angiopteris evecta* forms dense stands that displace and shade out native plants.

• *Axonopus fissifolius* can outcompete other grasses in wet forests and bogs and outcompetes native plants for moisture.

• *Buddleia asiatica* can tolerate a wide range of habitats, forms dense thickets, and is rapidly spreading into wet forest and lava and cinder substrate areas in Hawaii, displacing native vegetation.

• *Casuarina equisetifolia* forms monotypic stands under which little else grows. It is thought that the roots and needle litter exude a chemical that kills other plants.

• *Clidemia hirta* forms a dense understory, shades out native plants, and prevents their regeneration.

• *Delairea odorata* covers and suppresses growth and germination of native species by carpeting the ground and rooting down at leaf nodes. This species can also grow in the canopy, where it smothers native trees.

• *Digitaria setigera* propagates by seeds and runners; a single flowering stem produces hundreds of seeds.

• *Ehrharta stipoides* creates a thick mat in which other species cannot regenerate; its seeds are easily dispersed by awns (slender, terminal bristle-like process found at the spikelette in many grasses) that attach to fur or clothing.

• *Erigeron karvinskianus* spreads rapidly by stem layering and regrowth of broken roots to form dense mats, crowding out and displacing ground-level plants.

• *Falcataria moluccana* can quickly establish in disturbed and nondisturbed mesic to wet areas. Its rapid growth habit enables it to outcompete slow-growing native trees by reducing light availability, and its abundant, high-quality litter alters nutrient dynamics in the soil.

• *Grevillea* spp. leaves produce an allelopathic substance that inhibits the establishment of all other plant species underneath the canopy.

• *Hedychium* spp. form vast, dense colonies, displacing other plant species, and reproduce by rhizomes where already established. In addition to outcompeting native plants, *Hedychium* spp. reduce the amount of nitrogen in the *Metrosideros* forest canopy in Hawaii, impacting the availability of nutrients for native plants.

• *Heterotheca grandiflora* is an opportunistic colonizer that grows quickly, forms dense stands, and inhibits recruitment of native plants.

• *Juncus effusus* spreads by seeds and rhizomes, and forms dense mats that crowd out native plants.

• *Juncus* is a weedy colonizer that can tolerate environmental stress and outcompete native species.

• *Juncus planifolius* forms dense mats and has the potential to displace native plants by preventing establishment of native seedlings.

• *Lantana camara* is aggressive, thorny, and forms thickets, crowding out and preventing the establishment of native plants.

• *Leucaena leucocephala* is an aggressive competitor that often forms the dominant element of the vegetation in low-elevation, dry, disturbed areas in Hawaii.

• Plants in the genus *Melastoma* have high germination rates, exhibit rapid growth, have possible asexual reproduction, and are efficient at seed dispersal, especially by birds that are attracted by copious production of berries. These characteristics enable the plants to be aggressive competitors in Hawaiian ecosystems.

• *Melinis repens* invades disturbed dry areas from coastal regions to subalpine forest; dense stands of this species can contribute to recurrent fires.

• *Miconia calvescens* reproduces in dense shade, eventually shading out all other plants to form a monoculture.

• *Omalanthus populifolius* has the potential to colonize entire gulches, displacing and inhibiting the regeneration of native plants.

• *Paederia foetida* (skunk weed) is a perennial climbing or trailing vine in the coffee family (Rubiaceae) that can grow to 30 ft (9 m) long and occurs on Kauai, Oahu, Maui, and Hawaii Island (Center for Invasive Species and Ecosystem Health (CISEH 2010, in litt.; U.S. Forest Service 2013, in litt.). It reproduces vegetatively or by seed, and can invade natural and disturbed areas in Hawaii. It completely covers and smothers understory vegetation, outcompetes low-growing plants and small shrubs for light and space, and can form mat-like sheaths that may cover several acres (CISEH 2010, in litt.; U.S. Forest Service 2013, in litt.).

• *Paspalum conjugatum* has small, hairy seeds are easily transported on humans and animals, or are carried by the wind through native forests, where it establishes and displaces native vegetation.

• *Passiflora edulis* is a vigorous vine that overgrows and smothers the forest canopy; its fruit encourages rooting and trampling by feral pigs.

• *Passiflora tarminiana* is now a serious pest in mesic forest, where it overgrows and smothers the forest canopy. Seeds are readily dispersed by humans, birds, and feral pigs; fallen fruit encourage rooting and trampling by pigs.

• *Pennisetum setaceum* is an aggressive colonizer that outcompetes most native species by forming widespread, dense, thick mats. This species is also fire-adapted and burns swiftly and hot, causing extensive damage to the surrounding habitat.

• *Pluchea* spp. are adapted to a wide variety of soils and sites, tolerate excessively well-drained to poorly drained soil conditions, the full range of soil textures, acid and alkaline reactions, salt and salt spray, and compaction. They quickly invade burned areas, but being early successional, they are soon replaced by other species. These adaptive capabilities increase the species' competitive abilities over native plants.

• *Polygonum punctatum* forms dense patches that prohibit the establishment of native plants after disturbance events.

• *Prosopis pallida* overshadows other vegetation and has deep tap roots that significantly reduce available water for native dryland plants. This plant fixes nitrogen and can outcompete native species.

• *Psidium cattleianum* forms dense stands in which few other plants can grow, displacing native vegetation through competition. The fruit is eaten by feral pigs and birds that disperse the seeds throughout the forest.

• *Rubus argutus* displaces native vegetation through competition.

• *Rubus ellipticus* smothers smaller plants, including native species.

• *Rubus rosifolius* forms dense thickets and outcompetes native plant species. It easily reproduces from roots left in the ground, and seeds are spread by birds and feral animals.

• *Schefflera actinophylla* is shade tolerant and can spread deep into undisturbed forests, forming dense thickets, as its numerous seeds are readily dispersed by birds. It grows epiphytically, strangling its host tree.

• *Schinus terebinthifolius* forms dense thickets in all habitats, and its red berries are attractive to and dispersed by birds. The seedlings grow very slowly and can survive in dense shade, exhibiting vigorous growth when the canopy is opened after a disturbance, allowing it to displace native vegetation through competition.

• *Senecio madagascariensis* can produce abundant seeds each year that are easily distributed by wind. This combination of long-range dispersal of its seeds and its allelopathic properties enables this species to successfully outcompete native plants.

• *Setaria palmifolia* is resistant to fire and recovers quickly after being burned, outcompeting native vegetation.

• *Sphagneticola trilobata* is a creeping, mat-forming, fast-growing perennial herb in the sunflower (Asteraceae) family. It is found on all of the main Hawaiian Islands (Thaman 1999, pp. 1–10) and is considered one of Hawaii's most invasive horticultural plants. It has spread throughout the Pacific and in many cases has become a noxious weed, covering extensive areas in agricultural lands, along roadsides and trailsides, in open lots, in waste places and garbage dumps, and at other disturbed sites (Thaman 1999, pp. 1–10; HEAR 2013). This species can also be found in relatively undisturbed sites along coastlines, often out-competing native coastal herbaceous species, like *Bidens hillebrandiana* ssp. *hillebrandiana* (Thaman 1999, pp. 1–10).

• *Cyathea cooperi* can achieve high densities in native Hawaiian forests and displace native species. Understory disturbance by feral pigs facilitates the establishment of this species, which has been known to spread over 7 mi (12 km) through windblown dispersal of spores from plant nurseries.

• *Tibouchina* spp. is naturalized and abundant in disturbed mesic to wet forest on the islands of Molokai, Lanai, Maui, and Hawaii. It forms dense thickets, crowding out all other plant species, and inhibits regeneration of native plants.

• *Ulex europaeus* spreads numerous seeds by explosive opening of the pods. It can rapidly form extensive dense and impenetrable infestations, and competes with native plants, preventing their establishment.

Nonnative Plants in the Coastal Ecosystem

Nonnative plant species that pose a threat to *Bidens hillebrandiana* ssp. *hillebrandiana,* the only plant species in this final rule that inhabits the coastal ecosystem on Hawaii Island, include the understory and subcanopy species *Pluchea carolinensis* (sourbush), *P. indica* (Indian fleabane), *Lantana camara* (lantana), *Melastoma* spp., and *Sphagneticola trilobata* (wedelia) (Perlman and Wood 2006, in litt.; Bio 2011, pers. comm.; Perry 2012, in litt.). These nonnative plants species are fast growing, and form either thickets or dense mats that crowd out and prevent establishment of individuals of *Bidens hillebrandiana* ssp. *hillebrandiana.* Nonnative canopy species that pose a threat to *B. hillebrandiana* ssp. *hillebrandiana* include *Casuarina equisetifolia* (ironwood), which form monotypic stands that prevent the growth of *B. hillebrandiana* ssp. *hillebrandiana* below by over shading and accumulation of pine needle litter (Perlman and Wood 2006, in litt.). In addition, the nonnative grass *Pennisetum setaceum* (fountain grass) is a threat to *B. hillebrandiana* ssp. *hillebrandiana* (Perlman and Wood 2006, in litt.; Bio 2011, pers. comm.) because fountain grass forms dense mats that cover very large areas, thus outcompeting *B. hillebrandiana* ssp. *hillebrandiana,* in addition to being a notorious fire-adapted plant that burns swiftly and hot, causing extensive damage to surrounding habitat. These nonnative plant species pose serious and ongoing threats to the species *B. hillebrandiana* ssp. *hillebrandiana,* which depends on this ecosystem.

Nonnative Plants in the Dry Cliff Ecosystem

Nonnative plant species that are a threat to *Bidens hillebrandiana* ssp. *hillebrandiana,* the only plant species in this final rule that inhabits the dry cliff ecosystem on Hawaii Island, include the understory and subcanopy species *Lantana camara, Melastoma* spp., *Pluchea carolinensis,* and *Sphagneticola trilobata* (Perlman and Wood 2006, in litt.; Bio 2011, pers. comm.; Perry 2012, in litt.). These nonnative plants species are fast growing, and form either thickets or dense mats that crowd out and prevent establishment of individuals of *Bidens hillebrandiana* ssp. *hillebrandiana.* Nonnative canopy species that pose a threat to *B. hillebrandiana* ssp. *hillebrandiana* include *Casuarina equisetifolia* and *Psidium cattleianum* (Perlman and Wood 2006, in litt.; Bio 2011, pers. comm.), which form monotypic stands that prevent the growth of *B. hillebrandiana* ssp. *hillebrandiana* below by over shading and crowding out. In addition, *Casuarina equisetifolia* accumulates high levels of pine needle litter that further prevent understory growth. The nonnative grasses *Digitaria setigera* and *Pennisetum setaceum* pose a threat to this ecosystem (Perlman and Wood 2006, in litt.; Bio 2011, pers. comm.). Fountain grass forms dense mats that cover very large areas, thus outcompeting *Bidens hillebrandiana* ssp. *hillebrandiana,* in addition to being a notorious fire adapted plant that burns swiftly and hot, causing extensive damage to surrounding habitat. *Digitaria setigera* propagates by seeds and runners, and a single flower stem produces hundreds of seeds, which crowds out *Bidens hillebrandiana* ssp. *hillebrandiana,* thus preventing regeneration. These nonnative plant species pose serious and ongoing threats to *Bidens hillebrandiana* ssp. *hillebrandiana,* which depends on this ecosystem.

Nonnative Plants in the Lowland Wet Ecosystem

Nonnative plant species that are a threat to the 7 of the 13 plant species (*Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Phyllostegia floribunda, Platydesma remyi,* and *Pritchardia lanigera*) in this final rule that inhabit the lowland wet ecosystem on Hawaii Island include the understory and subcanopy species *Clidemia hirta* (Koster's curse), *Erigeron karvinskianus* (daisy fleabane), *Hedychium gardnerianum, Juncus effusus* (Japanese mat rush), *J. ensifolius* (dagger-leaved rush), *J. planifolius* (bog rush), *Melastoma* spp., *Paederia foetida* (skunk weed), *Passiflora edulis* (passion fruit), *P. tarminiana* (banana poka), *Polygonum punctatum* (water smartweed), *Rubus argutus* (prickly Florida blackberry), *R.ellipticus* (yellow Himalayan raspberry), *R. rosifolius, Cyathea cooperi* (Australian tree fern), *Tibouchina herbacea* (glorybush), and *T. urvilleana* (princess flower) (Wood 1995, in litt.; Perlman *et al.* 2001, in litt.; Perlman and Wood 2006, in litt.; Perlman and Perry 2003, in litt.; Lorence and Perlman 2007, pp. 357–361; PEPP 2007, pp. 1–65; PEPP 2008, pp. 87–111; Perlman and Bio 2008, in litt.; Perlman *et al.* 2008, in litt.; HBMP 2010c; HBMP 2010e; HBMP 2010f; HBMP 2010g; HBMP 2010h; HBMP 2010i; PEPP 2010, pp. 33–121; Perry 2012, in litt.). These understory nonnative plant species overcrowd, displace, smother, or shade out the seven plant species listed as endangered species in this rule (see above) that occupy the lowland wet ecosystem. Nonnative canopy species that are a threat to the seven species include *Angiopteris evecta* (mule's foot fern), *Falcataria moluccana* (albizia), *Miconia calvescens* (miconia), *Psidium cattleianum,* and *Schefflera actinophylla* (octopus tree) (Palmer 2003, p. 48; HBMP 2010c; HBMP 2010e; HBMP 2010f; HBMP 2010g; HBMP 2010h; HBMP 2010i; PEPP 2010, p. 62; Lau 2011, in litt.; Magnacca 2011b, pers. comm.; Pratt 2011a, in litt.; Price 2011, in litt.). These nonnative canopy species form dense stands that shade out and over crowd the 7 plant species listed as

endangered species in this rule (see above) that inhabit the lowland wet ecosystem. Nonnative grasses that pose a threat to this ecosystem are *Ehrharta stipoides* and *Setaria palmifolia* (palmgrass) (Lorence and Perlman 2007, pp. 357–361; PEPP 2007, pp. 1–65; HBMP 2010c; HBMP 2010f; HBMP 2010g), because they form thick mats that prevent growth and regeneration of the seven plant species listed as endangered species (see above) in this rule that occupy the lowland wet ecosystem.These nonnative plant species pose serious and ongoing threats to the seven species that depend on this ecosystem.

Nonnative Plants in the Wet Cliff Ecosystem

Nonnative plant species that pose a threat to the three plant species (*Cyanea tritomantha, Pritchardia lanigera,* and *Stenogyne cranwelliae*) in this final rule that inhabit the wet cliff ecosystem on Hawaii Island include the canopy, understory and subcanopy species *Hedychium coronarium, H. gardnerianum, Juncus effusus, Passiflora tarminiana, Psidium cattleianum, Rubus rosifolius, Tibouchina herbacea,* and *T. urvilleana* (HBMP 2010c; HBMP 2010f; HBMP 2010k; Perry 2012, in litt.). These understory nonnative plant species overcrowd, displace, smother, or shade out the three plant species listed as endangered species in this rule (see above) that occupy the wet cliff ecosystem. The nonnative grasses *Axonopus fissifolius, Ehrharta stipoides, Paspalum conjugatum,* and *Setaria palmifolia* also pose a threat to the three species in this ecosystem (HBMP 2010c; HBMP 2010f; HBMP 2010k), because they form thick mats that prevent growth and regeneration. These nonnative plant species pose serious and ongoing threats to the three species that depend on this ecosystem.

Habitat Destruction and Modification by Fire

Fire is an increasing, human-exacerbated threat to native species and native ecosystems in Hawaii. The historical fire regime in Hawaii was characterized by infrequent, low severity fires, as few natural ignition sources existed (Cuddihy and Stone 1990, p. 91; Smith and Tunison 1992, pp. 395–397). It is believed that prior to human colonization, fuel was sparse and inflammable in wet plant communities and seasonally flammable in mesic and dry plant communities. The primary ignition sources were volcanism and lightning (Baker *et al.* 2009, p. 43). Natural fuel beds were often discontinuous, and rainfall in many areas on most islands was, and is, moderate to high. Fires inadvertently or intentionally ignited by the original Polynesians in Hawaii probably contributed to the initial decline of native vegetation in the drier plains and foothills. These early settlers practiced slash-and-burn agriculture that created open lowland areas suitable for the later colonization of nonnative, fire-adapted grasses (Kirch 1982, pp. 5–6, 8; Cuddihy and Stone 1990, pp. 30–31). Beginning in the late 18th century, Europeans and Americans introduced plants and animals that further degraded native Hawaiian ecosystems. Pasturage and ranching, in particular, created high fire-prone areas of nonnative grasses and shrubs (D'Antonio and Vitousek 1992, p. 67). Although fires were historically infrequent in mountainous regions, extensive fires have recently occurred in lowland dry and lowland mesic areas, leading to grass-fire cycles that convert forest to grasslands (D'Antonio and Vitousek 1992, p. 77).

Because several Hawaiian plants show some tolerance of fire, Vogl proposed that naturally occurring fires may have been important in the development of the original Hawaiian flora (Vogl 1969 in Cuddihy and Stone 1990, p. 91; Smith and Tunison 1992, p. 394). However, Mueller-Dombois (1981 in Cuddihy and Stone 1990, p. 91) points out that most natural vegetation types in Hawaii would not carry fire before the introduction of alien grasses, and Smith and Tunison (1992, p. 396) state that native plant fuels typically have low flammability. Because of the greater frequency, intensity, and duration of fires that have resulted from the introduction of nonnative plants (especially grasses), fires are now destructive to native Hawaiian ecosystems (Brown and Smith 2000, p. 172), and a single grass-fueled fire can kill most native trees and shrubs in the burned area (D'Antonio and Vitousek 1992, p. 74).

Fire represents a threat to four of the species found in the lowland dry, lowland mesic, lowland wet, montane dry, and montane mesic ecosystems addressed in this final rule: the plants *Bidens micrantha* ssp. *ctenophylla, Phyllostegia floribunda,* and *Schiedea hawaiiensis;* and the picture-wing fly (see Table 3). Fire can destroy dormant seeds of these species as well as plants themselves, even in steep or inaccessible areas. Successive fires that burn farther and farther into native habitat destroy native plants and remove habitat for native species by altering microclimate conditions favorable to alien plants. Alien plant species most likely to be spread as a consequence of fire are those that produce a high fuel load, are adapted to survive and regenerate after fire, and establish rapidly in newly burned areas. Grasses (particularly those that produce mats of dry material or retain a mass of standing dead leaves) that invade native forests and shrublands provide fuels that allow fire to burn areas that would not otherwise easily burn (Fujioka and Fujii 1980 in Cuddihy and Stone 1990, p. 93; D'Antonio and Vitousek 1992, pp. 70, 73–74; Tunison *et al.* 2002, p. 122). Native woody plants may recover from fire to some degree, but fire shifts the competitive balance toward alien species (National Park Service (NPS) 1989, in Cuddihy and Stone 1990, p. 93). On a post-burn survey at Puuwaawaa on Hawaii Island, an area of native *Diospyros* forest with undergrowth of the nonnative grass *Pennisetum setaceum,* Takeuchi noted that ''no regeneration of native canopy is occurring within the Puuwaawaa burn area'' (Takeuchi 1991, p. 2). Takeuchi (1991, pp. 4, 6) also stated that ''burn events served to accelerate a decline process already in place, compressing into days a sequence that would ordinarily take decades,'' and concluded that in addition to increasing the number of fires, the nonnative *Pennisetum* acted to suppress the establishment of native plants after a fire.

For decades, fires have impacted rare or endangered species and their habitat (HDOFAW 2002, pp. 1, 4–6; Dayton 2007, in litt.; Joint Fire Science Program (JFSP) 2009, pp. 1–12; Weise *et al.* 2010, pp. 199–220; Kakesako 2011, in litt.). On the island of Hawaii, wildfires are caused primarily by lava flows, humans, and lightning, all of which are exacerbated by severe drought and nonnative grasses (e.g., *Pennisetum setaceum*) (Dayton 2007, in litt.; JFSP 2009, pp. 1–6; Armstrong and Media 2010, in litt.; Weise *et al.* 2010, pp. 199–216; Adkins *et al.* 2011, p. 17; Hawaii County Major.com–accessed September 7, 2011; Burnett 2010, in litt.; KHON2, June 6, 2011). Between 2002 and 2003, three successive lava-ignited wildfires in the east rift zone of HVNP affected native forests in lowland dry, lowland mesic, and lowland wet ecosystems (JFSP 2009, p. 3), cumulatively burning an estimated 11,225 ac (4,543 ha) (Wildfire News, June 9, 2003; JFSP 2009, p. 3). These fires destroyed over 95 percent of the canopy cover in the burned areas and encroached upon rainforests (i.e., forests in the lowland wet ecosystem) that were previously thought to have low susceptibility or

even be relatively immune to wildfires (JFSP 2009, pp. 2–3; Wildfire News, June 9, 2003). After the fires, nonnative ferns were reported in the higher elevation rainforests where they had not previously been observed, and were believed to inhibit the ability of the dominant native *Metrosideros polymorpha* (ohia) trees to recover (JFSP 2003, pp. 1–2). Nonnative flammable grasses also spread in the area, under the dead ohia trees (Ainsworth 2011, in litt.), increasing the risk of fire in surrounding native forested areas. In 2011, the Napau Crater wildfire, ignited by an eruption at the Kamoamoa fissure in HVNP, consumed over 2,076 ac (840 ha), including 100 ac (40 ha) of the 2,750-ac (1,113-ha) east rift zone's special ecological area (Ainsworth 2011, in litt.; Kakesako 2011, in litt.). Special ecological areas (SEA) are HVNP's most intact and intensively managed natural systems (Tunison and Stone 1992, pp. 781–798). The plant *Phyllostegia floribunda,* in this final rule, is known from the east rift zone's Napau Crater, in the lowland wet ecosystem (Belfield 1998, pp. 9, 11–13, 23; Pratt 2007b, in litt.; HBMP 2010h). In addition, historical records report that the plant *Cyanea tritomantha,* which is listed as endangered in this rule, also occurred in this area, in the same ecosystem; however, the last survey that reported this occurrence was over 25 years ago (Lamoureux *et al.* 1985, pp. 105, 107–108; HBMP 2010h).

Fire is a threat to the Kona (leeward) side of Hawaii Island. In the past 50 years, there have been three wildfires that burned 20,000 ac (8,094 ha) or more: (1) 20,000 ac (8,094 ha) burned at Puuwaawaa Ranch in 1985; (2) 20,000 acres (8,094 ha) burned at the U.S. Army's PTA in 1994; and (3) 25,000 ac (10,117 ha) burned in Waikoloa in 2005 (Thompson 2005, in litt.). The only known occurrence (25 to 40 individuals) of the plant *Schiedea hawaiiensis,* in this final rule, is found on PTA, and the 1994 fire burned to within 2 mi (4 km) of this species (U.S. Army Garrison 2006, p. 34; Evans 2011, in litt.). Although this fire may seem relatively distant from *S. hawaiiensis,* wildfires can travel from 4 to 8 miles per hour (mph) (6.5 to 13 kilometers per hour (kph)), and burn 2.5 ac (1 ha) to 6 ac (2.5 ha) per minute (the equivalent of 6 to 8 football fields per minute), depending on the fuel type, wind, and slope of land (Burn Institute 2009, p. 4). In 2011, a 500-ac (202-ha) wildfire ignited by lightning and fueled by nonnative *Pennisetum setaceum* burned within the State's Puu Anahulu Game Management Area (GMA) and encroached within a quarter-mile (0.5 km) of PTA (KHON2, June 6, 2011). The Puu Anahulu GMA lies just 3 mi (5 km) northwest of the only known occurrence of *S. hawaiiensis* in the montane dry ecosystem. Also in 2011, a 120-ac (49-ha) wildfire broke out near Kaiminani Street (Jensen 2011, in litt.), just north of Hina Lani Road, in the lowland dry ecosystem, where the largest occurrence of the plant species *Bidens micrantha* ssp. *ctenophylla,* which is listed as endangered in this rule, is found. In addition, the threat of fire to this species is increased by its occurrence in areas bordered by residential developments, schools, and roads, which provide numerous ignition sources from the high volume of human traffic. A recent fire at the Villages of Laiopua subdivision at Kealakehe, known to have been intentionally set, burned close to an area that supports *B. micrantha* ssp. *ctenophylla* (Knoche 2012, in litt.). Although no *B. micrantha* ssp. *ctenophylla* individuals were burned, the immediate proximity of the fire to occupied and unoccupied habitat for this species demonstrates the threat of fire to *B. micrantha* ssp. *ctenophylla* in the lowland dry ecosystem at Kealakehe.

Fire is also a threat to the picture-wing fly *Drosophila digressa* at one of its two known locations (the Manuka NAR) due to the ongoing extreme drought conditions in this region and the resulting accumulation of dead trees (i.e., fuel load), in the lowland mesic and montane mesic ecosystems (Magnacca 2011b, pers. comm.).

Throughout the Hawaiian Islands, increased fuel loads and human-ignited fires caused the average acreage burned to increase five-fold from the early 1900s (1904 to 1939) to the mid-1900s (1940 to 1976) (La Rosa *et al.* 2008, p. 231). In HVNP, fires were three times more frequent and 60 times larger, on average, from the late 1960s to 1995, when compared to data spanning 1934 to the late 1960s (Tunison *et al.* 2001 *in* La Rosa *et al.* 2008, p. 231). The historical fire regimes have been altered from typically rare events to more frequent events, largely a result of continuous fine fuel loads associated with the presence of the fire-tolerant, nonnative fountain grass and the grass-fire feedback cycle that promotes its establishment (La Rosa *et al.* 2008, pp. 240–241; Pau 2009, in litt.). Extreme drought conditions are also contributing to the number and intensity of the wildfires on Hawaii Island (Armstrong and Media 2010, in litt.; Loh 2010, in litt.). In addition, the combination of El Niño conditions (see ''Habitat Destruction and Modification by Climate Change,'' below) in the Pacific, a half-century decline in annual rainfall, and intermittent dry spells has fueled wildfires throughout all of the main Hawaiian Islands (Marcus 2010, in litt.). The entire State is experiencing dry conditions, but Hawaii Island appears to be significantly impacted (Kodama 2010, in litt.; USDA–FSA 2012, in litt.).

Fire is a threat to three plant species (*Bidens micrantha* ssp. *ctenophylla, Phyllostegia floribunda,* and *Schiedea hawaiiensis*), and the picture-wing fly (*Drosophila digressa*), reported from Hawaii Island's lowland dry, lowland mesic, lowland wet, montane dry, and montane mesic ecosystems, because individuals of these species or their habitat are located in or near areas that were burned in previous fires or in areas at risk for fire due to volcanic activity, drought, or the presence of highly flammable nonnative grasses and shrubs.

Habitat Destruction and Modification by Hurricanes

Hurricanes adversely impact native Hawaiian terrestrial habitat and exacerbate the impacts resulting from other threats such as habitat degradation by ungulates and competition with nonnative plants. They do this by destroying native vegetation, opening the canopy and thus modifying the availability of light, and creating disturbed areas conducive to invasion by nonnative pest species (see ''Specific Nonnative Plant Species Impacts,'' on page 63952 of our October 17, 2012, proposed rule (77 FR 63928)) (Asner and Goldstein 1997, p. 148; Harrington *et al.* 1997, pp. 539–540). Canopy gaps allow for the establishment of nonnative plant species, which may be present as plants or as seeds incapable of growing under shaded conditions. Because many Hawaiian plant and animal species, including the 15 species in this final rule, persist in low numbers and in restricted ranges, natural disasters, such as hurricanes, can be particularly devastating (Mitchell *et al.* 2005a, pp. 3–4), although we do not consider hurricanes to represent a present threat to *Vetericaris chaceorum.*

Hurricanes affecting Hawaii were only rarely reported from ships in the area from the 1800s until 1949. Between 1950 and 1997, 22 hurricanes passed near or over the Hawaiian Islands, 5 of which caused serious damage (Businger 1998, pp. 1–2). In November 1982, Hurricane Iwa struck the Hawaiian Islands, with wind gusts exceeding 100 mph (161 kph), causing extensive damage, especially on the islands of Niihau, Kauai, and Oahu (Businger 1998, pp. 2, 6). Many forest trees were

destroyed (Perlman 1992, pp. 1–9), which opened the canopy and facilitated the invasion of nonnative plants (Kitayama and Mueller-Dombois 1995, p. 671). Competition with nonnative plants is a threat to 9 of the 10 ecosystems that support all 13 plant species and the picture-wing fly listed as endangered in this final rule, as described above in ''Habitat Destruction and Modification by Nonnative Plants.'' Nonnative plants also compete with the native host plants of the picture-wing fly.

In addition to habitat destruction and nonnative plant introduction resulting from hurricanes, high winds and intense rains from hurricanes can directly kill individual picture-wing flies to the point of decimating an entire population (Carson 1986, p. 7; Foote and Carson 1995, pp. 369–370). High winds can also dislodge fly larvae from their host plants, destroy host plants, and expose the fly larvae to predation by nonnative yellowjacket wasps (see ''Nonnative Western Yellow-Jacket Wasps,'' under *Factor C. Disease or Predation,* below) (Carson 1986, p. 7; Foote and Carson 1995, p. 371).

Since 1950, 13 hurricanes have passed near but not over Hawaii Island. Eleven of these hurricanes brought heavy rain, strong wind, or high surf to the island, which caused erosion, flash floods, and other damage (Fletcher III *et al.* 2002, pp. 11–17; National Weather Service *et al.* 2010, pp. 1–22). In 1994, tropical depression 1C brought over 14 in (36 cm) of rain in just a few days to windward sections of Hawaii Island (National Oceanic Atmospheric Administration (NOAA) 1994, pp. 4–5; National Weather Service *et al.* 2010, pp. 4–5).

Although there is historical evidence of only one hurricane (1861) that approached from the east and impacted the islands of Maui and Hawaii (Businger 1998, p. 3), damage from future hurricanes could further decrease the remaining native plant-dominated habitat areas that support the 13 plant species and the picture-wing fly (*Drosophila digressa*) listed as endangered in this final rule, in 9 of the described ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff).

Habitat Destruction and Modification Due to Rockfalls, Treefalls, Landslides, Heavy Rain, Inundation by High Surf, Erosion, and Drought

Rockfalls, treefalls, landslides, heavy rain, inundation by high surf, and erosion damage and destroy individual plants, destabilize substrates, and alter hydrological patterns that result in changes to native plant and animal communities. In the open sea near Hawaii, rainfall averages 25 to 30 in (635 to 762 mm) per year, yet the islands may receive up to 15 times this amount in some places, caused by orographic features (physical geography of mountains) (Wagner *et al.* 1999a, pp. 36–44). During storms, rain may fall at 3 in (76 mm) per hour or more, and sometimes may reach nearly 40 in (1,000 mm) in 24 hours, causing destructive flash-flooding in streams and narrow gulches (Wagner *et al.* 1999a, pp. 36–44). Due to the steep topography of some areas on Hawaii Island where 4 of the 13 plants listed as endangered in this final rule remain, erosion and disturbance caused by introduced ungulates exacerbates the potential for rockfalls, treefalls, and landslides, which in turn are a threat to native plants. Such events have the potential to eliminate all individuals of a population, or even all populations of a species, resulting in a greater likelihood of extinction due to the lack of redundancy and resilience of the species caused by their reduced numbers and geographic range.

Rockfalls, treefalls, landslides, heavy rain, inundation by high surf, and subsequent erosion are a threat to four of the plant species (*Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyanea tritomantha,* and *Cyrtandra wagneri*) listed as endangered in this rule (Lorence and Perlman 2007, p. 359; PEPP 2010, p. 52; Bio 2011, pers. comm.). Monitoring data from PEPP and other field biologists and surveyors indicate that these four species are threatened by these events as they are found in landscape settings susceptible to these events (e.g., lava tubes, stream banks, steep slopes and cliffs). Field survey data presented by PEPP and other field biologists document that individuals of *Bidens hillebrandiana* ssp. *hillebrandiana* that occur on steep sea cliffs are threatened by rockfalls, landslides, inundation by high surf, and subsequent erosion; 1 of the 27 known individuals of *Cyanea marksii* is threatened by falling rocks and landslides; and individuals of *Cyanea tritomantha* are threatened by treefalls (PEPP 2007, p. 52; Bio 2011, pers. comm.; Perry 2012, in litt.). Field survey data presented by Lorence and Perlman (2007, p. 359) indicate that heavy rains and subsequent erosion threaten the only known location of *Cyrtandra wagneri* on a stream bank in the Laupahoehoe NAR. As *Cyrtandra wagneri* is currently only known from a total of eight individuals along the steep banks of Kilau Stream, heavy rains and erosion could lead to near extirpation or even extinction of this species by direct destruction of the individual plants, mechanical damage to individual plants that could lead to their death, or destabilization of the stream bank habitat leading to additional erosion.

Two plant species, *Bidens micrantha* ssp. *ctenophylla* and *Schiedea hawaiiensis,* and the picture-wing fly (*Drosophila digressa*), which are listed as endangered in this final rule, may also be affected by habitat loss or degradation associated with droughts, which are not uncommon in the Hawaiian Islands (HDLNR 2009, pp. 1–6; Hawaii State Civil Defense 2011, pp. 14–1—14–12; U.S. National Drought Mitigation Center (NDMC) 2012—*Online Archives*). Between 1901 and 2011, there have been at least 18 serious or severe droughts that have impacted Hawaii Island, including the current drought that began in 2008, and has led to the island's first ever drought exceptional designation (the highest drought level rating on the scale) (between March and December of 2010) (HDLNR 2009, pp. 1–6; Hawaii Civil Defense 2011, pp. 14–1—14–12). According to the NDMC's drought rating system, most of the island has been rated as in severe drought since 2008, with extreme drought ratings intermittently in some portions of the island (NDMC 2012—*Online Archives*). Giambelluca *et al.* (1991, pp. 3–4) compiled descriptive accounts of drought throughout the Hawaiian Islands between 1860 and 1986, and found that 87 episodes of drought occurred on Hawaii Island between those years, although some of those episodes occurred for periods as short as one month. The 2011 winter weather system brought periods of heavy rain from Kauai to Maui; however, these systems weakened or moved away from Hawaii Island, leaving the typically wet windward slopes of the island under moderate drought conditions (NOAA 2011—*Online Climate Data Center*). The entire windward side of Hawaii Island is currently in an abnormally dry state (NDMC 2011—*Online Archives;* NDMC 2012—*Online Archives*). As of March 2013, the U.S. Drought Monitor (USDM) (USDM 2013—*Online Database;* USDM 2013—*Online Archives*) continues to report severe drought (a D2 rating-on a scale ranging from D0 (abnormally dry), D1 (moderate), D3 (extreme), to D4 (exceptional)) along the entire leeward side of Hawaii Island, with extreme drought in some areas of North Kona and South Kohala. Drought conditions

are expected to continue on Hawaii Island (NOAA 2013, in litt.).

Pohakuloa Training Area (the location of the only known individuals of the plant *Schiedea hawaiiensis*) was rated as experiencing extreme drought during the spring of 2011 (Hawaii State Civil Defense 2011, pp. 14–1—14–12), and in 2010, as well as most of north and south Kona. North Kona, including the lowland dry ecosystem that supports the largest occurrence of the plant *Bidens micrantha* ssp. *ctenophylla,* has been experiencing conditions of extreme to severe drought over the past few years. One of the two known extant populations of the picture-wing fly *Drosophila digressa* is found in the lowland mesic and montane mesic ecosystems in south Kona, in an area that has also experienced extreme to severe drought over the past few years. Drought alters the decay processes of the picture-wing fly's host plants (*Charpentiera* spp. and *Pisonia* spp.) and the entire plant community on which the fly depends. The ongoing drought in south Kona has resulted in an increasing accumulation of dead trees in the Manuka NAR, which increases the fuel load and threat of wildfires in the area where one of the two known occurrences of the picture-wing fly is found (Magnacca 2011b, pers. comm.). According to Magnacca (2013, in litt.) almost the entire ohia (*Metrosideros polymorpha*) canopy at the Manuka NAR has died over the past 10 to 20 years, due to prolonged drought. This area previously received most of its water input from fog interception by the tall ohia trees rather than rainfall (Magnacca 2013, in litt.). Although the dominant host plant of the picture-wing fly at this site, *Pisonia* spp., is temporarily experiencing a growth spurt due to increase in sunlight caused from the ohia dieback, Magnacca believes this increase in *Pisonia* spp. seedlings and juveniles is unlikely to be sustained over time. If these plants survive to maturity, Magnacca doubts the much drier habitat conditions will be suitable to support the picture-wing fly (Magnacca 2013, in litt.). Monitoring data collected in HVNP during a drought period between 1981 and 1982 suggest that drought was associated with a reduction in the number of picture-wing flies one year following the drought (Carson 1986, pp. 4, 7).

Severe episodes of drought cannot only directly kill individuals of a species or entire populations, but drought frequently leads to an increase in the number and intensity of forest and brush fires (see ''Habitat Destruction and Modification by Fire,'' above), causing a reduction of native plant cover and habitat, an increase in nonnative plant and animal species, and a reduction in availability of host plants for the picture-wing fly (Giambelluca *et al.* 1991, p. v; D'Antonio and Vitousek 1992, pp. 77–79; HDLNR 2009, pp. 1–6; Hawaii Civil Defense 2011, pp. 14–1—14–12). Ecosystems altered by drought and subsequent fires are further altered by the introduction of nonnative species that outcompete native species for basic life-cycle requirements (see ''Habitat Destruction and Modification by Nonnative Plants,'' above). To further exacerbate the situation, nonnative ungulate patterns may be altered as observed on Maui, where recent episodes of drought have driven axis deer farther into urban and forested areas for food, increasing their negative impacts to native vegetation from herbivory and trampling (Waring 1996, in litt., p. 5; Nishibayashi 2001, in litt.; Medeiros 2010, pers. comm.). Due to the recent widespread increase in frequency and intensity of drought on the island of Hawaii, even the wettest forests on the windward side of the island may be threatened by long-term drought (JFSP 2009, pp. 1–12). Prolonged periods of water deprivation caused by drought can also lead to the direct death of the remaining individuals of the plants *Schiedea hawaiiensis* and *Bidens micrantha* ssp. *ctenophylla,* and the picture-wing fly, possibly leading to extinction of one or more of these species. Drought is a direct threat to two of the plant species (*Bidens micrantha* ssp. *ctenophylla* and *Schiedea hawaiiensis*), and the picture-wing fly (*Drosophila digressa*), which are listed as endangered in this final rule, as discussed above.

Habitat Destruction and Modification by Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate. The terms ''climate'' and ''climate change'' are defined by the Intergovernmental Panel on Climate Change (IPCC). ''Climate'' refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (Le Treut *et al.* 2007, pp. 93–127). The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (e.g., temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (Le Treut *et al.* 2007, pp. 93–127). Various types of changes in climate can have direct or indirect effects on species. These effects may be positive, neutral, or negative, and they may change over time, depending on the species and other relevant considerations, such as the effects of interactions of climate with other variables (e.g., habitat fragmentation) (IPCC 2007, pp. 8–14, 18–19). In our analyses, we use our expert judgment to weigh relevant information, including uncertainty, in our consideration of various aspects of climate change.

Climate change will be a particular challenge for the conservation of biodiversity because the introduction and interaction of additional stressors may push species beyond their ability to survive (Lovejoy 2005, pp. 325–326). The synergistic implications of climate change and habitat fragmentation are the most threatening facet of climate change for biodiversity (Hannah *et al.* 2005, p. 4).

The magnitude and intensity of the impacts of global climate change and increasing temperatures on native Hawaiian ecosystems are unknown. Currently, there are no climate change studies that specifically address impacts to the Hawaii Island ecosystems discussed here or the 15 species at issue in this rule. Based on the best available information, climate change impacts could lead to the loss of native species that comprise the communities in which the 15 species occur (Pounds *et al.* 1999, pp. 611–612; Still *et al.* 1999, p. 610; Benning *et al.* 2002, pp. 14,246–14,248; Allen *et al.* 2010, pp. 660–662; Sturrock *et al.* 2011, p. 144; Towsend *et al.* 2011, p. 15; Warren 2011, pp. 221–226). In addition, weather regime changes (droughts, floods) will likely result from increased annual average temperatures related to more frequent El Niño episodes in Hawaii (Giambelluca *et al.* 1991, p. v). Future changes in precipitation and the forecast of those changes are highly uncertain because they depend, in part, on how the El Niño-La Niña weather cycle (a disruption of the ocean atmospheric system in the tropical Pacific having important global consequences for weather and climate) might change (State of Hawaii 1998, pp. 2–10). The 15 species in this final rule may be especially vulnerable to extinction due to anticipated environmental changes that may result from global climate change, due to their small population size and highly restricted ranges. Environmental changes that may affect these species are expected to include habitat loss or alteration and changes in disturbance regimes (e.g., storms and hurricanes). The probability of a species going extinct as a result of these factors increases when its range is restricted,

habitat decreases, and population numbers decline (IPCC 2007, p. 8). The 15 species have limited environmental tolerances, limited ranges, restricted habitat requirements, small population sizes, and low numbers of individuals. Therefore, we would expect these species to be particularly vulnerable to projected environmental impacts that may result from changes in climate, and subsequent impacts to their habitats (e.g., Pounds *et al.* 1999, pp. 611–612; Still *et al.* 1999, p. 610; Benning *et al.* 2002, pp. 14,246–14,248). We believe changes in environmental conditions that may result from climate change may impact these 15 species and their habitat, and we do not anticipate a reduction in this potential threat in the near future.

Climate Change and Ambient Temperature

The average ambient air temperature (at sea level) is projected to increase by about 4.1 degrees Fahrenheit (°F) (2.3 degrees Centigrade (°C)) with a range of 2.7 °F to 6.7 °F (1.5 °C to 3.7 °C) by 2100 worldwide (Trenberth *et al.* 2007, pp. 235–336). These changes would increase the monthly average temperature of the Hawaiian Islands from the current value of 74 °F (23.3 °C) to between 77 °F and 86 °F (25 °C and 30 °C). Historically, temperature has been rising over the last 100 years, with the greatest increase after 1975 (Alexander *et al.* 2006, pp. 1–22; Giambelluca *et al.* 2008, p. 1). The rate of increase at low elevation (0.16 °F; 0.09 °C) per decade is below the observed global temperature rise of 0.32 °F (0.18 °C) per decade (Trenberth *et al.* 2007, pp. 235–336). However, at high elevations, the rate of increase (0.48 °F (0.27 °C) per decade) greatly exceeds the global rate (Trenberth *et al.* 2007, pp. 235–336).

Overall, the daily temperature range in Hawaii is decreasing, resulting in a warmer environment, especially at higher elevations and at night. In the main Hawaiian Islands, predicted changes associated with increases in temperature include a shift in vegetation zones upslope, shift in animal species' ranges, changes in mean precipitation with unpredictable effects on local environments, increased occurrence of drought cycles, and increases in the intensity and number of hurricanes (Loope and Giambelluca 1998, pp. 514–515; U.S. Global Change Research Program (US–GCRP) 2009, pp. 1–188). In addition, weather regime changes (e.g., droughts, floods) will likely result from increased annual average temperatures related to more frequent El Niño episodes in Hawaii (Giambelluca *et al.* 1991, p. v). However, despite considerable progress made by expert scientists toward understanding the impacts of climate change on many of the processes that contribute to El Niño variability, it is not possible to say whether or not El Niño activity will be affected by climate change (Collins *et al.* 2010, p. 391).

Globally, the warming atmosphere is creating a plethora of anticipated and unanticipated environmental changes such as melting ice caps, decline in annual snow mass, sea-level rise, ocean acidification, increase in storm frequency and intensity (e.g., hurricanes, cyclones, and tornadoes), and altered precipitation patterns that contribute to regional increases in floods, heat waves, drought, and wildfires that also displace species and alter or destroy natural ecosystems (Pounds *et al.* 1999, pp. 611–612; IPCC AR4 2007, pp. 26–73; Marshall *et al.* 2008, p. 273; U.S. Climate Change Science Program 2008, pp. 1–164; Flannigan *et al.* 2009, p. 483; US–GCRP 2009, pp. 1–188; Allen *et al.* 2010, pp. 660–662; Warren 2011, pp. 221–226). These environmental changes are predicted to alter species' migration patterns, lifecycles, and ecosystem processes, such as nutrient cycles, water availability, and decomposition (IPCC AR4 2007, pp. 26–73; Pounds *et al.* 1999, pp. 611–612; Sturrock *et al.* 2011, p. 144; Townsend *et al.* 2011, p. 15; Warren 2011, pp. 221–226). The species extinction rate is predicted to increase congruent with ambient temperature increase (US–GCRP 2009, pp. 1–188). In Hawaii, these environmental changes associated with a rise in ambient temperature can directly and indirectly impact the survival of native plants and animals, including the 15 species in this final rule, and the ecosystems that support them.

Climate Change and Precipitation

As global surface temperature rises, the evaporation of water vapor increases, resulting in higher concentrations of water vapor in the atmosphere, further resulting in altered global precipitation patterns (U.S. National Science and Technology Council (US–NSTC) 2008, pp. 69–94; US–GCRP 2009, pp. 1–188). While annual global precipitation has increased over the last 100 years, the combined effect of increases in evaporation and evapotranspiration is causing land surface drying in some regions leading to a greater incidence and severity of drought (US–NSTC 2008, pp. 69–94; US–GCRP 2009, pp. 1–188). Over the past 100 years, the Hawaiian Islands have experienced an annual decline in precipitation of just over 9 percent (US–NSTC 2008, p. 70). Other data on precipitation in Hawaii, which include sea-level precipitation and the added orographic effects, show a steady and significant decline of about 15 percent over the last 15 to 20 years (Chu and Chen 2005, pp. 4,881–4,900; Diaz *et al.* 2005, pp. 1–3). Exact future changes in precipitation in Hawaii and the forecast of those changes are uncertain because they depend, in part, on how the El Niño-La Niña weather cycle might change (State of Hawaii 1998, pp. 2–10).

In the oceans around Hawaii, the average annual rainfall at sea level is about 25 in (63.5 cm). The orographic features of the islands increase this annual average to about 70 in (177.8 cm) but can exceed 240 in (609.6 cm) in the wettest mountain areas. Rainfall is distributed unevenly across each high island, and rainfall gradients are extreme (approximately 25 in (63.5 cm) per mile), creating both very dry and very wet areas. Global climate modeling predicts that, by 2100, net precipitation at sea level near the Hawaiian Islands will decrease in winter by about 4 to 6 percent, with no significant change during summer (IPCC AR4 2007, pp. 1–73). Downscaling of global climate models indicates that wet-season (winter) precipitation will decrease by 5 percent to 10 percent, while dry-season (summer) precipitation will increase by about 5 percent (Timm and Diaz 2009, pp. 4,261–4,280). These data are also supported by a steady decline in stream flow beginning in the early 1940s (Oki 2004, p. 1). Altered seasonal moisture regimes can have negative impacts on plant growth cycles and overall negative impacts on natural ecosystems (US–GCRP 2009, pp. 1–188). Long periods of decline in annual precipitation result in a reduction in moisture availability; an increase in drought frequency and intensity; and a self-perpetuating cycle of nonnative plants, fire, and erosion (US–GCRP 2009, pp. 1–188; Warren 2011, pp. 221–226) (see ''Habitat Destruction and Modification by Fire,'' above). These impacts may negatively affect the 15 species in this final rule and the 10 ecosystems that support them.

Climate Change, and Tropical Cyclone Frequency and Intensity

A tropical cyclone is the generic term for a medium-scale to large-scale, low-pressure storm system over tropical or subtropical waters with organized convection (i.e., thunderstorm activity) and definite cyclonic surface wind circulation (counterclockwise direction in the Northern Hemisphere) (Holland

1993, pp. 1–8). In the Northeast Pacific Ocean, east of the International Date Line, once a tropical cyclone reaches an intensity of winds of at least 74 mi per hour (33 m per second), it is considered a hurricane (Neumann 1993, pp. 1–2). Climate modeling has projected changes in tropical cyclone frequency and intensity due to global warming over the next 100 to 200 years (Vecchi and Soden 2007, pp. 1,068–1,069, Figures 2 and 3; Emanuel *et al.* 2008, p. 360, Figure 8; Yu *et al.* 2010, p. 1,371, Figure 14). The frequency of hurricanes generated by tropical cyclones is projected to decrease in the central Pacific (e.g., the main and Northwestern Hawaiian Islands) while storm intensity (strength) is projected to increase by a few percent over this period (Vecchi and Soden 2007, pp. 1,068–1,069, Figures 2 and 3; Emanuel *et al.* 2008, p. 360, Figure 8; Yu *et al.* 2010, p. 1,371, Figure 14). There are no climate model predictions for a change in the duration of Pacific tropical cyclone storm season (which generally runs from May through November).

For more information on this topic, see ''Habitat Destruction and Modification by Hurricanes,'' above.

Climate Change, and Sea-Level Rise and Coastal Inundation

On a global scale, sea level is rising as a result of thermal expansion of warming ocean water; the melting of ice sheets, glaciers, and ice caps; and the addition of water from terrestrial systems (Climate Institute 2011, in litt.). Sea level rose at an average rate of 0.1 in (1.8 mm) per year between 1961 and 2003 (IPCC 2007, pp. 30–73), and the predicted increase by the end of this century, without accounting for ice sheet flow, ranges from 0.6 ft to 2.0 ft (0.18 m to 0.6 m) (IPCC AR4 2007, p. 30). When ice sheet and glacial melt are incorporated into models the average estimated increase in sea level by the year 2100 is approximately 3 to 4 ft (0.9 to 1.2 m), with some estimates as high as 6.6 ft (2.0 m) to 7.8 ft (2.4 m) (Rahmstorf 2007, pp. 368–370; Pfeffer *et al.* 2008, p. 1,340; Fletcher 2009, p. 7; US–GCRP 2009, p. 18). The species *Bidens hillebrandiana* ssp. *hillebrandiana* occurs within the coastal ecosystem. Although there is no specific data available on how sea-level rise and coastal inundation will impact this species, its occurrence in close proximity to the coastline places it at risk of the threat of sea-level rise and coastal inundation due to climate change. In addition, the anchialine pool ecosystem lies within the coastal ecosystem, and although there are no specific data available on how sea-level rise and coastal inundation will impact the anchialine pool shrimp, it is reasonable to conclude that potential impacts from sea-level rise and coastal inundation may include: (1) Complete inundation of pools and therefore elimination of entire anchialine pool habitats, particularly at Manuka; (2) an increase in the likelihood of exposure to predatory native marine fish not normally found in the anchialine pool ecosystem; and (3) powerful storm surf and rubble resulting from the predicted increase in storm intensity that can obliterate pools, create blockage and seal off the connection to the ocean, or interfere with the subterranean passages below.

In summary, increased interannual variability of ambient temperature, precipitation, hurricanes, and sea-level rise and inundation would provide additional stresses on the 10 ecosystems and the 15 associated species in this final rule because they are highly vulnerable to disturbance and related invasion of nonnative species. The probability of a species going extinct as a result of such factors increases when its range is restricted, habitat decreases, and population numbers decline (IPCC 2007, pp. 8–11). In addition, these 15 species are at a greater risk of extinction due to the loss of redundancy and resiliency created by their limited ranges, restricted habitat requirements, small population sizes, or low numbers of individuals. Therefore, we expect these 15 species to be particularly vulnerable to projected environmental impacts that may result from changes in climate and subsequent impacts to their habitats (e.g., Loope and Giambelluca 1998, pp. 504–505; Pounds *et al.* 1999, pp. 611–612; Still *et al.* 1999, p. 610; Benning *et al.* 2002, pp. 14,246–14,248; Giambelluca and Luke 2007, pp. 13–18). Based on the above information, we conclude that changes in environmental conditions that result from climate change have the potential to negatively impact the 15 species in this final rule, and exacerbate other threats. We have concluded from the available data that this potential threat will likely increase in the near future.

Habitat Destruction and Modification by Sedimentation

Anchialine pool habitats can gradually disappear when organic and mineral deposits from aquatic production and wind-blown materials accumulate through a process known as senescence (Maciolek and Brock 1974, p. 3; Brock 2004, pp. 11, 35–36). Conditions promoting rapid senescence are known to include an increased amount of sediment deposition, good exposure to light, shallowness, and a weak connection with the water table, resulting in sediment and detritus accumulating within the pool instead of being flushed away with tidal exchanges and groundwater flow (Maciolek and Brock 1974, p. 3; Brock 2004, pp. 11, 35–36).

Based upon what we know about healthy anchialine pool systems (Brock 2004, pp. 11, 35–36), one or more factors, combined with increased sedimentation, are degrading the health of the Lua o Palahemo pool system, one of the two known locations of *Vetericaris chaceorum*. First, sedimentation in the water column is reducing the capacity of the pool to produce adequate cyanobacteria and algae to support some of the pool's herbivorous hypogeal species. A decreased food supply (i.e., a reduction in cyanobacteria and algae) will lead to a lower abundance of herbivorous hypogeal shrimp species as well as a lower abundance of the known carnivorous species, *Metabetaeus lohena,* and possibly *V. chaceorum.*

Second, increased sedimentation in Lua o Palahemo is overloading the capacity of the pool and lava tube below to adequately flush water to maintain the water quality needed to support the micro-organisms that are fed upon by several of the pool's shrimp species (e.g., *Calliasmata pholidota, Halocaridina palahemo, Halocaridina rubra,* and *Procaris hawaiiana*) and their associated shrimp predators, *Antecaridina lauensis* and *V. chaceorum* (Brock 2004, pp. 10–11, 16).

Third, increased sedimentation and the inability of the pool system to adequately flush its waters are either diminishing or preventing migration and recolonization of the pool by the hypogeal shrimp species from the surrounding porous watertable bedrock. In other words, this lack of porosity is affecting the movement of shrimp to and from food resources, and the accumulating sediment and detritus reduce productivity within the pool. This reduction in productivity reduces the carrying capacity of the habitat to support hypogeal shrimp like *V. chaceorum,* which is listed as endangered in this final rule (Brock 2004, p. 10). Indeed, Brock (2004, p. 16) has established that pool productivity and shrimp presence are interdependent. In some cases, a pool that loses its shrimp populations due, for example, to the introduction of nonnative fish, more quickly loses its capacity to support shrimp in the future as a result of excessive buildup of algae and cyanobacterial mats that block and impede the pool's ability to flush and

maintain necessary water quality (Brock 2004, p. 16).

During a dive survey in 1985, visibility within the lava tube portion of Lua o Palahemo was as great as 20 m (66 ft) (Kinsley and Williams 1986, pp. 417–437). During this dive survey, Kensley and Williams (1986, p. 418) estimated that other species of hypogeal shrimp co-occurring with *V. chaceorum* numbered in the tens of thousands for *Halocaridina* sp., in the thousands for *Procaris hawaiiana,* and less than 100 for *Calliasmata* sp. By 2010, visibility had been reduced to 8 cm (3 in) within the pool itself, and underwater video taken during the survey shows continuous clouds of thick sediment and detritus within the water column below the pool (Wada 2010, in litt.). During this survey, only one *P. hawaiiana* individual was trapped, and seven others were observed in the video footage. No other species of shrimp, including *V. chaceorum,* were observed during the 2010 survey (Wada 2010, in litt.). Kensley and Williams (1986, p. 426) reported fragments of crustaceans, including *P. hawaiiana,* in the gut contents of *V. chaceorum.* While *P. hawaiiana* occurs in other anchialine pool habitats on Hawaii Island and Maui, *V. chaceorum* is currently only known from Lua o Palahemo and four pools at Manuka. A reduction in the abundance of *P. hawaiiana* in one of the two known locations of *V. chaceorum* indicates a loss of food resources for *V. chaceorum,* although further research is needed to confirm this.

During the 2010 survey, it was discovered that a possible partial collapse of the interior rock walls of Lua o Palahemo pool had occurred, and this collapse caused the difficulty experienced by the survey team to survey (via snorkeling) to any depth below the pool's surface (Wada 2010, in litt.). This collapse also contributed to the reduced flushing in the pool portion of Lua o Palahemo, leading to an accumulation of sediment and detritus in the pool. This accumulation of sediment is reducing both food productivity (i.e., reduce the abundance and availability of other species of hypogeal shrimp co-occurring with *V. chaceorum*) and the ability of *V. chaceorum* and other species of hypogeal shrimp co-occurring with *V. chaceorum* to move between the pool and the water table, thus leading to a reduction of their numbers within the pool. Although a recent 2012 survey conducted at Lua o Palahemo (Wada *et al* 2012, in litt.) reported that water visibility had improved since 2010 (Wada 2010, in litt.), particularly from 11 ft (3.5 m) below the surface, neither *V. chaceorum* nor species of *Halocaridina,* which were reported in the tens of thousands in 1985, were observed (Wada *et al.* 2012, in litt.). The Service concludes that degradation of Lua o Palahemo by senescence from sedimentation is an ongoing threat to the continued existence of *V. chaceorum* by degrading the conditions of one of only two known locations of anchialine pools that support this species and by reducing available food resources (Brock 2004, pp. 10–11, 16; Sakihara 2012, in litt.). Sedimentation is not reported to pose a threat to *V. chaceorum* in the pools at Manuka.

Conservation Efforts To Reduce Habitat Destruction, Modification, or Curtailment of Habitat or Range

There are no approved habitat conservation plans (HCPs), candidate conservation agreements (CCAs), or safe harbor agreements (SHAs) that specifically address these 15 species and threats from habitat destruction or modification. We acknowledge that in the State of Hawaii there are several voluntary conservation efforts that may be helping to ameliorate the threats to the 15 species listed as endangered in this final rule due to habitat destruction and modification by nonnative species, fire, natural disasters, and climate change, and the interaction of these threats. However, these efforts are overwhelmed by the number of threats, the extent of these threats across the landscape, and the lack of sufficient resources (e.g., funding) to control or eradicate them from all areas where these 15 species occur now or occurred historically. Some of the voluntary conservation efforts include the 11 island-based watershed partnerships, including the 3 partnerships on Hawaii Island (Three Mountian Alliance (TMA), Kohala Watershed Partnership (KWP), and the Mauna Kea Watershed Alliance (MKWA)). These partnerships are voluntary alliances of public and private landowners ''committed to the common value of protecting forested watersheds for water recharge, conservation, and other ecosystem services through collaborative management'' (*http://hawp.org/partnerships*). Most of the ongoing conservation management actions undertaken by the watershed partnerships address threats to upland habitat from nonnative species (e.g., feral ungulates, nonnative plants) and may include fencing, ungulate removal, and outplanting of native as well as rare, native species on lands within the partnership. Funding for the watershed partnerships is provided through a variety of State and Federal sources, public and private grants, and in-kind services provided by the partners or volunteers.

Current watershed partnership projects on Hawaii Island that will benefit one or more of the 15 species listed as endangered in this final rule include both the building of new fenced exclosures and the maintenance of existing exclosures to exclude feral ungulates. The TMA is preparing to build a fenced exclosure of approximately 12,000 ac (4,856 ha) in the Kau FR bordering the Kahuku Unit of HVNP (Big Island Video News, May 23, 2012) in an area where several occurrences of *Pittosporum hawaiiense* are known (Pratt 2011d, in litt.). At least some individuals of *P. hawaiiense* will be protected from direct impacts from feral pigs, cattle, mouflon, and axis deer, although the exact number of *P. hawaiiense* individuals that will be within the exclosure is unknown. In addition, control of nonnative plants (e.g., *Clidemia hirta, Hedychium gardnerianum, Psidium cattleianum, Rubus ellipticus, Setaria palmifolia, Cyathea cooperi,* and *Tibouchina* spp.) will be conducted within the fenced exclosure (Cole 2013, in litt.). The TMA is also working with the Plant Extinction Prevention Program (see below) on nonnative ungulate and nonnative plant removal in a 270-ac (109-ha) exclosure in the Puu Makaala NAR where one occurrence of *Cyanea tritomantha* and the last individual of *Schiedea diffusa* ssp. *macraei* are known (Ball 2013, pers. comm.). The KWP is constructing a 700-ac (283-ha) fenced exclosure in the Kohala Mountains in an area where individuals of *Pritchardia lanigera* are known. Completion of this fence is expected in 2016 (Ball 2013, pers. comm.; Purell 2013, in litt.). This exclosure will provide protection to individuals of *P. lanigera* from ungulates once the fence is completed and ungulates are removed within the fence. In addition, the KWP plans to control nonnative plants (i.e., *Hedychium gardnerianum* and *Psidium cattleianum*) within the exclosure (Purell 2013, in litt.).

The State of Hawaii's Plant Extinction Prevention (PEP) Program supports conservation of plant species by securing seeds or cuttings (with permission from the State, Federal, or private landowners) from the rarest and most critically endangered native species for propagation and outplanting (*http://pepphi.org*). The PEP Program focusses primarily on species that have fewer than 50 plants remaining in the wild. Funding for this program is from the State of Hawaii, Federal agencies (e.g., Service), and public and private grants. The PEP Program collects,

propagates, and outplants rare plant species on State, Federal, and private lands (with permission) in areas where the species currently and historically occurred, and in species-appropriate habitat. The PEP Program collects, propagates, or outplants eight plant species that are listed as endangered in this final rule (*Cyanea marksii, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Platydesma remyi, Schiedea diffusa* ssp. *macraei, S. hawaiiensis,* and *Stenogyne cranwelliae*) (PEPP 2012, pp. 1–6, 37–43). However, only 2 of these 8 species (*Cyrtandra wagneri* and *Platydesma remyi*) were monitored and checked for possible collection material in 2012 (PEPP 2012, pp. 55, 89). The PEP program is currently assisting TNC by maintaining sections of the Kona Hema Preserve (see below) (Yoshioka 2013, pers. comm.). Overall, the program has not yet been able to directly address broad-scale habitat threats to plants by invasive species.

Voluntary conservation actions undertaken by TNC on one (Kona Hema Preserve) of their three preserves on Hawaii Island provide a conservation benefit to individuals of the plants *Phyllostegia floribunda* and *Pittosporum hawaiiense,* which are listed as endangered in this final rule, that are in a fenced exclosure (the fence provides protection from mouflon, feral pigs, and cattle) (Ball 2013, pers. comm.). In addition, TNC is a member of two watershed partnerships, KWP and TMA.

Voluntary conservation actions undertaken by several private landowners (Kamehameha Schools; Kaloko Properties Corporation, Stanford Carr Development (SCD)—Takeshi Sekiguchi Associates (TSA) Kaloko Makai, LLC, and Takeshi Sekiguchi Associates (TSA) Corporation; Lanihau Properties; Palamanui Global Holdings, LLC; and DHHL) are described in our October 17, 2012, proposed rule (77 FR 63928). These conservation actions provide a conservation benefit and ameliorate some of the threats from nonnative species and wildfire to the plant *Bidens micrantha* ssp. *ctenophylla,* which is listed as endangered in this final rule. In addition, at least 400 individuals of *B. micrantha* ssp. *ctenophylla* have been propagated for the privately owned Koloko Makai Dryland Forest Preserve, and there are currently 300 surviving outplanted individuals (Hawaii Forest Institute 2013, in litt.). Other private landowners are engaged in, or initiating, voluntary conservation actions on their lands, including fencing to exclude ungulates, controlling nonnative plants, and propagation and outplanting of native plant species including *B. micrantha* ssp. *ctenophylla.* These private landowners include the Queen Liliuokalani Trust and the Waikoloa Village Association in partnership with the Waikoloa Dry Forest Initiative (Waikoloa Village Outdoor Circle 2009; Queen Liliuokalani Trust 2013, pers. comm.). The conservation actions provided by these landowners ameliorate some of the threats from nonnative plant species, ungulates, and fire to *B. micrantha* ssp. *ctenophylla.* In addition, with help from the Hawaii Forest Industry Association (HFIA), individuals of *Bidens micrantha* ssp. *ctenophylla* have been propagated and outplanted within the privately owned 70-ac (28-ha) Kaupulehu Dry Forest Preserve, as well as at Koloko-Honokohau National Historical Park (Ball 2013, pers. comm.). According to HFIA (2009, p. 2) and DHHL (2013, in litt.), DHHL's Aupaka Preserve and Uhiuhi Preserve, two of four described in the Laiopua Plant Mitigation and Preserve Restoration Plan, will benefit several listed plant species as well as *B. micrantha* ssp. *ctenophylla,* which is listed as endangered in this final rule, by removing nonnative plant species, outplanting associated native plant species found in the lowland dry ecosystem, and maintaining a system of firebreaks (Leonard Bisel Associates, LLC, and Geometrician Associates 2008, pp. 36–46).

Summary of Habitat Destruction and Modification

The threats to the habitats of each of the 15 species in this final rule are occurring throughout the entire range of each of the species, except where noted above. These threats include land conversion by agriculture and urbanization, nonnative ungulates and plants, fire, natural disasters, environmental changes resulting from climate change, sedimentation, and the interaction of these threats. While the conservation measures described above are a step in the right direction toward addressing the threats to the 15 species, due to the pervasive and expansive nature of the threats resulting in habitat degradation, these measures are insufficient across the landscape and in effort to eliminate these threats to any of the 15 species in this final rule.

Development and urbanization of lowland dry habitat on Hawaii Island represents a serious and ongoing threat to *Bidens micrantha* ssp. *ctenophylla* because of loss and degradation of habitat.

The effects from ungulates are ongoing because ungulates currently occur in all of the 10 ecosystems that support the 15 species in this final rule. The threat posed by introduced ungulates to the species and their habitats in this final rule that occur in these 10 ecosystems (see Table 3) is serious, because they cause: (1) Trampling and grazing that directly impact the plant communities, which include all 13 of the plant species listed as endangered in this rule, and impact the host plants used by the picture-wing fly for shelter, foraging, and reproduction; (2) increased soil disturbance, leading to mechanical damage to individuals of the 13 plant species listed as endangered in this final rule, and also plants used by the picture-wing fly for shelter, foraging, and reproduction; (3) creation of open, disturbed areas conducive to weedy plant invasion and establishment of alien plants from dispersed fruits and seeds, which results over time in the conversion of a community dominated by native vegetation to one dominated by nonnative vegetation (leading to all of the negative impacts associated with nonnative plants, listed below); and (4) increased erosion, followed by sedimentation, affecting the anchialine pool habitat of *V. chaceorum* at Lua o Palahemo. These threats are expected to continue or increase without ungulate control or eradication.

Nonnative plants represent a serious and ongoing threat to 14 of the 15 species listed as endangered in this final rule (all 13 plant species and the picture-wing fly (see Table 3)) through habitat destruction and modification, because they: (1) Adversely impact microhabitat by modifying the availability of light; (2) alter soil-water regimes; (3) modify nutrient cycling processes; (4) alter fire characteristics of native plant habitat, leading to incursions of fire-tolerant nonnative plant species into native habitat; (5) outcompete, and possibly directly inhibit the growth of, native plant species; and (6) create opportunities for subsequent establishment of nonnative vertebrates and invertebrates. Each of these threats can convert native-dominated plant communities to nonnative plant communities (Cuddihy and Stone 1990, p. 74; Vitousek 1992, pp. 33–35). This conversion has negative impacts on all 13 plant species listed as endangered here, as well as the native plant species upon which the picture-wing fly depends for essential life-history needs.

The threat from fire to 4 of the 15 species in this final rule that depend on lowland dry, lowland mesic, lowland wet, montane dry, and montane mesic ecosystems (the plants *Bidens micrantha* ssp. *ctenophylla, Phyllostegia*

floribunda, and *Schiedea hawaiiensis,* and the picture-wing fly; see Table 3) is serious and ongoing because fire damages and destroys native vegetation, including dormant seeds, seedlings, and juvenile and adult plants. Many nonnative, invasive plants, particularly fire-tolerant grasses, outcompete native plants and inhibit their regeneration (D'Antonio and Vitousek 1992, pp. 70, 73–74; Tunison *et al.* 2002, p. 122). Successive fires that burn farther and farther into native habitat destroy native plants and remove habitat for native species by altering microclimatic conditions and creating conditions favorable to alien plants. The threat from fire is unpredictable but increasing in frequency in ecosystems that have been invaded by nonnative, fire-prone grasses and that are experiencing abnormally dry to severe drought conditions.

Natural disasters, such as hurricanes, are a threat to native Hawaiian terrestrial habitat, including 9 of the 10 ecosystems (all except the anchialine pool ecosystem) addressed here, and the 13 plant species listed as endangered in this final rule, because they result in direct impacts to ecosystems and individual plants by opening the forest canopy, modifying available light, and creating disturbed areas that are conducive to invasion by nonnative pest plants (Asner and Goldstein 1997, p. 148; Harrington *et al.* 1997, pp. 346–347). In addition, hurricanes are a threat to the picture-wing fly species in this rule because strong winds and intense rainfall can kill individual host plants, and can dislodge individual flies and their larvae from their host plants and deposit them on the ground, where they may be crushed by falling debris or eaten by nonnative wasps and ants. The impacts of hurricanes and other stochastic natural events can be particularly devastating to 14 of the 15 species (all except the anchialine pool shrimp) because, as a result of other threats, they now persist in low numbers or occur in restricted ranges and are therefore less resilient to such disturbances, rendering them highly vulnerable. Furthermore, a particularly destructive hurricane holds the potential of driving a localized endemic species to extinction in a single event. Hurricanes pose an ongoing and ever-present threat because they are unpredictable and can happen at any time.

Rockfalls, treefalls, landsides, heavy rain, inundation by high surf, and erosion are a threat to four of the species in this final rule (the plants *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyanea tritomantha,* and *Cyrtandra wagneri;* see Table 3) by destabilizing substrates, damaging and destroying individual plants, and altering hydrological patterns, which result in habitat destruction or modification and changes to native plant and animal communities. Drought adversely impacts two plant species (*Bidens micrantha* ssp. *ctenophylla* and *Schiedea hawaiiensis*) and the picture-wing fly (*Drosophila digressa*) by the loss or degradation of habitat due to death of individual native plants and host tree species, as well as an increase in forest and brush fires. These threats are serious and unpredictable, and have the potential to occur at any time.

Changes in environmental conditions that may result from global climate change include increasing temperatures, decreasing precipitation, increasing storm intensities, and sea-level rise and coastal inundation. The consequent impacts on the 15 species listed as endangered in this final rule are related to changes in microclimatic conditions in their habitats. These changes have the potential to cause the loss of native species, including the 15 species being listed as endangered in this final rule, due to direct physiological stress, the loss or alteration of habitat, or changes in disturbance regimes (e.g., droughts, fire, storms, and hurricanes).

Sedimentation of the Lua o Palahemo pool system is a threat to the anchialine pool shrimp (*Vetericaris chaceorum*), which is listed as endangered in this final rule. In particular, the accumulation of sediment and detritus reduces the abundance of food resources, such as *Procaris hawaiiana* and other co-occurring hypogeal shrimp, for *V. chaceorum.*

Factor B. Overutilization for Commercial, Recreational, Scientific or Educational Purposes

The plant species *Pritchardia lanigera* is threatened by overcollection for commercial and recreational purposes (Hillebrand 1888, pp. 21–27; Chapin *et al.* 2004, pp. 273, 278), as discussed below. We are aware that some species of Hawaiian anchialine pool shrimp are sold and purchased on the Internet. However, we do not believe that the anchialine pool shrimp listed as endangered in this final rule is threatened by overcollection for commercial or recreational purposes for the following reasons: (1) The remoteness of Lua o Palahemo, one of two known locations of *Vetericaris chaceorum,* and the difficulty of accessing this species within the deeper lava tube portions of the anchialine pool; and (2) although a second occurrence has now been confirmed at Manuka throughout the epigeal (open surface) sections of four pools, *V. chaceorum* is still considerably less common and much more elusive than *Halocaridina rubra* and the other anchialine pool shrimp species found in these four pools. In addition, there are prohibitions against collecting from the pools in the natural area reserve, although the State does not actively monitor the site (Hadway 2013, pers. comm.). We are not aware of any threats to the remaining 12 plant species or the picture-wing fly listed as endangered in this final rule that would be attributed to overutilization for commercial, recreational, scientific or educational purposes.

Pritchardia lanigera

The genus *Pritchardia* has 28 known species, 14 of which are endemic to the Hawaiian Islands, and its range is restricted to the Pacific archipelagos of Hawaii, Fiji, the Cook Islands, Tonga, and Tuamotus (Chapin *et al.* 2004, p. 273). *Pritchardia* palms have been valued as collectibles for centuries (Hillebrand 1888, pp. 21–27; Chapin *et al.* 2004, pp. 273, 278). In 1888, botanist Wilhelm Hillebrand noted that, ''. . . one species of *Pritchardia* in Nuuanu, . . . was completely exterminated when natives found that the trees were saleable to amateurs of gardening in Honolulu.'' *Pritchardia* has become one of the most widely cultivated ornamental palm genera in the world (Maunder *et al.* 2001 in Chapin *et al.* 2004, p. 278). There is an international trade in *Pritchardia* seeds and seedlings that has created a market in which individual *Pritchardia* seeds sell for 5 to 35 dollars each (Chapin *et al.* 2004, p. 278; Clark 2010, in litt.; *http://rarepalmseeds.com*). Most seeds sold are cultivated; however, wild collection of some ''highly-threatened'' species does occur (Chapin *et al.* 2004, p. 278). There are over a dozen Internet Web sites that offer Hawaiian *Pritchardi*a plants and seeds for sale, including *Pritchardia lanigera* (e.g., *http://www.eBay.com*). Based on the history of collection of endemic Hawaiian *Pritchardia* plants and seeds, the market for Hawaiian *Pritchardia* plants and seeds, and the vulnerability of the small populations of *Pritchardia lanigera* to the negative impacts of any collection, we consider overcollection of *Pritchardia lanigera* to pose a serious and ongoing threat, because it can occur at any time, although its occurrence is not predictable.

Anchialine Pool Shrimp

While we are aware of two collections of the anchialine pool shrimp

Vetericaris chaceorum for scientific and educational purposes (Kensley and Williams, 1986, pp. 419–429; Sakihara 2013, in litt.), there is no information available that indicates this species has ever been collected for commercial or recreational purposes. Other Hawaiian anchialine pool shrimp (e.g., opaeula (*Halocaridina rubra*)) and the candidate species *Metabetaeus lohena* (NCN) are collected for the aquarium market (e.g., *http://Fuku-Bonsai.com; http://ecosaqua.com; http://www.eBay.com; http://www.seahorse.com*), including self-contained aquariums similar to those marketed by Ecosphere Associates, Inc. (Ecosphere Associates 2011, p. 1). Two of these companies are located in Hawaii (FukuBonsai and Stockly's Aquariums of Hawaii). Although other species are collected, the Service lacks sufficient information to suggest that collection is or is not a threat to *V. chaceorum.*

Conservation Efforts To Reduce Overutilization for Commercial, Recreational, Scientific or Educational Purposes

We are unaware of voluntary conservation efforts to reduce overcollection of Hawaiian *Prichardia* species, including *P. lanigera,* which is listed as endangered in this final rule. There are no approved HCPs, SHAs, CCAs, memoranda of understanding (MOUs), or other voluntary actions that specifically address *P. lanigera* and the threat from overcollection.

Summary of Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We have no evidence to suggest that overutilization for commercial, recreational, scientific, or educational purposes poses a threat to 12 of the 13 plant species, the picture-wing fly, or the anchialine pool shrimp in this final rule. The plant species *Pritchardia lanigera* is vulnerable to the impacts of overutilization due to collection for trade or market. Based on the history of collection of endemic Hawaiian *Pritchardia* spp., the market for Hawaiian *Pritchardia* trees and seeds, and the inherent vulnerability of the small populations of *Pritcharidia lanigera* to the removal of individuals (seeds), we consider collection to pose a serious and ongoing threat to this species.

Factor C. Disease or Predation

Disease

We are not aware of any threats to the 13 plant species, anchialine pool shrimp, or picture-wing fly listed as endangered in this final rule that are attributable to disease.

Predation and Herbivory

Hawaii's plants and animals evolved in nearly complete isolation from continental influences. Successful colonization of these remote volcanic islands was infrequent, and many organisms never succeeded in establishing populations. As an example, Hawaii lacks any native ants or conifers, has very few families of birds, and has only a single native land mammal—a bat (Loope 1998, p. 748). In the absence of any grazing or browsing mammals, plants that became established did not need mechanical or chemical defenses against mammalian herbivory such as thorns, prickles, and production of toxins. As the evolutionary pressure to either produce or maintain such defenses was lacking, Hawaiian plants either lost or never developed these adaptations (Carlquist 1980, p. 173). Likewise, native Hawaiian birds and insects experienced no evolutionary pressure to develop anti-predator mechanisms against mammals or invertebrates that were not historically present on the island. The native flora and fauna of the islands are thus particularly vulnerable to the impacts of introduced nonnative species, as discussed below.

Introduced Ungulates

In addition to the habitat impacts discussed above (see ''Habitat Destruction and Modification by Introduced Ungulates'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range*), introduced ungulates and their resulting impacts are a threat to the 13 plant species in this final rule by grazing and browsing individual plants (this information is also presented in Table 3): *Bidens hillebrandiana* ssp. *hillebrandiana* (pigs and goats), *B. micrantha* ssp. *ctenophylla* (pigs and goats), *Cyanea marksii* (pigs, cattle, and mouflon), *Cyanea tritomantha* (pigs and cattle), *Cyrtandra nanawaleensis* (pigs), *Cyrtandra wagneri* (pigs), *Phyllostegia floribunda* (pigs), *Pittosporum hawaiiense* (pigs, cattle, and mouflon), *Platydesma remyi* (pigs), *Pritchardia lanigera* (pigs, goats, and mouflon), *Schiedea diffusa* ssp. *macraei* (pigs and cattle), *Schiedea hawaiiensis* (pigs, goats, sheep, and mouflon), and *Stenogyne cranwelliae* (pigs). In addition, introduced ungulates are a threat to the picture-wing fly in this final rule by grazing and browsing individuals of its host plants, *Charpentiera* spp. and *Pisonia* spp. (pigs, goats, cattle, and mouflon).

We have direct evidence of ungulate damage to the 13 plant species listed as endangered species in this final rule, as well as to the two host plants of the picture-wing fly listed as an endangered species in this final rule. Magnacca *et al.* (2008, p. 32) and others (Maui Forest Bird Recovery Project 2011, in litt.) found that native plant species such as the Hawaiian lobelioids (e.g., *Cyanea* spp.) and plants in the African violet family (e.g., *Cyrtandra* spp.) are particularly vulnerable to pig disturbance. In a study conducted by Diong (1982, p. 160) on Maui, feral pigs were observed browsing on young shoots, leaves, and fronds of a wide variety of plants, of which over 75 percent were endemic species. A stomach content analysis in this study showed that 60 percent of the pigs' food source consisted of the endemic *Cibotium* (hapuu, tree fern). Pigs were observed to fell plants and remove the bark from native plant species within the genera *Cibotium, Clermontia, Coprosma, Hedyotis, Psychotria,* and *Scaevola,* resulting in larger trees being killed over a few months of repeated feeding (Diong 1982, p. 144). Beach (1997, pp. 3–4) found that feral pigs in Texas spread disease and parasites, and their rooting and wallowing behavior led to spoilage of watering holes and loss of soil through leaching and erosion. Rooting activities also decreased the survivability of some plant species through disruption at root level of mature plants and seedlings (Beach 1997, pp. 3–4; Anderson *et al.* 2007, pp. 2–3). In Hawaii, pigs dig up forest ground cover consisting of delicate and rare species of orchids, ferns, mints, lobeliads, and other taxa, including roots, tubers and rhizomes (Stone and Anderson 1988, p. 137).

In addition, there are direct observations of pig herbivory, on either the fresh seedlings, fruits, seeds, or leaves, on each of the 13 plant species in this final rule, including *Bidens hillebrandiana* ssp. *hillebrandiana* (Bio 2011, pers. comm.), *B. micrantha* ssp. *ctenophylla* (Bio 2011, pers. comm.), *Cyanea marksii* (PEPP 2010, p. 52; Bio 2011, pers. comm.), *Cyanea tritomantha* (HBMP 2010f; PEPP 2010, p. 60), *Cyrtandra nanawaleensis* (Bio 2011, pers. comm.), *Cyrtandra wagneri* (Lorence and Perlman 2007, p. 359; PEPP 2010, p. 63), *Phyllostegia floribunda* (Perlman and Wood 1993—*Hawaii Plant Conservation Maps database;* Perry 2006, in litt.; Pratt 2007b, in litt.; USFWS 2010, p. 4–66), *Pittosporum hawaiiense* (Bio 2011, pers. comm.), *Platydesma remyi* (PEPP 2008, p. 107), *Pritchardia lanigera* (Wood

1995, in litt.; HBMP 2010c; Crysdale 2013, pers. comm.), *Schiedea diffusa* ssp. *macraei* (Wagner *et al.* 2005d, p. 32), *Schiedea hawaiiensis* (Mitchell *et al.* 2005a; Wagner *et al.* 2005d, p. 32; Bio 2011, pers. comm.), and *Stenogyne cranwelliae* (HBMP 2010k). According to Magnacca *et al.* (2008, p. 32; 2013, in litt.) several of the host plants of Hawaiian picture-wing flies, including *Charpentiera* spp. and *Pisonia* spp., the two host plants that support the picture-wing fly in this rule, are susceptible to damage from feral ungulates such as pigs. As pigs occur in 9 of the 10 ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) on Hawaii Island, the results of the studies described above suggest that pigs can also alter these ecosystems and directly damage or destroy the 13 plant species listed as endangered species in this final rule, and the two plants that support the picture-wing fly that is being listed as endangered in this final rule (see above and Table 3).

Feral goats thrive on a variety of food plants, and are instrumental in the decline of native vegetation in many areas (Cuddihy and Stone 1990, p. 64). Feral goats trample roots and seedlings, cause erosion, and promote the invasion of alien plants. They are able to forage in extremely rugged terrain and have a high reproductive capacity (Clarke and Cuddihy 1980, p. C–20; van Riper and van Riper 1982, pp. 34–35; Tomich 1986, pp. 153–156; Cuddihy and Stone 1990, p. 64). Goats were observed to browse on native plant species in the following genera: *Argyroxiphium, Canavalia, Plantago, Schiedea,* and *Stenogyne* (Cuddihy and Stone 1990, p. 64). A study on the island of Hawaii demonstrated that *Acacia koa* seedlings are unable to survive due to browsing and grazing by goats (Spatz and Mueller-Dombois 1973, p. 874). If goats are maintained at constantly high numbers, mature *A. koa* trees will eventually die, and with them the root systems that support suckers and vegetative reproduction. One study demonstrated a positive height-growth response of *A. koa* suckers to the 3-year exclusion of goats (1968–1971) inside a fenced area, whereas suckers were similarly abundant but very small outside of the fenced area (Spatz and Mueller-Dombois 1973, p. 873). Another study at Puuwaawaa demonstrated that prior to management actions in 1985, regeneration of endemic shrubs and trees in the goat-grazed area was almost totally lacking, contributing to the invasion of the forest understory by exotic grasses and weeds. After the removal of grazing animals in 1985, *A. koa* and *Metrosideros* spp. seedlings were observed germinating by the thousands (HDOFAW 2002, p. 52). Based on a comparison of fenced and unfenced areas, it is clear that goats can devastate native ecosystems (Loope *et al.* 1988, p. 277).

Goats seek out seedlings and juveniles of *Bidens* spp. (Bio 2011, pers. comm.), and are known to indiscriminately graze on and eat the seeds of native Hawaiian *Pritchardia* species (Chapin *et al.* 2004, p. 274; Chapin *et al.* 2007, p. 20). The two known occurrences of the plant *Pritchardia lanigera* are found in an unfenced area of the Kohala Mountains, where they are impacted by browsing and grazing by goats and other ungulates (Warshauer *et al.* 2009, pp. 10, 24; Laws *et al.* 2010, in litt.). *Schiedea* spp. are favored by grazing goats, and goat browsing adversely impacts the only known population of the plant species *Schiedea hawaiiensis* (Wagner *et al.* 2005d, p. 32; Chynoweth *et al.* 2011, in litt.). In addition, there are direct observations of goat herbivory, on either the fresh seedlings, fruit, seeds, or leaves, of four of the plant species in this final rule, including *Bidens hillebrandiana* ssp. *hillebrandiana* (Bio 2011, pers. comm.), *B. micrantha* ssp. *ctenophylla* (Bio 2011, pers. comm.; Knoche 2011, in litt.), *Pritchardia lanigera* (Wood 1995, in litt.; Chapin *et al.* 2004, p. 274), and *Schiedea hawaiiensis* (Mitchell *et al.* 2005a). According to Magnacca *et al.* (2008, p. 32) several of the host plants of Hawaiian picture-wing flies, including the host plants of the picture-wing fly listed as endangered in this rule (*Charpentiera* spp. and *Pisonia* spp.), are susceptible to damage from feral ungulates such as goats. As goats occur in nine of the ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) on Hawaii Island, the results of the studies described above suggest that goats can also alter these ecosystems and directly damage or destroy four of the plant species being listed as endangered in this final rule (*Bidens micrantha* ssp. *ctenophylla, B. hillebrandiana* ssp. *hillebrandiana, Pritchardia lanigera,* and *Schiedea hawaiiensis*), and the two host plants that support the picture-wing fly being listed as an endangered species in this final rule (see above and Table 3).

Four of the plant species listed as endangered in this final rule (*Cyanea marksii, C. tritomantha, Pittosporum hawaiiense,* and *Schiedea diffusa* ssp. *macraei*), and the two host plants that support the picture-wing fly in this rule (*Charpentiera* spp. and *Pisonia* spp.), are impacted by browsing and grazing by feral cattle. Cattle, either feral or domestic, are considered one of the most significant factors in the destruction of Hawaiian forests (Baldwin and Fagerlund 1943, pp. 118–122). Currently, feral cattle are found only on Maui and Hawaii, typically in accessible forests and certain coastal and lowland leeward habitats (Tomich 1986, pp. 140–144).

In HVNP, Cuddihy reported that there were twice as many native plant species as nonnatives found in areas that had been fenced to exclude feral cattle, whereas on the adjacent, nonfenced cattle ranch, there were twice as many nonnative plant species as natives (Cuddihy 1984, pp. 16, 34). Skolmen and Fujii (1980, pp. 301–310) found that *Acacia koa* seedlings were able to reestablish in a moist *A. koa*—*Metrosideros polymorpha* forest on Hawaii Island after the area was fenced to exclude feral cattle (Skolmen and Fujii 1980, pp. 301–310). Cattle eat native vegetation, trample roots and seedlings, cause erosion, create disturbed areas conducive to invasion by nonnative plants, and spread seeds of nonnative plants in their feces and on their bodies. Cattle have been observed accessing native plants in Hakalau NWR by breaking down ungulate exclosure fences (Tummons 2011, p. 4). In addition, there are direct observations of cattle herbivory on three of the plant species in this rule, including *Cyanea marksii* (PEPP 2010, p. 52), *C. tritomantha* (PEPP 2010, p. 60), and *Pittosporum hawaiiense* (Bio 2011, pers. comm.). In addition, although we have no direct observations, we also consider the plant *Schiedea diffusa* ssp. *macraei* to be susceptible to herbivory by cattle because cattle are reported to favor plants in the genus *Schiedea* (Wagner *et al.* 2005d, pp. 31–32) and feral cattle still occur in the Kohala Mountains, the location of the only known individual of this species. Between 1987 and 1994, populations of *Schiedea salicaria* on West Maui were grazed so extensively by cattle, all of the individuals of this species in accessible areas disappeared by 1994 (Wagner *et al.* 2005d, p. 32). Cattle are also known to browse *Charpentiera* spp. and *Pisonia* spp., the two host plants that support the picture-wing fly in this final rule (Magnacca *et al.* 2008, p. 32; Magnacca 2011b, pers. comm.). As feral cattle occur in five of the described ecosystems (anchialine pool, lowland mesic, lowland wet, montane mesic, and montane wet) on Hawaii Island, the results of the studies

described above suggest that feral cattle can also alter these ecosystems and directly damage or destroy four of the plant species listed as endangered species in this final rule (*Cyanea marksii, C. tritomantha, Pittosporum hawaiiense,* and *Schiedea diffusa* ssp. *macraei*), and the two host plants that support the picture-wing fly listed as an endangered species in this rule (*Charpentiera* spp. and *Pisonia* spp.) (Table 3).

Feral sheep browse and trample native vegetation, and have decimated large areas of native forest and shrubland (Tomich 1986, pp. 156–163; Cuddihy and Stone 1990, p. 65–66). Large areas of Hawaii Island have been devastated by sheep. For example, sheep browsing reduced seedling establishment of *Sophora chrysophylla* (mamane) so severely that it resulted in a reduction of the tree line elevation on Mauna Kea (Warner 1960 in Juvik and Juvik 1984, pp. 191–202). Currently there is a large sheep-mouflon sheep hybrid population (see ''Habitat Destruction and Modification by Introduced Ungulates'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above) on Mauna Kea that extends into the saddle and northern part of Mauna Loa, and there are reports that these animals are destroying endangered plants (Hess 2008, p. 1). There are direct observations of feral sheep herbivory on individuals of the only known occurrence of the plant species *Schiedea hawaiiensis* at PTA (Mitchell *et al.* 2005a; U.S. Army Garrison 2006, p. 34). As feral sheep occur in one of the described ecosystems (montane dry) on Hawaii Island, the results of the studies described above suggest that sheep can also alter this ecosystem and directly damage or destroy individuals of *Schiediea hawaiiensis* (Table 3).

Mouflon sheep graze native vegetation, trample undergrowth, spread weeds, and cause erosion. On the island of Hawaii, mouflon sheep browsing led to the decline in the largest population of the endangered *Argyroxiphium kauense* (kau silversword, Mauna Loa silversword, or ahinahina) located on the former Kahuku Ranch, reducing it from a ''magnificent population of several thousand'' (Degener *et al.* 1976, pp. 173–174) to fewer than 2,000 individuals (unpublished data in Powell 1992, in litt., p. 312) over a period of 10 years (1974–1984). The native tree *Sophora chrysophylla* is also a preferred browse species for mouflon. According to Scowcroft and Sakai (1983, p. 495), mouflon eat the shoots, leaves, flowers, and bark of this species. Bark stripping on the thin bark of a young tree is potentially lethal. Mouflon are also reported to strip bark from *Acacia koa* trees (Hess 2008, p. 3) and to seek out the threatened plant *Silene hawaiiensis* (Benitez *et al.* 2008, p. 57). In the Kahuku section of HVNP, mouflon jumped the park boundary fence and reduced one population of *S. hawaiiensis* to half its original size over a 3-year period (Belfield and Pratt 2002, p. 8). Other native species browsed by mouflon include *Geranium cuneatum* ssp. *cuneatum* (hinahina, silver geranium), *G. cuneatum* ssp. *hypoleucum* (hinahina, silver geranium), and *Sanicula sandwicensis* (NCN) (Benitez *et al.* 2008, pp. 59, 61). On Lanai, mouflon were once cited as one of the greatest threats to the endangered *Gardenia brighamii* (Mehrhoff 1993, p. 11), although fencing has now proven to be an effective mechanism against mouflon herbivory on this plant (Mehrhoff 1993, pp. 22–23). Due to their high agility and reproductive rates, mouflon sheep have the potential to occupy most ecosystems found on Hawaii Island, from sea-level to very high elevations (Hess 2010, pers. comm.; Ikagawa 2011, in litt.). Further, *Ovis* spp. are known throughout the world for chewing vegetation right down to the soil (Ikagawa 2011, in litt.).

Recent research by Ikagawa (2011, in litt.) suggests that the plant species *Pritchardia lanigera* occurs within the observed range of mouflon, and is potentially impacted by mouflon browsing. In addition, there are direct observations or reports that mouflon sheep browsing and grazing significantly impact the plant species *Cyanea marksii, Pittosporum hawaiiense,* and *Schiedea hawaiiensis* (Bio 2011, pers. comm.; Pratt 2011e, in litt.), which are listed as endangered in this final rule. Further, *Charpentiera* spp., one of the two host plants that support the picture-wing fly in this rule, appears to be decreasing throughout its range due to impacts from mouflon browsing (Science Panel 2005, pp. 1–23; Magnacca 2011b, pers. comm.). As mouflon occur in five of the described ecosystems (lowland wet, lowland mesic, montane dry, montane mesic, and montane wet) on Hawaii Island, the results of the studies described above suggest that mouflon sheep can also alter these ecosystems and directly damage or destroy four plants listed as endangered species in this final rule (*Cyanea marksii, Pittosporum hawaiiense, Pritchardia lanigera,* and *Schiedea hawaiiensis*), and one of the two host plants (see above) that support the picture-wing fly listed as an endangered species in this final rule (Table 3).

The recent introduction of axis deer to Hawaii Island raises a significant concern due to the reported damage axis deer cause on the island of Maui (see *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above). Most of the available information on axis deer in the Hawaiian Islands concerns observations and reports from the island of Maui. On Maui, axis deer were introduced by the State as a game animal, but their numbers have steadily increased, especially in recent years on Haleakala (Luna 2003, p. 44). During the 4-year El Niño drought from 1998 through 2001, Maui experienced an 80 to 90 percent decline in shrub and vine species caused by deer browsing and girdling of young saplings. High mortality of rare and native plant species was observed (Medeiros 2010, pers. comm.). Axis deer consume progressively less palatable plants until no edible vegetation is left (Hess 2008, p. 3). Axis deer are highly adaptable to changing conditions and are characterized as ''plastic'' (meaning flexible in their behavior) by Ables (1977, cited in Anderson 1999, p. 5). They exhibit a high degree of opportunism regarding their choice of forage (Dinerstein 1987, cited in Anderson 1999, p. 5) and can be found in all but the highest elevation ecosystems (subalpine and alpine) and montane bogs, according to Medeiros (2010, pers. comm.).

Axis deer on Maui follow a cycle of grazing and browsing in open lowland grasslands during the rainy season (November–March) and then migrate to the lava flows of montane mesic forests during the dry summer months to graze and browse native plants (Medeiros 2010, pers. comm.). Axis deer are known to favor the native plants *Abutilon menziesii* (an endangered species), *Erythrina sandwicensis* (wiliwili), and *Sida fallax* (ilima) (Medeiros 2010, pers. comm.). During the driest months of summer (July and August), axis deer can even be found along Maui's coastal roads as they search for food. Hunting pressure also appears to drive the deer into native forests, particularly the lower rainforests up to 4,000 to 5,000 ft (1,220 and 1,525 m) in elevation (Medeiros 2010, pers. comm.), and according to Kessler and Hess (2010, pers. comm.), axis deer can be found up to 9,000 ft (2,743 m) elevation. On Lanai, grazing by axis deer has been reported as a major threat to the endangered *Gardenia brighamii* (nau) (Mehrhoff 1993, p. 11). Swedberg and Walker (1978, cited in Anderson

2003, pp. 124–125) reported that in the upper forests of Lanai, the native plants *Osteomeles anthyllidifolia* (ulei) and *Leptecophylla tameiameiae* (pukiawe) comprised more than 30 percent of axis deer rumen volume. On Molokai browsing by axis deer has been reported on *Erythrina sandwicensis* and *Nototrichium sandwicense* (kului) (Medeiros *et al.* 1996, pp. 11, 19). Other native plant species consumed by axis deer include *Achyranthes splendens* (NCN), *Bidens campylotheca* ssp. *pentamera* (kookoolau) and *B. campylotheca* ssp. *waihoiensis* (kookoolau), *Chamaesyce celastroides* var. *lorifolia* (akoko), *Diospyros sandwicensis* (lama), *Geranium multiflorum* (nohoanu; an endangered species), *Lipochaeta rockii* var. *dissecta* (nehe), *Osmanthus sandwicensis* (ulupua), *Panicum torridum* (kakonakona), and *Santalum ellipticum* (laau ala) (Anderson 2002, poster; Perlman 2009, in litt., pp. 4–5). As demonstrated on the Islands of Lanai, Maui, and Molokai, axis deer will spread into nine of the described ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff) on Hawaii Island if not controlled. The newly established axis deer partnership (see *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above) is currently implementing an axis deer response and removal plan, and just recently reported their first confirmed removal on April 11, 2012 (Osher 2012, in litt.). In addition, there is a proposed revision to the State of Hawaii's HRS 91 (see *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above, and *Factor D. The Inadequacy of Existing Regulatory Mechanisms,* below) that would address the gap in the current emergency rules authority and expand the ability of State agencies to adopt emergency rules to include situations that impose imminent threats to natural resources (e.g., axis deer on Hawaii Island). The results from the studies above, combined with direct observations from field biologists, suggest that grazing and browsing by axis deer can impose negative impacts to the nine ecosystems above and their associated native plants, including the 13 plant species listed as endangered species in this final rule, and the two host plants that support the picture-wing fly (see above) listed as an endangered species in this final rule, should this nonnative ungulate increase in number and range on Hawaii Island.

Other Introduced Vertebrates

Rats

There are three species of introduced rats in the Hawaiian Islands: Polynesian rat (*Rattus exulans*), black rat (*R. rattus*), and Norway rat (*R. norvegicus*). The Polynesian rat and the black rat are primarily found in the wild, in dry to wet habitats, while the Norway rat is typically found in manmade habitats, such as urban areas or agricultural fields (Tomich 1986, p. 41). The black rat is widely distributed among the main Hawaiian Islands and can be found in a broad range of ecosystems up to 9,744 ft (2,970 m), but it is most common at low- to mid-elevations (Tomich 1986, pp. 38–40). While Sugihara (1997, p. 194) found both the black and Polynesian rats up to 6,972 ft (2,125 m) elevation on Maui, the Norway rat was not seen at the higher elevations in his study. Rats occur in nine of the described ecosystems (coastal, lowland dry, lowland mesic, lowland wet, montane dry, montane mesic, montane wet, dry cliff, and wet cliff), and predation by rats adversely impacts 11 of the 13 plant species listed as endangered in this final rule (rats are not a reported threat to the picture-wing fly or anchialine pool shrimp listed as endangered in this rule) (see Table 3).

Rats impact native plants by eating fleshy fruits, seeds, flowers, stems, leaves, roots, and other plant parts (Atkinson and Atkinson 2000, p. 23), and can seriously affect regeneration. Research on rats in forests in New Zealand has also demonstrated that, over time, differential regeneration as a consequence of rat predation may alter the species composition of forested areas (Cuddihy and Stone 1990, pp. 68–69). Rats have caused declines or even the total elimination of island plant species (Campbell and Atkinson 1999, cited in Atkinson and Atkinson 2000, p. 24). In the Hawaiian Islands, rats may consume as much as 90 percent of the seeds produced by some trees, or in some cases prevent the regeneration of forest species completely (Cuddihy and Stone 1990, pp. 68–69). All three species of rat (black, Norway, and Polynesian) have been reported to be a serious threat to many endangered or threatened Hawaiian plants (Stone 1985, p. 264; Cuddihy and Stone 1990, pp. 67–69). Plants with fleshy fruits are particularly susceptible to rat predation, including some of the species listed as endangered in this rule. For example, the fruits of plants in the bellflower family (e.g., *Cyanea* spp.) appear to be a target of rat predation (Cuddihy and Stone 1990, pp. 67–69). In addition to both species of *Cyanea* (*Cyanea marksii* and *Cyanea tritomantha*), nine other species of plants in this final rule are adversely impacted by rat predation: *Bidens hillebrandiana* ssp. *hillebrandiana, B. micrantha* ssp. *ctenophylla* (Bio 2011, pers. comm.), *Cyrtandra nanawaleensis, Cyrtandra wagneri* (Lorence and Perlman 2007, pp. 357–361; Bio 2011, pers. comm.), *Pittosporum hawaiiense, Pritchardia lanigera, Schiedea diffusa* ssp. *macraei, Schiedea hawaiiensis,* and *Stenogyne cranwelliae* (Cuddihy and Stone 1990, pp. 67–69; Gon III and Tierney 1996, in litt.; Bio 2008, in litt.; Pratt 2008b, in litt.; Bio 2010, pers. comm.; HBMP 2010c; HBMP 2010f; HBMP 2010j; HBMP 2010k; PEPP 2010, pp. 101, 113; Pratt 2011f, in litt.; Crysdale 2013, pers. comm.).

Nonnative Fish

In Hawaii, the introduction of nonnative fish, including bait-fish, into anchialine pools has been a major contributor to the decline of native shrimp (TNC 1987 cited in Chan 1995, p. 1; Chan 1995, pp. 1, 8, 17–18; Brock and Kam 1997, p. 50; Brock 2004, p. 13–17; Kinzie 2012, in litt.). Predation by, and competition with, introduced nonnative fish is considered the greatest threat to native shrimp within anchialine pool ecosystems (Bailey-Brock and Brock 1993, p. 354; Brock 2004, pp. 13–17). These impacts are discussed further under *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence,* below.

Invertebrates

Nonnative Slugs

Predation by nonnative slugs adversely impacts 5 of the 13 plant species (*Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri,* and *Stenogyne cranwelliae;* see Table 3) in this final rule through mechanical damage, destruction of plant parts, and mortality (U.S. Army Garrison 2006, p. 3–51; Joe 2006, p. 10; Lorence and Perlman 2007, p. 359; Bio 2008, in litt.; Perlman and Bio 2008, in litt.; HBMP 2010k). On Oahu, slugs have been reported to destroy the endangered plants *Cyanea calycina* and *Cyrtandra kaulantha* in the wild, and have been observed eating leaves and fruit of wild and cultivated individuals of *Cyanea* (Mehrhoff 1995, in litt.; Pratt and Abbott 1997, p. 13; U.S. Army Garrison 2006, pp. 3–34, 3–51). In addition, slugs have damaged individuals of other *Cyanea* and *Cyrtandra* species in the wild (Wood *et al.* 2001, p. 3; Sailer and Keir 2002, in litt., p. 3; PEPP 2007, p. 38; PEPP 2008, pp. 23, 49, 52–53, 57).

Little is known about predation of certain rare plants by slugs; however, information in the U.S. Army's 2005 ''Status Report for the Makua Implementation Plan'' indicates that slugs can be a threat to all species of *Cyanea* (U.S. Army Garrison 2006, p. 3–51). Research investigating slug herbivory and control methods shows that slug impacts on seedlings of *Cyanea* spp. results in up to 80 percent seedling mortality (U.S. Army Garrison 2006, p. 3–51). Slug damage has also been reported on other Hawaiian plants including *Argyroxiphium grayanum* (greensword), *Alsinidendron* sp., *Hibiscus* sp., the endangered plant *Schiedea kaalae* (maolioli), the endangered plant *Solanum sandwicense* (popolo aiakeakua), and *Urera* sp. (Gagne 1983, pp. 190–191; Sailer 2002 cited in Joe 2006, pp. 28–34).

Joe and Daehler (2008, p. 252) found that native Hawaiian plants are more vulnerable to slug damage than nonnative plants. In particular, they found that the individuals of the endangered plants *Cyanea superba* and *Schiedea obovata* had 50 percent higher mortality when exposed to slugs when compared to individuals of the same species that were protected within slug exclosures. Slug damage has been documented on the plant *Stenogyne cranwelliae* (HBMP 2010k). As slugs are found in three of the described ecosystems (lowland wet, montane wet, and wet cliff) on Hawaii Island, the data from the above studies, in addition to direct observations from field biologists, suggest that slugs can directly damage or destroy native plants, including five of the plant species listed as endangered species in this final rule (*Cyanea marksii, C. tritomantha, Cyrtandra nanawaleensis, C. wagneri,* and *Stenogyne cranwelliae*).

Nonnative Western Yellow-Jacket Wasps

The western yellow-jacket wasp (*Vespula pensylvanica*) is a social wasp species native to the mainland of North America. It was first reported from Oahu in the 1930s (Nishida and Evenhuis in Sherley 2000, p. 121), and an aggressive race became established in 1977 (Gambino *et al.* 1987, p. 170). This species is now particularly abundant between 1,969 and 5,000 ft (600 and 1,524 m) in elevation (Gambino *et al.* 1990, pp. 1,088–1,095; Foote and Carson 1995, p. 371) on Kauai, Oahu, Molokai, Maui, Lanai, and Hawaii Island (GISD 2012b). The western yellow-jacket wasp is an aggressive, generalist predator (Gambino *et al.* 1987, p. 170). In temperate climates, the western yellow-jacket wasp has an annual life cycle, but in Hawaii's tropical climate, colonies of this species persist through a second year, allowing them to have larger numbers of individuals and thus a greater impact on prey populations (Gambino *et al.* 1987, pp. 169–170). In Haleakala National Park on Maui, western yellow-jacket wasps were found to forage predominantly on native arthropods (Gambino *et al.* 1987, pp. 169–170; Gambino *et al.* 1990, pp. 1,088–1,095; Gambino and Loope 1992, pp. 15–21). Western yellow-jacket wasps have also been observed carrying and feeding upon recently captured adult Hawaiian *Drosophila* (Kaneshiro and Kaneshiro 1995, pp. 40–45). These wasps are also believed to feed upon picture-wing fly larvae within their host plants (Carson 1986, pp. 3–9). In addition, native picture-wing flies, including the species in this final rule, may be particularly vulnerable to predation by wasps due to their lekking (male territorial defensive displays during courtship and mating) behavior and conspicuous courtship displays that can last for several minutes (Kaneshiro 2006, pers. comm.). The concurrent arrival of the western yellow-jacket wasp and decline of picture-wing fly observations in some areas suggest that the wasp may have played a significant role in the decline of some of the picture-wing fly populations, including populations of the picture-wing fly listed as endangered in this rule (Carson 1986, pp. 3–9; Foote and Carson 1995, p. 371; Kaneshiro and Kaneshiro 1995, pp. 40–45; Science Panel 2005, pp. 1–23). As the western yellow-jacket wasp is widespread within three ecosystems (lowland mesic, montane mesic, and montane wet) on Hawaii Island in which the two known occurrences of the picture-wing fly listed as endangered in this final rule occur, the results from the studies above, in addition to observations by field biologists, suggest that western yellow-jacket wasps can directly kill individuals of the picture-wing fly (Foote and Carson 1995, p. 371; Kaneshiro and Kaneshiro 1995, pp. 40–45; Science Panel 2005, pp. 1–23).

Nonnative Parasitoid Wasps

The number of native parasitic Hymenoptera (parasitic wasps) in Hawaii is limited, and only species in the family Eucoilidae are known to use Hawaiian picture-wing flies as hosts (Montgomery 1975, pp. 74–75; Kaneshiro and Kaneshiro 1995, pp. 44–45). However, several species of small parasitic wasps (Family Braconidae), including *Diachasmimorpha tryoni* (NCN), *D. longicaudata* (NCN), *Opius vandenboschi* (NCN), and *Biosteres arisanus* (NCN), were purposefully introduced into Hawaii to control nonnative pest tephritid fruit flies (Funasaki *et al.* 1988, pp. 105–160). These parasitic wasps are also known to attack other species of flies, including native flies in the family Tephritidae. While these parasitic wasps have not been recorded parasitizing Hawaiian picture-wing flies and, in fact, may not successfully develop in Drosophilidae, females will indiscriminately sting any fly larvae in their attempts to oviposit (lay eggs), resulting in mortality (Evans 1962, pp. 468–483). Because of this indiscriminate predatory behavior, we consider nonnative parasitoid wasps to represent a threat to the picture-wing fly listed as an endangered species in this final rule.

Nonnative Ants

Ants are not a natural component of Hawaii's arthropod fauna, and native species evolved in the absence of predation pressure from ants. Ants can be particularly destructive predators because of their high densities, recruitment behavior, aggressiveness, and broad range of diet (Reimer 1993, pp. 13–17). Ants can prey directly upon native arthropods, exclude them through interference or exploitation competition for food resources, or displace them by monopolizing nesting or shelter sites (Krushelnychy *et al.* 2005, p. 6). The threat of ant predation on the picture-wing fly species in this final rule is amplified by the fact that most ant species have winged reproductive adults (Borror *et al.* 1989, p. 738) and can quickly establish new colonies in additional suitable habitats (Staples and Cowie 2001, p. 55). These attributes allow some ants to destroy otherwise geographically isolated populations of native arthropods (Nafus 1993, pp. 19, 22–23).

At least 47 species of ants are known to be established in the Hawaiian Islands (Krushelnycky 2008, pp. 1–11), and at least 4 particularly aggressive species (the big-headed ant (*Pheidole megacephala*), the long-legged ant (also known as the yellow crazy ant) (*Anoplolepis gracilipes*), *Solenopsis papuana* (NCN), and *Solenopsis geminata* (NCN)) have severely impacted the native insect fauna, likely including native picture-wing flies (Reimer 1993, pp. 13–17). Numerous other species of ants are recognized as threats to Hawaii's native invertebrates, and an unknown number of new species are established every few years (Staples and Cowie 2001, p. 53). As a group, ants occupy most of Hawaii's habitat types, from coastal to subalpine ecosystems;

however, many species are still invading mid-elevation montane mesic forests, and few species have been able to colonize undisturbed montane wet ecosystems (Reimer 1993, pp. 13–17). The lowland forests are a portal of entry to the montane and subalpine ecosystems, and, therefore, because ants are actively invading increasingly elevated ecosystems, ants are more likely to occur in high densities in the lowland mesic and montane mesic ecosystems currently occupied by the picture-wing fly (Reimer 1993, pp. 13–17).

The big-headed ant originated in central Africa (Krushelnycky *et al.* 2005, p. 24) and was first reported in Hawaii in 1879 (Krushelnycky *et al.* 2005, p. 24). This species is considered one of the most invasive and widely distributed ants in the world (Holway *et al.* 2002, pp. 181–233; Krushelnycky *et al.* 2005, p. 5). In Hawaii, this species is the most ubiquitous ant species found, from coastal to mesic habitat up to 4,000 ft (1,219 m) in elevation, including within the habitat areas of the picture-wing fly listed as endangered in this rule. With few exceptions, native insects have been eliminated in habitats where the big-headed ant is present (Gagne 1979, p. 81; Gillespie and Reimer 1993, p. 22). Consequently, big-headed ants represent a threat to the picture-wing fly, in the lowland mesic and montane mesic ecosystems (Reimer 1993, pp. 14, 17; Holway *et al.* 2002, pp. 181–233; Daly and Magnacca 2003, pp. 9–10; Krushelnycky *et al.* 2005, p. 5).

The long-legged ant appeared in Hawaii in 1952, and now occurs on Hawaii, Kauai, Maui, and Oahu (Reimer *et al.* 1990, p. 42; *http://www.antweb.org,* 2011). It inhabits low-to-mid-elevation (less than 2,000 ft (600 m)), rocky areas of moderate rainfall (less than 100 in (250 cm) annually) (Reimer *et al.* 1990, p. 42). Although surveys have not been conducted to ascertain this species' presence in the two known sites occupied by the picture-wing fly, we believe that the long-legged ant likely occurs within the lowland mesic ecosystem that supports the picture-wing fly due to the ant's aggressive nature and ability to spread and colonize new locations (Foote 2008, pers. comm.). Direct observations indicate Hawaiian arthropods are susceptible to predation by this species; Gillespie and Reimer (1993, p. 21) and Hardy (1979, pp. 37–38) documented the complete extirpation of several native insects within the Kipahulu area on Maui after this area was invaded by the long-legged ant. Lester and Tavite (2004, p. 391) found that long-legged ants in the Tokelau Atolls (New Zealand) can form very high densities in a relatively short period of time with locally serious consequences for invertebrate diversity. Densities of 3,600 individuals collected in pitfall traps within a 24-hour period were observed, as well as predation upon invertebrates ranging from crabs to other ant species. On Christmas Island in the Indian Ocean, numerous studies have documented the range of impacts to native invertebrates, including the red land crab (*Gecarcoidea natalis*), as a result of predation by supercolonies of the long-legged ant (Abbott 2006, p. 102). Long-legged ants have the potential as predators to profoundly affect the endemic insect fauna in territories they occupy. Studies comparing insect populations at otherwise similar ant-infested and ant-free sites found extremely low numbers of large endemic noctuid moth larvae (*Agrotis* spp. and *Peridroma* spp.) in ant-infested areas. Nests of groundnesting colletid bees (*Nesoprosopis* spp.) were eliminated from ant-infested sites (Reimer *et al.* 1990, p. 42). Although only cursory observations exist in Hawaii (Reimer *et al.* 1990, p. 42), we believe long-legged ants are a threat to the picture-wing fly listed as endangered in this rule in the lowland mesic ecosystem.

Solenopsis papuana is the only abundant, aggressive ant that has invaded intact mesic to wet forest, as well as coastal and lowland dry habitats. This species occurs from sea level to over 2,000 ft (600 m) on all of the main Hawaiian Islands, and is still expanding its range (Reimer 1993, p. 14). Although surveys have not been conducted to ascertain this species' presence in either of the two known sites occupied by the picture-wing fly, because of the ant's expanding range and its widespread occurrence in coastal, lowland dry, and lowland mesic habitats, we believe *S. papuana* is a threat to the picture-wing fly in the lowland mesic and montane mesic ecosystems.

Like *Solenopsis papuana, S. geminata* is also considered a significant threat to native invertebrates (Gillespie and Reimer 1993, pp. 21–33) and occurs on all the main Hawaiian Islands (Reimer *et al.* 1990, p. 42; Loope and Krushelnycky 2007, p. 70). Found in drier areas of the Hawaiian Islands, it has displaced *Pheidole megacephala* as the dominant ant in some areas (Wong and Wong 1988, p. 175). Known to be a voracious, nonnative predator in many areas to where it has spread, the species was documented to significantly increase fruit fly mortality in field studies in Hawaii (Wong and Wong 1988, p. 175). In addition to predation, *S. geminata* workers tend honeydew-producing members of the Homoptera suborder, especially mealybugs, which can impact plants directly and indirectly through the spread of disease (Manaaki Whenua Landcare Research 2012—*Ant Distribution Database*). *Solenopsis geminata* was included among the eight species ranked as having the highest potential risk to New Zealand in a detailed pest risk assessment for the country (GISD 2012c), and is included as one of five ant species listed among the ''100 of the World's Worst Invaders'' (Manaaki Whenua Landcare Research 2012—*Ant Distribution Database*). Although surveys have not been conducted to ascertain this species' presence in either of the two sites occupied by the picture-wing fly, because of the ant's expanding range and its widespread occurrence in coastal, lowland dry, and lowland mesic habitats, it is a potential threat to the picture-wing fly in the lowland mesic ecosystem.

The Argentine ant (*Linepithema humile*) was discovered on the island of Oahu in 1940, and is now established on all the main Hawaiian Islands (Reimer *et al.* 1990, p. 42). Argentine ants do not disperse by flight, instead colonies are moved about with soil and construction material. The Argentine ant is found from coastal to subalpine ecosystems on the island of Maui, and on the slopes of Mauna Loa, in the lowland mesic and montane mesic ecosystems on Hawaii Island, the location of one of the two occurrences of the picture-wing fly (Hartley *et al.* 2010, pp. 83–94; Krushelnychy and Gillespie 2010, pp. 643–655). The Argentine ant has been documented to reduce populations of, or even eliminate, native arthropods in Haleakala National Park on Maui (Cole *et al.* 1992, pp. 1313–1322). On Maui, Argentine ants are significant predators on pest fruit flies (Wong *et al.* 1984, pp. 1454–1458), and Krushelychy and Gillespie (2010, pp. 643–655) found that Argentine ants on Hawaii Island are associated with the decline of an endemic phorid fly (*Megaselia* sp.). Krushelychy and Gillespie (2010, pp. 643–655) suggest that ants severely impact larval stages of many flies. While we are not aware of documented occurrences of predation by Argentine ants on picture-wing flies, including the species listed as endangered in this rule, these ants are considered to be a threat to native arthropods located at higher elevations (Cole *et al.* 1992, pp. 1313–1322) and thus potentially to the picture-wing fly that occurs from 2,000

ft to 4,500 ft (610 m to 1,372 m) in elevation, in the lowland mesic, montane mesic, and montane wet ecosystems on Hawaii Island (Science Panel 2005, pp. 1–23; Magnacca 2011b, pers. comm.).

The rarity or disappearance of native picture-wing fly species, including the species listed as endangered in this final rule, from historical observation sites over the past 100 years is due to a variety of factors. While there is no documentation that conclusively ties the decrease in picture-wing fly observations to the establishment of nonnative ants in lowland mesic, montane mesic, and montane wet ecosystems on Hawaii Island, the presence of nonnative ants in these habitats and the decline of picture-wing fly observations in some areas in these habitats suggest that nonnative ants may have played a role in the decline of some populations of the picture-wing fly listed as endangered in this rule. As nonnative predatory ants are found in three of the described ecosystems (lowland mesic, montane mesic, and montane wet) on Hawaii Island in which the picture-wing fly occurs, the data from the above studies, in addition to direct observations from field biologists, suggest that nonnative predatory ants contribute to the reduction in range and abundance of the picture-wing fly (Science Panel 2005, pp. 1–23).

Two-Spotted Leaf Hopper

Predation by the two-spotted leaf-hopper (*Sophonia rufofascia*) has been reported on plants in the genus *Pritchardia* throughout the main Hawaiian Islands and may be a threat to the plant *Pritchardia lanigera* in this final rule (Chapin *et al.* 2004, p. 279). This nonnative insect damages the leaves it feeds on, typically causing chlorosis (yellowing due to disrupted chlorophyll production) to browning and death of foliage (Jones *et al.* 2000, pp. 171–180). The damage to plants can result in the death of affected leaves or the whole plant, owing to the combined action of its feeding and oviposition behavior (Alyokhin *et al.* 2004, p. 1). In addition to the mechanical damage caused by the feeding process, the insect may introduce plant pathogens that lead to eventual plant death (Jones *et al.* 2006, p. 2). The two-spotted leafhopper is a highly polyphagous insect (it feeds on many different types of food). Sixty-eight percent of its recorded host plant species in Hawaii are fruit, vegetable, and ornamental crops, and 22 percent are endemic plants, over half of which are rare and endangered (Alyokhin *et al.* 2004, p. 6). Its range is limited to below 4,000 ft (1,219 m) in elevation, unless there is a favorable microclimate. While there has been a dramatic reduction in the number of two-spotted leafhopper populations between 2005 and 2007 (possibly due to egg parasitism), this nonnative insect has not been eradicated, and predation by this nonnative insect remains a threat (Fukada 2007, in litt.). Chapin *et al.* (2004, p. 279) believe that constant monitoring of both wild and cultivated *Pritchardia* populations will be necessary to abate this threat.

Nonnative Beetles

The Hawaiian Islands now support several species of nonnative beetles (family Scolytidae, genus *Coccotrypes*), a few of which bore into and feed on the nuts produced by certain native and nonnative palm trees, including those in the genus *Pritchardia* (Swezey 1927, in litt.; Science Panel 2005, pp. 1–23; Magnacca 2011b, pers. comm.). Species of *Coccotrypes* beetles prefer trees with large seeds, like those of *Pritchardia* spp. (Beaver 1987, p. 11). Trees of *Pritchardia* spp. drop their fruit before the fruit reaches maturity due to the boring action of the *Coccotrypes* spp. beetles, thereby reducing natural regeneration in the wild (Beaver 1987, p. 11; Magnacca 2005, in litt.; Science Panel 2005, pp. 1–23). The threat from *Coccotrypes* spp. beetles on *Pritchardia* spp. in Hawaii is expected to increase with time if the beetles are not controlled (Richardson 2011, pers. comm.). Although *Pritchardia* spp. are long-lived (up to 100 years), over time, *Coccotrypes* spp. beetles may severely impact Hawaiian species of *Pritchardia,* including *Pritchardia lanigera,* which is listed as endangered in this final rule.

Conservation Efforts To Reduce Disease or Predation

There are no approved HCPs, CCAs, or SHAs that specifically address these 15 species and threats from predation. We acknowledge that in the State of Hawaii there are several voluntary conservation efforts (e.g., construction of fences) that may be helping to ameliorate the threats to the 15 species listed as endangered in this final rule due to predation by nonnative animal species, specifically predation by feral ungulates on the 13 plants species. However, these efforts are overwhelmed by the number of threats, the extent of these threats across the landscape, and the lack of sufficient resources (e.g., funding) to control or eradicate them from all areas where these 15 species occur now or occurred historically. See ''Conservation Efforts to Reduce Habitat Destruction, Modification, or Curtailment of Range'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above, for a summary of some voluntary conservation actions to address threats from feral ungulates. We are unaware of voluntary conservation measures to address the following threats: (1) Predation by rats on 11 of the 13 plants; (2) predation by nonnative slugs on 5 of the 13 plant species; (3) predation by nonnative insects (e.g., western yellow-jacket wasp, ants, parasitoid wasps) on the picture-wing fly; and (4) predation by nonnative insects on *Pritchardia lanigera.*

Summary of Disease or Predation

We are unaware of any information that indicates that disease is a threat to any of the 15 species in this final rule.

Although conservation measures are in place in some areas where each of the 15 species in this final rule occurs, information does not indicate that they are ameliorating the threat of predation described above. Therefore, we consider predation by nonnative animal species (pigs, goats, cattle, sheep, mouflon sheep, rats, slugs, wasps, ants, the two-spotted leaf hopper, and beetles) to pose an ongoing threat to all 13 plant species and the picture-wing fly in this final rule throughout their ranges for the following reasons:

(1) Observations and reports have documented that pigs, goats, cattle, sheep, and mouflon sheep browse and trample all 13 plant species and the host plants of the picture-wing fly in this rule (see Table 3), in addition to other studies demonstrating the negative impacts of ungulate browsing and trampling on native plant species of the islands (Spatz and Mueller-Dombois 1973, p. 874; Diong 1982, p. 160; Cuddihy and Stone 1990, p. 67).

(2) Nonnative rats and slugs cause mechanical damage to plants and destruction of plant parts (branches, fruits, and seeds), and are considered a threat to 11 of the 13 plant species in this rule (see Table 3). All of the plants and the picture-wing fly in this final rule are impacted by either introduced ungulates, as noted in item (1) above, or nonnative rats and slugs, or both.

(3) Predation of adults and larvae of Hawaiian picture-wing flies by the western yellow-jacket wasp has been observed, and it has been suggested that wasp predation has played a significant role in the dramatic declines of some populations of picture-wing flies (Carson 1986, pp. 3–9; Foote and Carson 1995, p. 371; Kaneshiro and Kaneshiro 1995, pp. 40–45; Science Panel 2005, pp. 1–23). Because western yellow-jacket wasps are found in the three

ecosystems in which the picture-wing fly is found, and western yellow-jacket wasps are known to prey on picture-wing flies, we consider predation by the western yellow-jacket wasp to be a serious and ongoing threat to *Drosophila digressa.*

(4) Parasitic wasps purposefully introduced to Hawaii to control nonnative pest fruit flies will indiscriminately sting any fly larvae when attempting to lay their eggs. Predation by one or more of these nonnative parasitic wasps is a threat to *Drosophila digressa.*

(5) Picture-wing flies are vulnerable to predation by ants, and the range of *Drosophila digressa* overlaps that of particularly aggressive, nonnative, predatory ant species that currently occur from sea level to the montane mesic ecosystem (over 3,280 ft (1,000 m) elevation) on all of the main Hawaiian Islands. We therefore consider predation by these nonnative ants to be a threat to *Drosophila digressa.*

(6) The plant *Pritchardia lanigera* is vulnerable to predation by nonnative invertebrates. The two-spotted leafhopper has been observed on plants in the genus *Pritchardia* throughout the main Hawaiian Islands, and poses a threat to *Pritchardia lanigera* (Chapin *et al.* 2004, p. 279). Two-spotted leafhopper damage results in the death of affected leaves or the entire plant (Alyokhin *et al.* 2004, p. 1). In addition, several species of nonnative beetles (*Coccotrypes* spp.) bore into and feed upon the seeds of the native palm genus *Pritchardia* (Swezey 1927, in litt.; Science Panel 2005, pp. 1–23; Magnacca 2011b, pers. comm.), which results in reduced natural regeneration of the plants (Beaver 1987, p. 11; Magnacca 2005, in litt.; Science Panel 2005, pp. 1–23).

These threats are serious and ongoing, act in concert with other threats to the species, and are expected to continue or increase in magnitude and intensity into the future without effective management actions to control or eradicate them. In addition, negative impacts to native Hawaiian plants on Hawaii Island from grazing and browsing by axis deer are likely should this nonnative ungulate increase in numbers and range on the island.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Feral Ungulates

Nonnative ungulates pose a major ongoing threat to all 13 plant species, and to the picture-wing fly, through destruction and degradation of terrestrial habitat, and through direct predation of the 13 plant species (see Table 3). In addition, nonnative ungulates (feral goats and cattle) pose an ongoing threat to the anchialine pool shrimp through destruction and degradation of its anchialine pool habitat at Lua o Palahemo (feral ungulates are not reported to pose a threat to the anchialine pool habitat at Manuka). Feral goats and cattle trample and forage on both native and nonnative plants around and near the pool opening at Lua o Palahemo, and increase erosion around the pool and sediment entering the pool. The State of Hawaii provides game mammal (feral pigs, goats, cattle, sheep, and mouflon sheep) hunting opportunities on 42 State-designated public hunting areas on the island of Hawaii (H.A.R. 13–123; Mello 2011, pers. comm.). The State's management objectives for game animals range from maximizing public hunting opportunities (e.g., ''sustained yield'') in some areas to removal by State staff, or their designees, in other areas (H.A.R. 13–123). Ten of the 13 plant species (*Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Platydesma remyi, Pritchardia lanigera, Schiedea hawaiiensis,* and *Stenogyne cranwelliae*) and the picture-wing fly have occurrences in areas where terrestrial habitat may be manipulated for game enhancement and where game populations are maintained at prescribed levels using public hunting (Perlman *et al.* 2001, in litt.; Perlman *et al.* 2004, in litt.; Lorence and Perlman 2007, pp. 357–361; PEPP 2007, p. 61; Pratt 2007a, in litt.; Pratt 2007b, in litt.; Benitez *et al.* 2008, p. 58; Agorastos 2010, in litt.; HBMP 2010c; HBMP 2010e; HBMP 2010f; HBMP 2010g; HBMP 2010h; HBMP 2010i; HBMPk; PEPP 2010, p. 63; Bio 2011, pers. comm.; Evans 2011, in litt.; Perry 2011, in litt.; Magnacca 2011b, pers. comm.; H.A.R. 13–123). Public hunting areas are not fenced, and game mammals have unrestricted access to most areas across the landscape, regardless of underlying land-use designation. While fences are sometimes built to protect areas from game mammals, the current number and locations of fences are not adequate to prevent habitat degradation and destruction for all 15 species, or the direct predation of the 13 plant species on Hawaii Island (see Table 3). However, the State game animal regulations are not designed nor intended to provide habitat protection, and there are no other regulations designed to address habitat protection from ungulates.

The capacity of Federal and State agencies and their nongovernmental partners in Hawaii to mitigate the effects of introduced pests, such as ungulates and weeds, is limited due to the large number of taxa currently causing damage (Coordinating Group on Alien Pest Species (CGAPS) 2009). Many invasive weeds established on Hawaii Island have currently limited but expanding ranges and are of concern. Resources available to reduce the spread of these species and counter their negative ecological effects are limited. Control of established pests is largely focused on a few invasive species that cause significant economic or environmental damage to public and private lands. Comprehensive control of an array of invasive pests and management to reduce disturbance regimes that favor certain invasive species remain limited in scope. If current levels of funding and regulatory support for invasive species control are maintained on Hawaii Island, the Service expects existing programs to continue to exclude or, on a very limited basis, control invasive species only in high-priority areas. Threats from established pests (e.g., nonnative ungulates, weeds, and invertebrates) are ongoing and expected to continue into the future.

Introduction of Nonnative Species

Currently, four agencies are responsible for inspection of goods arriving in Hawaii (CGAPS 2009). The Hawaii Department of Agriculture (HDOA) inspects domestic cargo and vessels, and focuses on pests of concern to Hawaii, especially insects or plant diseases not yet known to be present in the State (HDOA 2009). The U.S. Department of Homeland Security's Customs and Border Protection (CBP) is responsible for inspecting commercial, private, and military vessels and aircraft, and related cargo and passengers arriving from foreign locations. CBP focuses on a wide range of quarantine issues involving non-propagative plant materials (processed and unprocessed); wooden packing materials, timber, and products; internationally regulated commercial species under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); seeds and plants listed as noxious; soil; and pests of concern to the greater United States, such as pests of mainland U.S. forests and agriculture. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service, Plant Protection and Quarantine (USDA–APHIS–PPQ) inspects propagative plant material,

provides identification services for arriving plants and pests, conducts pest risk assessments, trains CBP personnel, conducts permitting and preclearance inspections for products originating in foreign countries, and maintains a pest database that, again, has a focus on pests of wide concern across the United States. The Service inspects arriving wildlife products, with the goal of enforcing the injurious wildlife provisions of the Lacey Act (18 U.S.C. 42; 16 U.S.C. 3371 *et seq.*), and identifying CITES violations.

The State of Hawaii's unique biosecurity needs are not recognized by Federal import regulations. Under the USDA–APHIS–PPQ's commodity risk assessments for plant pests, regulations are based on species considered threats to the mainland United States and do not address many species that could be pests in Hawaii (Hawaii Legislative Reference Bureau (HLRB) 2002, pp. 1–109; USDA–APHIS–PPQ 2010, pp. 1–88; CGAPS 2009, pp. 1–14). Interstate commerce provides the pathway for invasive species and commodities infested with non-Federal quarantine pests to enter Hawaii. Pests of quarantine concern for Hawaii may be intercepted at Hawaiian ports by Federal agents, but are not always acted on by them because these pests are not regulated under Federal mandates. Hence, Federal protection against pest species of concern to Hawaii has historically been inadequate. It is possible for the USDA to grant Hawaii protective exemptions under the ''Special Local Needs Rule,'' when clear and comprehensive arguments for both agricultural and conservation issues are provided; however, this exemption procedure operates on a case-by-case basis. Therefore, that avenue may only provide minimal protection against the large diversity of foreign pests that threaten Hawaii.

Adequate staffing, facilities, and equipment for Federal and State pest inspectors and identifiers in Hawaii devoted to invasive species interdiction are critical biosecurity gaps (HLRB 2002, pp. 1–14; USDA–APHIS–PPQ 2010, pp. 1–88; CGAPS 2009, pp. 1–14). State laws have recently been passed that allow the HDOA to collect fees for quarantine inspection of freight entering Hawaii (e.g., Act 36 (2011) H.R.S. 150A–5.3). Legislation passed and enacted on July 8, 2011 (H.B. 1568), requires commercial harbors and airports in Hawaii to provide biosecurity and inspection facilities to facilitate the movement of cargo through the ports. This enactment is a significant step toward optimizing the biosecurity capacity in the State of Hawaii; however, only time will determine the true effectiveness of this legislation. From a Federal perspective, there is a need to ensure that all civilian and military port and airport operations and construction are in compliance with the Federal Endangered Species Act of 1973, as amended. The introduction of new pests to the State of Hawaii is a significant risk to federally listed species because the existing regulations are inadequate for the reasons discussed in the sections below.

Nonnative Animal Species

Vertebrate Species

The State of Hawaii's laws prohibit the importation of all animals unless they are specifically placed on a list of allowable species (HLRB 2002, pp. 1–109; CGAPS 2010, pp. 1–14). The importation and interstate transport of invasive vertebrates is federally regulated by the Service under the Lacey Act as ''injurious wildlife'' (Fowler *et al.* 2007, pp. 353 – 359); the list of vertebrates considered ''injurious wildlife'' is provided at 50 CFR 16. However, the law in its current form has limited effectiveness in preventing invasive vertebrate introductions into the State of Hawaii due to the following factors: (1) The list of vertebrates considered as ''injurious wildlife'' and provided at 50 CFR 16 includes a relatively limited list of vertebrate species that are federally enforceable under the Lacey Act; (2) the current list of vertebrates that are considered ''injurious wildlife'' may not include injurious wildlife that are identified under individual State laws or regulations; and (3) listing additional vertebrate species under 50 CFR 16 may entail a long process or timeframe. On June 21, 2012, a new State law, Act 144 (''Relating to Wildlife''), was signed into law. Act 144 prohibits the interisland possession, transfer, transport, or release after transport of wild or feral deer, and establishes mandatory fines. On June 21, 2012, Act 149 (''Relating to Emergency Rules for Threats to Natural Resources or the Health of the Environment'') was also signed into State law. Act 149 expands the ability of State agencies to adopt emergency rules to address situations that impose imminent threats to natural resources (Aila 2012a, in litt.; Martin 2012, in litt.). However, the effectiveness of these two recently enacted laws has not yet been demonstrated.

Recently (2010–2011), unauthorized introduction of axis deer (*Axis axis*) to the island of Hawaii as a game animal has occurred (Kessler 2011, in litt.; Aila 2012a, in litt.). They have been observed in the regions of Kohala, Kau, Kona, and Mauna Kea (HDLNR 2011, in litt.). The Hawaii Department of Land and Natural Resources-Department of Forestry and Wildlife (HDLNR–HDOFAW) has developed a response-and-removal plan, including a partnership now underway between HDLNR, Hawaii Department of Agriculture (HDOA), the Big Island Invasive Species Committee (BIISC), Federal natural resource management agencies, ranchers, farmers, private landowners, and concerned citizens (*http://www.bigisland-bigisland.com/,* June 6, 2011). The partnership is working with animal trackers and game cameras to survey locations where axis deer have been observed in an effort to eradicate them on the island (*http://www.bigisland-bigisland.com/,* June 6, 2011; Osher 2012, in litt.). There is a high level of concern by the partnership due to the negative impacts of axis deer on agriculture and native ecosystems on neighboring islands (e.g., Maui) (Aila 2011, in litt.; Schipper 2011, in litt.; Aila 2012b, in litt.). In response to the presence of axis deer on Hawaii Island, the Hawaii Invasive Species Council drafted a bill to allow State agencies to adopt emergency rules in instances of imminent peril to the public health, safety, or morals, or to livestock and poultry health (Aila 2012a, in litt.). This was intended to address a gap in the current emergency rules authority, expanding the ability of State agencies to adopt emergency rules to address situations that impose imminent threats to natural resources (Aila 2012a, in litt.; Martin 2012, in litt.). This bill was enacted into State law on June 21, 2012.

Invertebrate Species

Predation by nonnative invertebrate pests (slugs, wasps, ants, leafhoppers, and beetles) negatively impacts 6 of the 13 the plant species and the picture-wing fly (see Table 3 and *Factor C. Disease or Predation,* above). It is likely that the introduction of most nonnative invertebrate pests to the State has been and continues to be accidental and incidental to other intentional and permitted activities. Although Hawaii State government and Federal agencies have regulations and some controls in place (see above), and a few private organizations are voluntarily addressing this issue, the introduction and movement of nonnative invertebrate pest species between islands and from one watershed to the next continues. For example, an average of 20 new alien invertebrate species have been introduced to Hawaii per year since 1970, an increase of 25 percent over the previous totals between 1930 and 1970 (The Nature Conservancy of Hawaii

(TNCH) 1992, p. 8). Existing regulatory mechanisms therefore appear inadequate to ameliorate the threat of introductions of nonnative invertebrates, and we have no evidence to suggest that any changes to these regulatory mechanisms are anticipated in the future.

Nonnative Plant Species

Nonnative plants destroy and modify habitat throughout the ranges of 14 of the 15 species listed as endangered in this final rule (see Table 3, above). As such, they represent a serious and ongoing threat to each of these species. In addition, nonnative plants have been shown to outcompete native plants and convert native-dominated plant communities to nonnative plant communities (see ''Habitat Destruction and Modification by Nonnative Plants,'' under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above).

The State of Hawaii allows the importation of most plant taxa, with limited exceptions, if shipped from domestic ports (HLRB 2002; USDA–APHIS–PPQ 2010; CGAPS 2010). Hawaii's plant import rules (H.A.R. 4–70) regulate the importation of 13 plant taxa of economic interest; regulated crops include pineapple, sugarcane, palms, and pines. Certain horticultural crops (e.g., orchids) may require import permits and have pre-entry requirements that include treatment or quarantine or both, prior to or following entry into the State. The State noxious weed list (H.A.R. 4–68) and USDA–APHIS–PPQ's Restricted Plants List restrict the import of a limited number of noxious weeds. If not specifically prohibited, current Federal regulations allow plants to be imported from international ports with some restrictions. The Federal Noxious Weed List (see 7 CFR 360.200) includes few of the many globally known invasive plants, and plants in general do not require a weed risk assessment prior to importation from international ports. USDA–APHIS–PPQ is in the process of finalizing rules to include a weed risk assessment for newly imported plants. Although the State has general guidelines for the importation of plants, and regulations are in place regarding the plant crops mentioned above, the intentional or inadvertent introduction of nonnative plants outside the regulatory process and movement of species between islands and from one watershed to the next continues, which represents a threat to native flora for the reasons described above. In addition, government funding is inadequate to provide for sufficient inspection services and monitoring. One study concluded that the plant importation laws virtually ensure new invasive plants will be introduced via the nursery and ornamental trade, and that outreach efforts cannot keep up with the multitude of new invasive plants being distributed. The author states the only thing that wide-scale public outreach can do in this regard is to let the public know new invasive plants are still being sold, and they should ask for noninvasive or native plants instead (Martin 2007, in litt.).

In 1995, the Coordinating Group on Alien and Plant Species (CGAPS), a partnership comprised primarily of managers from every major Federal, State, County, and private agency and organization involved in invasive species work in Hawaii, facilitated the formation of the Hawaii Invasive Species Council (HISC), which was created by gubernatorial executive order in 2002, to coordinate local initiatives for the prevention and control of invasive species by providing policy-level direction and planning for the State departments responsible for invasive species issues. In 2003, the Governor signed into law Act 85, which conveys statutory authority to the HISC to continue to coordinate approaches among the various State and Federal agencies, and international and local initiatives for the prevention and control of invasive species (HDLNR 2003, p. 3–15; HISC 2009; H.R.S. 194–2(a)). Some of the recent priorities for the HISC include interagency efforts to control nonnative species such as the plants *Miconia calvescens* (miconia) and *Cortaderia* spp. (pampas grass), coqui frogs (*Eleutherodactylus coqui*), and ants (HISC 2009). Since 2009, State funding for HISC has been cut by approximately 50 percent (total funding dropped from $4 million in fiscal year FY 2009 to $2 million in FY 2010, and to $1.8 million for FY 2011 to FY 2013 (Atwood 2012, in litt.; Atwood 2013, in litt.). Congressional earmarks made up some of the shortfall in State funding in 2010 and into 2011. These funds supported ground crew staff that would have been laid off due to the shortfall in State funding (Clark 2012, in litt.). Following a 50-percent reduction from FY 2009 funding, the HISC budget has remained relatively flat (i.e., State funding is equal to funding provided in 2009) from FY 2010 to FY 2013 (Atwood 2013, in litt.).

Dumping of Trash and Introduction of Nonnative Fish

The Lua o Palahemo anchialine pool is located in a remote, largely undeveloped area, but is well known and frequently visited by residents and visitors for recreational opportunities, as indicated by the numerous off-road vehicle tracks around the pool (USFWS 2012 in litt.; Richardson 2012, in litt., pp. 1–2). As of the 2010 survey, a sign posted near Lua o Palahemo indicates that individuals who disturb the site are subject to fines under Haw. Rev. Stat. 6E (Hawaii's State Historic Preservation Act (SHPA)). This statute makes it unlawful for any person to take, appropriate, excavate, injure, destroy, or alter any historic property or aviation artifact located upon lands owned or controlled by the State or any of its political subdivisions, except as permitted by the State. Violators are subject to fines of not less than $500 nor more than $10,000 for each separate offense. However, regardless of the above warning, sometime between the 2010 survey and the June 2012 visit by Service biologists, the sign had been removed by unknown persons (Richardson 2012, in litt., pp. 1–2).

Three of the four anchialine pools in Manuka that support *Vetericaris chaceorum* are located between 10 and 33 ft (3 and 10 m) from the jeep road, which provides access to popular coastal fishing and recreational locations frequented by the public, and one pool is approximately 60 ft (18 m) from the road (Sakihara 2013, in litt.). The intentional introduction of nonnative freshwater fish is possible at these pools because there is evidence that at least one pool in Manuka harbors nonnative freshwater poeciliids (see Factors Affecting the 15 Species, below) and marine fish, likely introduced by fishermen. Three of the four anchialine pools are located in Manuka NAR. Prohibited activities in the State natural area reserve include, but are not limited to, the removal, injury, or killing of any plant or animal life (except game mammals and birds), the introduction of any plant or animal life, and littering or deposition of refuse or any other substance (NAR System-Title 13, Subtitle 9 Natural Area Reserve System, Chap. 209 Sect. 13–209–4 Prohibited activities). The minimum fine for anyone convicted of violation of any laws or rules applicable to the natural area reserve system is $1,000. The maximum fine that may be collected is $10,000 for a third violation within 5 years. The State may also initiate legal action to recover administrative costs. However, there are no signs in place informing the public about the unique animals that inhabit the anchialine pools, the threats posed by dumping fish in the pools, or the prohibitions

against the introduction of plants or animals into the pools. In addition, there are no law enforcement officers or NAR staff assigned to regularly patrol the area for prohibited activities such as fish dumping in the anchialine pools (Hadway 2013, pers. comm.). Although the introduction of animals, such nonnative freshwater fish and marine fish, into Manuka NAR is a prohibited activity, an introduction has been documented in at least one pool in Manuka. Therefore, the existing State NARs rules are not adequately preventing the introduction of nonnative freshwater fish into the anchialine pools within the NAR.

On the basis of the above information, existing State and Federal regulatory mechanisms are not adequately preventing the introduction of nonnative species to Hawaii via interstate and international mechanisms, or intrastate movement of nonnative species between islands, and watersheds in Hawaii, and thus do not adequately protect each of the 13 plant species and the picture-wing fly in this final rule from the threat of new introductions of nonnative species, or from the continued expansion of nonnative species populations on and between islands and watersheds. Nonnative species prey upon species, modify or destroy habitat, or directly compete with one or more of these 14 species for food, space, and other necessary resources. The impacts from these introduced threats are ongoing and are expected to continue into the future.

In addition, the existing regulatory mechanisms do not provide adequate protection for the anchialine pool shrimp, *Vetericaris chaceorum,* from the intentional dumping of trash and introduction of nonnative fish into the pools that support this pool shrimp (at Lua o Palahemo and Manuka NAR, see above) (see *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence,* below). Existing regulatory mechanisms are therefore inadequate to ameliorate the threat of introductions of trash and nonnative fish into the pools that support the anchialine pool shrimp listed as endangered in this final rule, and we have no evidence to suggest that any changes to these regulatory mechanisms are anticipated in the future.

Summary of Inadequacy of Existing Regulatory Mechanisms

The State's current management of nonnative game mammals is inadequate to prevent the degradation and destruction of habitat of the 13 plant species, the anchialine pool shrimp, and the picture-wing fly (*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range*), and to prevent predation of all 13 plant species and the host plants of the picture-wing fly *Drosophila digressa* (*Factor C. Disease or Predation*).

Existing State and Federal regulatory mechanisms are not effectively preventing the introduction and spread of nonnative species from outside the State of Hawaii and between islands and watersheds within the State of Hawaii. Habitat-altering, nonnative plant species (*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range*) and predation by nonnative animal species (*Factor C. Disease or Predation*) pose a major ongoing threat to the 13 plant species and the picture-wing fly listed in this final rule.

Existing State and Federal regulatory mechanisms do not provide adequate protection for the anchialine pool shrimp *Vetericaris chaceorum,* from the intentional dumping of trash and introduction of nonnative fish into Lua o Palahemo and the four pools at Manuka that support the anchialine pool shrimp (see *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence*).

As all 13 plant species and the picture-wing fly experience threats from habitat degradation and loss by nonnative plants (*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range*), and all 15 species experience threats from nonnative animals (including nonnative fish) (*Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range* and *Factor C. Disease or Predation*), we conclude the existing regulatory mechanisms are inadequate to sufficiently reduce these threats to all 15 species.

Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence

Other factors that pose threats to some or all of the 15 species include dumping of trash and the introduction of nonnative fish, small numbers of populations and small population sizes, hybridization, lack of or declining regeneration, loss of host plants, and other activities. Each threat is discussed in detail below, along with identification of which species are affected by these threats.

Dumping of Trash and Introduction of Nonnative Fish

The depressional features of anchialine pools make them susceptible to dumping. Refuse found in degraded pools and pools that have been filled in with rubble has been dated to about 100 years old, and the practice continues today (Brock 2004, p. 15). Lua o Palahemo, one of the two known locations of *Vetericaris chaceorum,* the anchialine pool shrimp listed in this final rule, is located approximately 558 ft (170 m) from a sandy beach frequented by visitors who fish and swim. In addition, there are multiple dirt roads that surround the pool, making it highly accessible. Plastic bags, paper, fishing line, water bottles, soda cans, radios, barbed wire, and a bicycle have been documented within the pool (Kensley and Williams 1986, pp. 417–418; Bozanic 2004, p. 1; Wada 2010, in litt.). Physical trash can increase the accumulation of sediment in the pool portion of Lua o Palahemo by plugging up the cracks and trapping sediments, which subsequently negatively impacts adequate water flushing. Also, physical trash can block the currently narrow passage into the much larger water body in the lava tube below. The degree of impact that trash imposes on a given anchialine pool habitat depends on the ratio between the size of the pool and the amount and type of trash (i.e., in a smaller pool, the negative impacts of trash on flushing would be greater because of the reduced aquatic substrate area). Introduction of trash involving chemical contamination into anchialine pools, as has been observed elsewhere on Hawaii Island (Brock 2004, pp. 15–16), will more drastically affect water quality and result in local extirpation of hypogeal shrimp species. Biologists did not record an accumulation of trash in the pool during the December 2012 survey (Wada 2012, in litt.). According to Sakihara, the pools at Manuka are threatened by nonnative species, trash, human waste, and physical alteration (at least one pool has been physically altered by the public). Dumping of trash has not been observed at the four pools that support *V. chaceorum* at Manuka, although trash dumping has been documented in and around other anchialine pools at Manuka, including at Keawaiki, where this species has been documented (Sakihara 2009, pp. 1, 21, 23, 25, 30). In addition, physical alteration (e.g., filling with trash such as aluminum cans and paper by campers), has been reported in at least one anchialine pool at Keawaiki, although it has not been observed in the four pools

that support *V. chaceorum* (Sakihara 2009, pp. 4, 23, 25).

In general, the accidental or intentional introduction and spread of nonnative fish (bait and aquarium fish) is considered the greatest threat to anchialine pools in Hawaii (Brock 2004, p. 16). Maciolek (1983, p. 612) found that the abundance of shrimp in a given population is indirectly related to predation by fish. The release of mosquito fish (*Gambusia affinis*) and tilapia (*Oreochromis mossambica* (synonym: *Tilapia mossambica*) into the Waikoloa Anchialine Pond Preserve (WAAPA) at Waikoloa, North Kona, Hawaii, resulted in the infestation of all ponds within an approximately 3.2-ha (8-ac) area, which represented approximately two-thirds of the WAAPA. Within 6 months, all native hypogeal shrimp species disappeared (Brock 2004, pp. iii). Nonnative fish drive anchialine species out of the lighted, higher productivity portion of the pools, into the surrounding water table bedrock, subsequently leading to the decimation of the benthic community structure of the pool (Brock 2004, p. iii). In addition, nonnative fish prey on and exclude native hypogeal shrimp that are usually a dominant and essential (Brock 2004, p. 16) faunal component of anchialine pool ecosystems (Bailey-Brock and Brock 1993, pp. 338–355). The loss of the shrimp changes ecological succession by reducing herbivory of macroalgae, allowing an overgrowth and change of pool flora. This overgrowth changes the system from clear, well-flushed basins to a system characterized by heavy sedimentation and poor water exchange, which increases the rate of pool senescence (Brock 2004, p. 16). Nonnative fish, unlike native fish, are able to complete their life cycles within anchialine habitats, and remain a permanent, detrimental presence in all pools into which they are introduced (Brock 2004, p. 16). In Hawaii, the most frequently illegally introduced fish are in the Poeciliidae family (freshwater fish that bear live young) and include mosquito fish, various mollies (*Poecilia* spp.), and tilapia, which prey on and exclude native hypogeal shrimp such as the herbivorous species upon which *Vetericaris chaceorum* presumably feed.

Lua o Palahemo is highly accessible to off-road vehicle traffic and located near an area frequented by residents and visitors for fishing and other outdoor recreational activities. The pool is vulnerable to the intentional dumping of trash and introduction of nonnative fish (bait and aquarium fish) because the area is easily accessible to vehicles and human traffic, and yet due to its remote location, is far from regulatory oversight by the DHHL or the Hawaii State Deparment of Aquatic Resources (DAR). According to Brock (2012, pers. comm.), sometime in the 1980s, nonnative fish were introduced into Lua o Palahemo. It is our understanding that the fish were subsequently removed with a fish poison, and to our knowledge the pool currently remains free of nonnative fish. The most commonly used piscicide (fish pesticide) in the United States for management of fish in freshwater systems is a naturally occurring chemical, marketed as Rotenone. Rotenone use in marine systems (including anchialine pools) is illegal according to the Environmental Protection Agency (EPA 2007, pp. 22–23, 29, 32; Finlayson et al. 2010, p. 2).

Three of the four pools that support *Vetericaris chaceorum* at Manuka are located between 10 and 33 ft (3 and 10 m) from a jeep road that provides access to coastal fishing and recreational locations frequented by the public (Sakihara 2013, in litt.). The fourth pool is approximately 60 ft (18 m) from the jeep road (Sakihara 2013, in litt.). The pools are vulnerable to the intentional dumping of trash and introduction of nonnative fish because trash dumping has been documented in and around anchialine pools at Manuka, including at Keawaiki, where this species has been documented (Sakihara 2009, pp. 21, 25, 30), and nonnative freshwater poeciliids (fish in the Poeciliidae family and that bear live young) have been introduced and established in at least one pool in the Manuka pool complex (Sakihara 2012, in litt.). This pool is approximately 0.3 mi (0.5 km) from the four pools that support *V. chaceorum.* Marine fish have been detected in the same pool, and it is speculated that these fish were intentionally introduced into the pool by fishermen (Sakihara 2012, in litt.). Recreational users utilize anchialine pools as ''holding pools'' for bait fish (e.g., nonnative freshwater fish like tilapia, mosquito fish, and marine fish like aholehole (*Kuhlia* sp.) and kupipi (blackspot sergeant; *Abudefduf sordidus*)) used for fishing (Wada 2013, in litt.). The impacts of native marine fish on *V. chaceorum* are unknown. In addition, the pools that support *V. chaceorum* at Manuka are vulnerable to intentional physical alteration because at least one anchialine pool at Keawaiki (where this species has been documented) has been altered, although pool alteration has not been observed in the four pools that support *V. chaceorum* (Sakihara 2009, p. 23).

As the anchialine pool shrimp *Vetericaris chaceorum* is only known from two locations, the introduction of nonnative fish, which prey on and exclude native hypogeal shrimp like *V. chaceorum* or its associated prey shrimp species, would lead to the extirpation of this species at one or both of its known locations, directly or indirectly due to the lower abundance of co-occurring shrimp species that provide food resources to *V. chaceorum.* In addition, the loss of native shrimp species leads to changes in ecological succession in anchialine pools, leading to senescence of the pool habitat, thereby rendering the pool unsuitable habitat (Brock 2004, p. 16). Dumping of nonnative fish into one or more of the three anchialine pools at Manuka, which are believed to have a subterranean connection, would impact the integrity of all three pools should nonnative fish spread from the pool of introduction to the other two pools. Although not common, experts agree that the dumping of nonnative fish can happen (Sakihara 2013, in litt.; Wada 2013, pers. comm.). A fourth pool that supports *V. chaceorum* is not believed to have a subterranean connection to other pools at Manuka.

Recreational Use of Off-Road Vehicles

Off-road vehicles frequent the area surrounding the Lua o Palahemo anchialine pool that supports one of the two known occurrences of *Vetericaris chaceorum,* resulting in increased erosion and accumulation of sediment, which negative impacts the anchialine pool habitat. The negative impacts from sedimentation are discussed under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above (Richarson 2012, in litt.)

Small Number of Individuals and Populations

Species that are endemic to single islands are inherently more vulnerable to extinction than are widespread species, because of the increased risk of genetic bottlenecks; random demographic fluctuations; climate change effects; and localized catastrophes, such as hurricanes, drought, rockfalls, landslides, and disease outbreaks (Pimm *et al.* 1988, p. 757; Mangel and Tier 1994, p. 607). These problems are further magnified when populations are few and restricted to a very small geographic area, and when the number of individuals in each population is very small. Populations with these characteristics face an increased likelihood of stochastic extinction due to changes in demography, the environment, genetics, or other factors (Gilpin and Soulé 1986, pp. 24–34). Small, isolated populations often exhibit reduced levels of genetic

variability, which diminishes the species' capacity to adapt and respond to environmental changes, thereby lessening the probability of long-term persistence (e.g., Barrett and Kohn 1991, p. 4; Newman and Pilson 1997, p. 361). Very small, isolated populations are also more susceptible to reduced reproductive vigor due to ineffective pollination (plants), inbreeding depression (plants and shrimp), and hybridization (plants and flies). The problems associated with small population size and vulnerability to random demographic fluctuations or natural catastrophes are further magnified by synergistic interactions with other threats, such as those discussed above (see *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range* and *Factor C. Disease or Predation,* above).

Plants

A limited number of individuals (fewer than 50 individuals) is a threat to the following six plant species listed as endangered in this final rule: *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyrtandra wagneri, Platydesma remyi, Schiedea diffusa* ssp. *macraei,* and *S. hawaiiensis.* We consider these species highly vulnerable to extinction due to threats associated with small population size or small number of populations because:

- The only known occurrences of *Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii,* and *Cyrtandra wagneri* are threatened either by landslides, rockfalls, inundation by high surf, or erosion, or a combination of these, because of their locations in lowland wet, montane wet, coastal, and dry cliff ecosystems.
- *Platydesma remyi* is known from fewer than 40 scattered individuals (Stone *et al.* 1999, p. 1210; HBMP 2010i). Declining or lack of regeneration in the wild appears to threaten this species.
- *Schiedea diffusa* ssp. *macraei* is known from a single individual in the Kohala Mountains (Perlman *et al.* 2001, in litt.; Wagner *et al.* 2005d, p. 106; HBMP 2010j; Bio 2011, pers. comm.).
- Habitat destruction or direct predation by ungulates, nonnative plants, drought, and fire are threats to the 25 to 40 individuals of *Schiedea hawaiiensis* (Mitchell *et al.* 2005a; NDMC 2012—*Online Archives*).

Animals

Like most native island biota, the endemic anchialine pool shrimp and Hawaiian picture-wing fly are particularly sensitive to disturbances due to low number of individuals, low population numbers, and small geographic ranges. We consider the picture-wing fly vulnerable to extinction due to threats associated with low number of individuals and low number of populations because *Drosophila digressa* is known from only two of its five historically known locations. The following threats to this species have all been documented: Predation by nonnative wasps and ants; habitat degradation and destruction by nonnative ungulates, fire, and drought; loss of its host plants; and competition with nonnative flies for its host plants (Science Panel 2005, pp. 1–23; Magnacca 2011b, pers. comm.).

Hybridization

Natural hybridization is a frequent phenomenon in plants and can lead to the formation of new species (Orians 2000, p. 1,949), or sometimes to the decline of species through genetic assimilation or ''introgression'' (Ellstrand 1992, pp. 77, 81; Levine *et al.* 1996, pp. 10–16; Rhymer and Simberloff 1996, p. 85). Hybridization, however, is especially problematic for rare species that come into contact with species that are abundant or more common (Rhymer and Simberloff 1996, p. 83). We consider hybridization to be a threat to three species, and potentially a threat to one more additional species in this final rule because hybridization may lead to extinction of the original genotypically distinct species. Hybrid swarms (hybrids between parent species, and subsequently formed progeny from crosses among hybrids and crosses of hybrids to parental species) have been reported between the plant *Bidens micrantha* ssp. *ctenophylla* and *B. menziesii* ssp. *filiformis* near Puuwaawaa in north Kona (Ganders and Nagata 1983, p. 12; Ganders and Nagata 1999, p. 278); the plant *Cyrtandra nanawaleensis* is known to hybridize with *C. lysiosepala* in and around the Nanawale FR (Price 2011, in litt.); and *Cyrtandra wagneri* is reported to hybridize with *C. tintinnabula.* Only eight individuals express the true phenotype of *C. wagneri,* and only three of these individuals are reproducing successfully (PEPP 2010, p. 102; Bio 2011, pers. comm.). Native species can also hybridize with related nonnative species. For example, native species of *Pittosporum,* including the plant *Pittosporum hawaiiense,* are known to exhibit high levels of gene flow, and hybridization between native *Pittosporum* and nonnative species of *Pittosporum* may occur when they occupy similar habitat and elevation (Daehler and Carino 2001, pp. 91–96; Bacon *et al.* 2011, p. 733).

Regeneration

Lack of, or low levels of, regeneration (reproduction and recruitment) in the wild has been observed, and is a threat to, *Pittosporum hawaiiense, Platydesma remyi,* and *Pritchardia lanigera* (Bio 2011, pers. comm.; Magnacca 2011b, pers. comm.). The reasons for this are not well understood: however, seed predation by rats, ungulates, and beetles is thought to play a role (Bio 2011, pers. comm.; Magnacca 2011b, pers. comm.; Crysdale 2013, pers. comm.). In addition, *Cyanea tritomantha* is reported to produce few seeds with low viability. The reasons for this are unknown (Bio 2008, in litt.).

Competition

Competition with nonnative tipulid flies (large crane flies, family Tipulidae) for larvae host plants adversely impacts the picture-wing fly listed in this final rule. The Hawaiian Islands now support several species of nonnative tipulid flies, and the larvae of some species within this group feed within the decomposing bark of some of the host plants utilized by picture-wing flies, including *Cheirodendron, Clermontia, Pleomele,* and *Charpentiera,* one of the two host plants for *Drosophila digressa* (Science Panel 2005, pp. 1–23; Magnacca 2005, in litt.). The effect of this competition is a reduction of available host plant material for the larvae of the picture-wing fly. In laboratory studies, Grimaldi and Jaenike (1984, pp. 1,113–1,120) demonstrated that competition between *Drosophila* larvae and other fly larvae can exhaust food resources, which affects both the probability of larval survival and the body size of adults, resulting in reduced adult fitness, fecundity, and lifespan. Both soldier and neriid flies have been suggested to impose a similar threat to Hawaiian picture-wing flies (Montgomery 2005, in litt.; Science Panel 2005, pp. 1–23).

Loss of Host Plants

Drosophila digressa is dependent on decaying stem bark from plants in the genera *Charpentiera* and *Pisonia* for oviposition and larval development (Montgomery 1975, p. 95; Magnacca 2013, in litt.). *Charpentiera* and *Pisonia* are considered highly susceptible to damage from alien ungulates, such as pigs, cattle, mouflon, and goats, as well as competition with nonnative plants (e.g., *Omalanthus populifolius, Schinus terebinthifolius,* and *Psidium cattleianum*) (Foote and Carson 1995, pp. 370–37; Science Panel 2005, pp.

1–23; Magnacca 2011b, pers. comm.; Magnacca 2013, in litt.). Bark-breeding *Drosophila* species are sensitive to bottlenecks in host plant populations due to their dependence on older, senescent, or dying plants (Magnacca *et al.* 2008, p. 32). Altered decay cycles in host plants caused by genetic bottlenecks, or decreasing availability of host plants due to browsing and trampling by nonnative ungulates (pigs, goats, cattle, and mouflon), competition with nonnative plants, drought, or other phenomena can subsequently alter the life cycle of the picture-wing fly by disrupting the early stages of development. The habitat of *Drosophila digressa* at Manuka has experienced extreme to severe drought for several years, which has resulted in overall habitat degradation and appears to alter decay processes in the picture-wing fly host plants (both *Charpentiera* spp. and *Pisonia* spp.). Magnacca (2013, in litt.) anticipates an alteration in host plant decay will lead to a long-term decline in availability of host plants that can support the life-history requirements of *D. digressa* (see ''Habitat Destruction and Modification Due to Rockfalls, Treefalls, Landslides, Heavy Rain, Inundation by High Surf, Erosion, and Drought,'' above). In addition, predation by nonnative beetles (the branch and twig borer (*Amphicerus cornutus*), the black twig borer (*Xylosandrus compactus*), and weevils (*Oxydema fusiforme*) has been documented as a threat to *Charpentiera* spp. (Medeiros *et al.* 1986, p. 29; Giffin 2009, p. 81).

Conservation Efforts To Reduce Other Natural or Manmade Factors Affecting Their Continued Existence

There are no approved HCPs, CCAs, SHAs, MOUs, or other voluntary actions that specifically address these 15 species and the threats from other natural or manmade factors. We are unaware of any voluntary conservation actions to address the threat of dumping of trash and introduction of nonnative fish into anchialine pools that support the anchialine pool shrimp, *Vetericaris chaceorum,* which is listed as endangered in this final rule. The State's PEP Program identified 8 of the 13 plant species (*Cyanea marksii, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Platydesma remyi, Schiedea diffusa* ssp. *macraei, S. hawaiiensis,* and *Stenogyne cranwelliae*) in this final rule as priority species for collection, propagation, and outplanting; however, due to other workload priorities and limited funding, they have not been able to carry out all of these actions (PEPP 2012, pp. 1–169). While the actions they have been able to implement are a step toward increasing the overall numbers and populations of PEPP species in the wild, these actions are insufficient to eliminate the threat of limited numbers at this time. In addition, successful reproduction and replacement of outplanted individuals by seedlings, juveniles, and adults has not yet been observed in the wild. We are unaware of any voluntary conservation actions to address the threat to the picture-wing fly from low number of individuals. We are unaware of any voluntary conservation actions to address the threat to three plant species from hybridization, the threat of lack of regeneration to four plant species, or the threats from competition with nonnative tipulid flies and the loss of host plants for the picture-wing fly.

Summary of Other Natural or Manmade Factors Affecting Their Continued Existence

The conservation measures described above are insufficient to eliminate the threat from other natural or manmade factors to each of the 15 species listed as endangered in this final rule. We consider the threats from dumping of trash and introduction of nonnative fish into the pools that support the anchialine pool shrimp in this final rule to be serious threats that can occur at any time, although their occurrence is not predictable. The use of anchialine pools for dumping of trash and introduction of nonnative fish are widespread practices in Hawaii and can occur at any time at the Lua o Palahemo and Manuka pools. Nonnative fish prey on or outcompete native, herbivorous anchialine pool shrimp that serve as the prey base for predatory species of shrimp, including the anchialine pool shrimp listed as endangered in this rule. In addition, recreational use of off-road vehicles that frequent Lua o Palahemo are a threat to the shrimp, due to the resulting erosion and sedimentation that builds up in the pool (for impacts associated with sedimentation, see *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range,* above; and for impacts associated with off-road vehicles, see *Factor E. Other Natural or Manmade Factors Affecting Their Continued Existence,* above). The occurrence of off-road vehicle traffic is not predictable; however, it happens frequently and is expected to continue.

We consider the threat from limited number of populations and few (less than 50) individuals to be a serious and ongoing threat to 6 plant species in this final rule (*Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyrtandra wagneri, Platydesma remyi, Schiedea diffusa* ssp. *macraei,* and *S. hawaiiensis*) because: (1) These species may experience reduced reproductive vigor due to ineffective pollination or inbreeding depression; (2) they may experience reduced levels of genetic variability, leading to diminished capacity to adapt and respond to environmental changes, thereby lessening the probability of long-term persistence; and (3) a single catastrophic event may result in extirpation of remaining populations and extinction of the species. This threat applies to the entire range of each species.

The threat to the picture-wing fly from limited numbers of individuals and populations is ongoing and is expected to continue into the future because: (1) This species may experience reduced reproductive vigor due to inbreeding depression; (2) it may experience reduced levels of genetic variability leading to diminished capacity to adapt and respond to environmental changes, thereby lessening the probability of long-term persistence; (3) a single catastrophic event (e.g., hurricane, drought) may result in extirpation of remaining populations and extinction of this species; and (4) species with few known locations, such as *Drosophila digressa,* are less resilient to threats that might otherwise have a relatively minor impact on widely distributed species. For example, the reduced availability of host trees or an increase in predation of the picture-wing fly adults that might be absorbed in a widely distributed species could result in a significant decrease in survivorship or reproduction of a species with limited distribution. The limited distribution of this species thus magnifies the severity of the impact of the other threats discussed in this final rule.

The threat from hybridization is unpredictable but an ongoing and ever-present threat to *Bidens micrantha* ssp. *ctenophylla, Cyrtandra nanawaleensis,* and *Cyrtandra wagneri,* and a potential threat to *Pittosporum hawaiiense.* We consider the threat to *Cyanea tritomantha, Pittosporum hawaiiense, Platydesma remyi,* and *Pritchardia lanigera* from lack of regeneration to be ongoing and to continue into the future because the reasons for the lack of recruitment in the wild are unknown and uncontrolled, and any competition from nonnative plants or habitat modification by ungulates or fire could lead to the extirpation of these species.

Competition for host plants with nonnative tipulid flies is a threat to *Drosophila digressa* and is expected to continue into the future because field

biologists report that these nonnative flies are widespread and there is no mechanism in place to control their population growth. Loss of host plants (*Charpentiera* spp. and *Pisonia* spp.) is a threat to the picture-wing fly, and we consider this threat to continue into the future because field biologists have reported that species of *Charpentiera* and *Pisonia* are declining overall in the wild (see *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range* and *Factor C. Disease or Predation,* above).

Summary of Factors

The primary factors that pose serious and ongoing threats to one or more of the 15 species throughout their ranges in this final rule include: Habitat degradation and destruction by agriculture and urbanization, nonnative ungulates and plants, fire, natural disasters, sedimentation, and potentially climate change, and the interaction of these threats (Factor A); overutilization due to collection of seeds and seedlings of the plant *Pritchardia lanigera* for trade or market (Factor B); predation by nonnative animal species (pigs, goats, sheep, mouflon sheep, cattle, rats, nonnative fish, slugs, wasps, ants, two-spotted leaf hopper, and beetles) (Factor C); inadequate regulatory mechanisms to address nonnative species, and human dumping of nonnative fish and trash into anchialine pools (Factor D); and dumping of trash, introduction of nonnative fish, recreational use, limited numbers of populations and individuals, hybridization, lack of regeneration, competition, and loss of host plants (Factor E). While we acknowledge the voluntary conservation measures described above may help to ameliorate one or more of the threats to the 15 species listed as endangered in this final rule, these conservation measures are insufficient to control or eradicate these threats from all areas where these species occur now or occurred historically.

Determination

We have carefully assessed the best scientific and commercial information available regarding threats to each of the 15 species. We find that each of the 13 plant species and the picture-wing fly face threats that are ongoing and expected to continue into the future throughout their ranges from the present destruction and modification of their habitats from nonnative feral ungulates and nonnative plants (Factor A). Destruction and modification of habitat by development and urbanization is a threat to one plant species (*Bidens micrantha* ssp. *ctenophylla*). Habitat destruction and modification from fire is a threat to three of the plant species (*Bidens micrantha* ssp. *ctenophylla, Phyllostegia floribunda,* and *Schiedea hawaiiensis*) and the picture-wing fly *Drosophila digressa.* Destruction and modification of habitat from rockfalls, landslides, treefalls, heavy rain, inundation by high surf, and subsequent erosion are a threat to four plant species (*Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyanea tritomantha,* and *Cyrtandra wagneri*). Habitat loss or degradation due to drought is a threat to two plants, *Bidens micrantha* ssp. *ctenophylla* and *Schiedea hawaiiensis,* as well as to the picture-wing fly. We are concerned about the effects of projected climate change on all 15 species, particularly rising temperatures, but recognize there is limited information on the exact nature of impacts that these species may experience.

We find that the anchialine pool shrimp faces threats that are ongoing and expected to continue into the future from the present destruction and modification of its anchialine pool habitat at Lua o Palahemo, one of only two known locations for this species, due to sedimentation resulting from degradation of the immediate area surrounding this anchialine pool from nonnative feral ungulates (cattle and goats). Sedimentation reduces both food productivity and the ability of Lua o Palahemo to support the anchialine pool shrimp (Factor A).

Overcollection for commercial and recreational purposes poses a threat to *Pritchardia lanigera* (Factor B).

Predation and herbivory on all 13 plant species by feral pigs, goats, cattle, sheep, mouflon, rats, slugs, two-spotted leaf hoppers, or beetles poses a serious and ongoing threat, as does predation of the picture-wing fly by nonnative wasps and ants (Factor C).

Existing regulatory mechanisms are inadequate to reduce current and ongoing threats posed by nonnative plants and animals to all 15 species, and human dumping of nonnative fish and trash into the anchialine pools that support the anchialine pool shrimp *Vetericaris chaceorum* (Factor D).

There are serious and ongoing threats to six plant species (*Bidens hillebrandiana* ssp. *hillebrandiana, Cyanea marksii, Cyrtandra wagneri, Platydesma remyi, Schiedea diffusa* ssp. *macraei,* and *S. hawaiiensis*) and the picture-wing fly due to factors associated with small numbers of populations and individuals; to *Bidens micrantha* ssp. *ctenophylla, Cyrtandra nanawaleensis, Cyrtandra wagneri,* and potentially to *Pittosporum hawaiiense* from hybridization; to *Cyanea tritomantha, Pittosporum hawaiiense, Platydesma remyi,* and *Pritchardia lanigera* from the lack of regeneration in the wild; and to the picture-wing fly from competition for host plants with nonnative flies and declining numbers of host plants (Factor E) (see Table 3).

The anchialine pool shrimp faces threats from the intentional dumping of trash and introduction of nonnative fish into its pool habitat in the two known locations. In addition, the pools that support *Vetericaris chaceorum* at Lua o Palahemo are potentially vulnerable to intentional physical alteration (i.e., sedimentation) (Bailey-Brock and Brock 1993, pp. 338–355; Brock 2004, pp. iii and 16) (Factor E) (see Table 3).

These threats are exacerbated by these species' inherent vulnerability to extinction from stochastic events at any time because of their endemism, small numbers of individuals and populations, and restricted habitats.

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that each of these 15 endemic species is presently in danger of extinction throughout its entire range, based on the severity and scope of the ongoing and projected threats described above. These threats are exacerbated by small population sizes, the loss of redundancy and resiliency of these species, and the continued inadequacy of existing protective regulations. Based on our analysis, we have no reason to believe that population trends for any of the species that are the subjects of this final rule will improve, nor will the negative impacts of current threats acting on the species be effectively ameliorated in the future. Therefore, on the basis of the best available scientific and commercial information, we are listing the following 15 species as endangered species in accordance with section 3(6) of the Act: The plants *Bidens hillebrandiana* ssp. *hillebrandiana, Bidens micrantha* ssp. *ctenophylla, Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Phyllostegia floribunda, Pittosporum hawaiiense, Platydesma remyi, Pritchardia lanigera, Schiedea diffusa* ssp. *macraei, Schiedea hawaiiensis,* and *Stenogyne cranwelliae;* the anchialine pool shrimp, *Vetericaris chaceorum;* and the picture-wing fly, *Drosophila digressa.*

Under the Act and our implementing regulations, a species may warrant

listing if it is endangered or threatened throughout all or a significant portion of its range. Each of the 15 Hawaii Island species listed as endangered in this final rule is highly restricted in its range, and the threats occur throughout its range. Therefore, we assessed the status of each species throughout its entire range. In each case, the threats to the survival of these species occur throughout the species' ranges and are not restricted to any particular portion of those ranges. Accordingly, our assessment and determination applies to each species throughout its entire range.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing results in public awareness and conservation by Federal, State, and local agencies: Private organizations; and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection measures required of Federal agencies and the prohibitions against certain activities involving listed animals and plants are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed, preparation of a draft and final recovery plan, and revisions to the plan as significant new information becomes available. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. The recovery plan identifies site-specific management actions that will achieve recovery of the species, measurable criteria that help to determine when a species may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (comprised of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outlines, draft recovery plans, and the final recovery plans will be available from our Web site (*http://www.fws.gov/endangered*), or from our Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private and State lands.

Funding for recovery actions may be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, under section 6 of the Act, the State of Hawaii will be eligible for Federal funds to implement management actions that promote the protection and recovery of the 15 species. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Please let us know if you are interested in participating in recovery efforts for these species. Additionally, we invite you to submit any new information on these species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(1) of the Act mandates that all Federal agencies shall utilize their authorities in furtherance of the purposes of the Act by carrying out programs for the conservation of endangered and threatened species listed pursuant to section 4 of the Act. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or result in destruction or adverse modification of critical habitat. If a Federal action may affect the continued existence of a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

For the 15 plants and animals listed as endangered species in this final rule, Federal agency actions that may require consultation as described in the preceding paragraph include, but are not limited to, actions within the jurisdiction of the Natural Resources Conservation Service, the U.S. Army Corps of Engineers, the U.S. Fish and Wildlife Service, and branches of the Department of Defense (DOD). Examples of these types of actions include activities funded or authorized under the Farm Bill Program, Environmental Quality Incentives Program, Ground and Surface Water Conservation Program, Clean Water Act (33 U.S.C. 1251 et seq.), Partners for Fish and Wildlife Program, and DOD construction activities related to training or other military missions.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered wildlife and plants. The prohibitions, codified at 50 CFR 17.21 for wildlife and 17.61 for plants, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these), import, export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed wildlife species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction on areas under Federal jurisdiction and the removal, cutting, digging up, or damaging or destroying of such plants in knowing violation of any State law or regulation, including State criminal trespass law. Certain exceptions to the

prohibitions apply to agents of the Service and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered or threatened wildlife or plant species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 and 17.62 for endangered wildlife and plants, respectively. With regard to endangered wildlife, a permit must be issued for the following purposes: For scientific purposes, to enhance the propagation and survival of the species, and for incidental take in connection with otherwise lawful activities. For endangered plants, a permit must be issued for scientific purposes or for the enhancement of propagation or survival. Requests for copies of the regulations regarding listed species and inquiries about prohibitions and permits may be addressed to U.S. Fish and Wildlife Service, Pacific Region, Ecological Services, Eastside Federal Complex, 911 NE. 11th Avenue, Portland, OR 97232–4181 (telephone 503–231–6131; facsimile 503–231–6243).

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a listing on proposed and ongoing activities within the range of listed species. The following activities could potentially result in a violation of section 9 of the Act; however, this list is not comprehensive:

(1) Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the species, including import or export across State lines and international boundaries, except for properly documented antique specimens of these taxa at least 100 years old, as defined by section 10(h)(1) of the Act;

(2) Activities that take or harm the picture-wing fly or anchialine pool shrimp by causing significant habitat modification or degradation such that it causes actual injury by significantly impairing its essential behavior patterns. This may include introduction of nonnative species that compete with or prey upon the picture-wing fly or anchialine pool shrimp, or the unauthorized release of biological control agents that attack any life stage of these two species; and

(3) Damaging or destroying any of the 13 listed plants in violation of the Hawaii State law prohibiting take of listed species.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Pacific Islands Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). Requests for copies of the regulations concerning listed animals and general inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Pacific Region, Ecological Services, Endangered Species Permits, Eastside Federal Complex, 911 NE. 11th Avenue, Portland, OR 97232–4181 (telephone 503–231–6131; facsimile 503–231–6243).

Federal listing of the 15 species included in this rule automatically invokes State listing under Hawaii's Endangered Species law (H.R.S. 195D 1–32) and supplements the protection available under other State laws. These protections prohibit take of these species and encourage conservation by State government agencies. Further, the State may enter into agreements with Federal agencies to administer and manage any area required for the conservation, management, enhancement, or protection of endangered species (H.R.S. 195D–5). Funds for these activities could be made available under section 6 of the Act (Cooperation with the States). Thus, the Federal protection afforded to these species by listing them as endangered species is reinforced and supplemented by protection under State law.

Required Determinations

National Environmental Policy Act (NEPA)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this rule is available on the Internet at *http://www.regulations.gov* under Docket No. FWS–R1–ES–2012–0070 and upon request from the Pacific Islands Fish and Wildlife Office (see **ADDRESSES,** above).

Authors

The primary authors of this final rule are the staff members of the Pacific Islands Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—AMENDED

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h), the List of Endangered and Threatened Wildlife, as follows:

■ a. By adding an entry for ''Fly, Hawaiian picture-wing'' in alphabetical order under INSECTS; and

■ b. By adding an entry for the ''Shrimp, anchialine pool'' in alphabetical order under CRUSTACEANS, to read as set forth below.

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
INSECTS							
*	*	*	*	*	*		*
Fly, Hawaiian picture-wing.	*Drosophila digressa*	U.S.A. (HI)	Entire	E	818	NA	NA
*	*	*	*	*	*		*
CRUSTACEANS							
*	*	*	*	*	*		*
Shrimp, anchialine pool.	*Vetericaris chaceorum.*	U.S.A. (HI)	Entire	E	818	NA	NA
*	*	*	*	*	*		*

■ 3. Amend § 17.12(h), the List of Endangered and Threatened Plants, as follows:

■ a. By removing the entry for *Caesalpinia kavaiense* under FLOWERING PLANTS; and

■ b. By adding entries for *Bidens hillebrandiana* ssp. *hillebrandiana, Bidens micrantha* ssp. *ctenophylla, Cyanea marksii, Cyanea tritomantha, Cyrtandra nanawaleensis, Cyrtandra wagneri, Mezoneuron kavaiense, Phyllostegia floribunda, Pittosporum hawaiiense, Platydesma remyi, Pritchardia lanigera, Schiedea diffusa* ssp. *macraei, Schiedea hawaiiensis,* and *Stenogyne cranwelliae,* in alphabetical order under FLOWERING PLANTS, to read as set forth below.

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS.							
*	*	*	*	*	*		*
Bidens hillebrandiana ssp. *hillebrandiana.*	Kookoolau	U.S.A. (HI)	Asteraceae	E	818	NA	NA
Bidens micrantha ssp. *ctenophylla.*	Kookoolau	U.S.A. (HI)	Asteraceae	E	818	NA	NA
*	*	*	*	*	*		*
Cyanea marksii	Haha	U.S.A. (HI)	Campanulaceae	E	818	NA	NA
*	*	*	*	*	*		*
Cyanea tritomantha	Aku	U.S.A. (HI)	Campanulaceae	E	818	NA	NA
*	*	*	*	*	*		*
Cyrtandra nanawaleensis.	Haiwale	U.S.A. (HI)	Gesneriaceae	E	818	NA	NA
*	*	*	*	*	*		*
Cyrtandra wagneri	Haiwale	U.S.A. (HI)	Gesneriaceae	E	818	NA	NA
*	*	*	*	*	*		*
Mezoneuron kavaiense.	Uhi uhi	U.S.A. (HI)	Fabaceae	E	238	NA	NA
*	*	*	*	*	*		*
Phyllostegia floribunda.	None	U.S.A. (HI)	Lamiaceae	E	818	NA	NA
*	*	*	*	*	*		*
Pittosporum hawaiiense.	Hoawa, haawa	U.S.A. (HI)	Pittosporaceae	E	818	NA	NA
*	*	*	*	*	*		*
Platydesma remyi	None	U.S.A. (HI)	Rutaceae	E	818	NA	NA
*	*	*	*	*	*		*
Pritchardia lanigera	Loulu	U.S.A. (HI)	Arecaceae	E	818	NA	NA

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
*	*	*	*	*	*		*
Schiedea diffusa ssp. *macraei*.	None	U.S.A. (HI)	Caryophyllaceae	E	818	NA	NA
*	*	*	*	*	*		*
Schiedea hawaiiensis.	None	U.S.A. (HI)	Caryophyllaceae	E	818	NA	NA
*	*	*	*	*	*		*
Stenogyne cranwelliae.	None	U.S.A. (HI)	Lamiaceae	E	818	NA	NA
*	*	*	*	*	*		*

* * * * *

Dated: September 3, 2013.

Rowan W. Gould,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–24103 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–55–P

FEDERAL REGISTER

Vol. 78 Tuesday,

No. 209 October 29, 2013

Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Listing Five Foreign Bird Species in Colombia and Ecuador, South America, as Endangered Throughout Their Range; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R9–IA–2009–12; 4500030115]

RIN 1018–AV75

Endangered and Threatened Wildlife and Plants; Listing Five Foreign Bird Species in Colombia and Ecuador, South America, as Endangered Throughout Their Range

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), hereby list four Colombian species, the blue-billed curassow (*Crax alberti*), brown-banded antpitta (*Grallaria milleri*), Cauca guan (*Penelope perspicax*), and gorgeted wood-quail (*Odontophorus strophium*), and one Ecuadorian species, the Esmeraldas woodstar (*Chaetocercus berlepschi*), as endangered under the Endangered Species Act of 1973 (Act) (16 U.S.C. 1531 *et seq.*), as amended. This final rule implements the Federal protections provided by the Act for these species.

DATES: This rule becomes effective November 29, 2013.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* and comments and materials received, as well as supporting documentation used in the preparation of this rule, will be available for public inspection, by appointment, during normal business hours at: U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Suite 400, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Janine Van Norman, Chief, Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 420, Arlington, VA 22203; telephone 703–358–2171; facsimile 703–358–1735. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of the Regulatory Action

Under the Endangered Species Act (Act), a species may warrant protection through listing if it is an endangered or threatened species throughout all or a significant portion of its range. Under the Act, if a species is determined to be endangered or threatened we are required to publish in the **Federal Register** a proposed rule to list the species and, within 1 year of publication of the proposed rule, a final rule to add the species to the Lists of Endangered and Threatened Wildlife and Plants. On July 7, 2009, we published a proposed rule in which we determined that the blue-billed curassow, brown-banded antpitta, Cauca guan, gorgeted wood-quail, and Esmeraldas woodstar currently face numerous threats and warrant listing under the Act as endangered species (74 FR 32308). Therefore, we proposed listing all five species as endangered. This final rule constitutes our final determination for these species as required by the Act.

II. Major Provision of the Regulatory Action

Under the Endangered Species Act, we are required to determine whether a species is endangered or threatened because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that the blue-billed curassow, Cauca guan, and gorgeted wood-quail are facing threats due to all of these five factors, and the brown-banded antpitta and Esmeraldas woodstar are facing threats due to four of these five factors (factors A, C, D, and E).

In this final rule, we utilize public comments and peer review to inform our final determination, as required under the Act. When we published the proposed rule on July 7, 2009, we opened a 60-day comment period on the proposed listing for these five species. On November 10, 2009, we reopened the comment period for an additional 60 days (74 FR 57987). During the comment periods, we sought comments from independent specialists (peer reviewers) on the specific assumptions and conclusions in our listing proposal to ensure that the designation of these species as endangered is based on scientifically sound data, assumptions, and analyses. In addition, we sought comments from interested parties and the general public. We considered all comments and information received during the comment periods. In this final rule, we present and respond to peer reviewer and public comments. This rule finalizes the protection proposed for these five foreign bird species as endangered, following careful consideration of all comments we received during the public comment periods.

III. Costs and Benefits

We have not analyzed the costs or benefits of this rulemaking action because the Act precludes consideration of such impacts on listing and delisting determinations. Instead, listing and delisting decisions are based solely on the best scientific and commercial information available regarding the status of the subject species.

Previous Federal Action

On November 24, 1980, the Service received a petition (1980 petition) from Dr. Warren B. King, Chairman of the International Council for Bird Preservation (ICBP), to add 60 foreign bird species to the List of Endangered and Threatened Wildlife (50 CFR 17.11(h)), including two species from Colombia (the Cauca guan and the gorgeted wood-quail). In response to the 1980 petition, we published a positive 90-day finding on May 12, 1981 (46 FR 26464), to initiate a status review for 58 foreign species, noting that two of the species identified in the petition were already listed under the Act. On January 20, 1984 (49 FR 2485), we published a 12-month finding within an annual review on pending petitions and description of progress on all species petition findings addressed therein. In that notice, we found that all 58 foreign bird species from the 1980 petition were warranted but precluded by higher-priority listing actions. On May 10, 1985, we published the first annual notice (50 FR 19761), in which we continued to find that listing all 58 foreign bird species from the 1980 petition was warranted but precluded. In our next annual notice, published on January 9, 1986 (51 FR 996), we found that listing 54 species from the 1980 petition, including the two Colombian species mentioned above, continued to be warranted but precluded, whereas new information caused us to find that listing four other species in the 1980 petition was no longer warranted. We published additional annual notices on the remaining 54 species included in the 1980 petition on July 7, 1988 (53 FR 25511); December 29, 1988 (53 FR 52746); and November 21, 1991 (56 FR 58664), in which we indicated that the Cauca guan and the gorgeted wood-quail, along with the remaining species in the 1980 petition, continued to be warranted but precluded.

On May 6, 1991, we received a petition (1991 petition) from Alison

Stattersfield, of ICBP, to add 53 species of foreign birds to the List of Endangered and Threatened Wildlife, including the blue-billed curassow and the brown-banded antpitta, from Colombia, and Esmeraldas woodstar, from Ecuador. In response to the 1991 petition, we published a positive 90-day finding on December 16, 1991 (56 FR 65207), for all 53 species and announced the initiation of a status review. On March 28, 1994 (59 FR 14496), we published a 12-month finding on the 1991 petition, along with a proposed rule to list 30 African birds under the Act (15 each from the 1980 petition and 1991 petition). In that document, we announced our finding that listing the remaining 38 species from the 1991 petition, including the blue-billed curassow and the brown-banded antpitta, from Colombia, and Esmeraldas woodstar, from Ecuador, was warranted but precluded by higher-priority listing actions. On January 12, 1995 (60 FR 2899), we reiterated the warranted-but-precluded status of the remaining species from the 1991 petition. We made subsequent warranted but precluded findings for all outstanding foreign species from the 1980 and 1991 petitions, including all five of the Colombian and Ecuadorian bird species that are the subject of this final rule, as published in our annual notices of review (ANOR) on May 21, 2004 (69 FR 29354), and April 23, 2007 (72 FR 20184).

Per the Service's listing priority guidelines (September 21, 1983; 48 FR 43098), we identified the listing priority numbers (LPNs) (ranging from 1 to 12) for all outstanding foreign species in our 2007 ANOR (72 FR 20184), published on April 23, 2007. In that notice, the five species included in this final rule were designated with an LPN of 2, and it was determined that their listing continued to be warranted but precluded because of other listing activity. A listing priority of 2 indicates that the subject species face imminent threats of high magnitude. With the exception of LPN 1, which addresses monotypic genera that face imminent threats of high magnitude, category 2 represents the Service's highest priority.

On July 29, 2008 (73 FR 44062), we published in the **Federal Register** a notice announcing our annual petition findings for foreign species (2008 ANOR). In that notice, we announced that listing was warranted for 30 foreign bird species, including the 5 species that are the subject of this final rule. The five species were selected from the list of warranted-but-precluded species because of their LPN, their similarity of habitat, and the similarity of threats to these species. Combining species that face similar threats within the same general geographic area into one proposed rule allows us to maximize our limited staff resources, thus increasing our ability to complete the listing process for warranted-but-precluded species.

On July 7, 2009, the Service published in the **Federal Register** a rule proposing to list these five foreign bird species as endangered under the Act (74 FR 32308). Following publication of the proposed rule, we implemented the Service's peer review process and opened a 60-day comment period to solicit scientific and commercial information on the species from all interested parties. For more detailed information on previous Federal actions, please refer to the July 2009 proposed rule.

On November 10, 2009, the Service published in the **Federal Register** a reopening of the public comment period (74 FR 57987) for a rule proposing to list these five foreign bird species as endangered under the Act (74 FR 32308). Following publication of the reopening of the public comment period, we implemented the Service's peer review process and opened a 60-day comment period to solicit scientific and commercial information on the species from all interested parties. For more detailed information on previous Federal actions, please refer to the July 2009 proposed rule.

Summary of Comments and Recommendations

We base this finding on a review of the best scientific and commercial information available, including all information received during the public comment period. In the July 7, 2009, proposed rule, we requested that all interested parties submit information that might contribute to development of a final rule. On November 10, 2009, we reopened the public comment period where we again requested that all interested parties submit information that might contribute to development of a final rule. We also contacted appropriate scientific experts and organizations and invited them to comment on the proposed listings. We received comments from five individuals; four of which were from peer reviewers.

We reviewed all comments we received from the public and peer reviewers for substantive issues and new information regarding the proposed listing of these species, and we address those comments below. All the commenters and peer reviewers supported the proposed listing. Two comments included additional information for consideration; the remaining three comments simply supported the proposed listing without providing scientific or commercial data.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we solicited expert opinions from individuals with scientific expertise that included familiarity with the species, the geographic region in which the species occurs, and conservation biology principles. We received responses from four of the peer reviewers from whom we requested comments. They generally agreed that the description of the biology and habitat for the species was accurate and based on all relevant literature. Some new information was provided for one of the species, as described below. Some of the new information has been incorporated into this final rule. In some cases, it has been indicated in the citations by ''personal communication'' (pers. comm.), which indicates an email, facsimile, or telephone conversation; while in other cases, the research citation is provided.

Peer Reviewer Comments

(1) Comment: One peer reviewer stated that he found active blue-billed curassow nests and reproductive behaviors in June, July, and August confirming a second or alternative reproductive season.

Our Response: We reviewed additional literature and revised the blue-billed curassow life-history description to state that a breeding season also occurs from June through August.

(2) Comment: One peer reviewer commented that, despite the El Paujíl Bird Reserve's increased community environmental education effort, the program has little effect on a continually changing migratory worker population. These workers include loggers and coca plant cultivators, and their environmental impact negatively affects the blue-billed curassow's survival.

Our Response: Each year, the El Paujíl Bird Reserve's educational outreach efforts continue to expand. The 2012 Eighth Annual El Paujil Blue Billed Curassow Festival included over 400 participants and focused on raising conservation awareness among communities living near the El Paujíl Bird Reserve. However, these efforts are not aimed toward migratory workers. Therefore, we included information about the diminished impact of outreach efforts on transitory

populations in our discussion of blue-billed curassow conservation education.

(3) Comment: One peer reviewer commented that the El Paujíl Bird Reserve's acquisition of additional land since 2004 has created a shortage of field staff. The reviewer recommends an increase in funding to ensure adequate protection of the blue-billed curassow within the reserve.

Our Response: The Act authorizes the provision of limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered and threatened species in foreign countries. It is unknown at this time whether funds will be available to support the El Paujíl Bird Reserve.

(4) Comment: One peer reviewer commented on the need to establish new natural reserves for the blue-billed curassow in Cuchilla del Rio Minero and to support the recent reserves established in the Serrania de las Quinchas.

Our Response: The Service does not have the authority to purchase or similarly protect habitat in areas under the jurisdiction of other countries. However, recognition through listing results in public awareness, and encourages conservation actions by Federal and State governments, private agencies and groups, and individuals; these actions may address the conservation of habitat needed by foreign-listed species. The Act also authorizes the provision of limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered and threatened species in foreign countries; these programs may also be aimed at the conservation of habitat needed by listed species.

Summary of Changes to the Proposed Rule

Based on the comments we received during the comment period, we revised the blue-billed curassow life-history description to state that a breeding season also occurs in June through August. We also included information about the diminished impact of outreach efforts on transitory populations in our discussion of blue-billed curassow conservation education. In addition to these revisions, we made several minor editorial changes and corrections to text in this final rule.

Species Information and Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act. The five factors are: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence.

Under the Act, we may determine a species to be endangered or threatened. An endangered species is defined as a species that is in danger of extinction throughout all or a significant portion of its range. A threatened species is defined as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. Therefore, we evaluated the best available scientific and commercial information on each species under the five listing factors to determine whether they met the definition of endangered or threatened.

On a species-by-species basis, a summary of the biology and distribution of each species, followed by information regarding the status of, and threats to, the species in relation to the five factors provided in section 4(a)(1) of the Act are discussed below. The Colombian species are considered first, in alphabetical order, as follows: Blue-billed curassow, brown-banded antpitta, Cauca guan, and gorgeted wood-quail. These are followed by the Ecuadorian species, the Esmeraldas woodstar.

Blue-billed Curassow (Crax Alberti) Biology and Distribution

Species Description

The blue-billed curassow, endemic to Colombia, is a large (82–92 centimeters (cm) (32–36 inches (in)), tree-dwelling member of the Cracid family (Cracidae) (Salaman *et al.* 2001, p. 183; del Hoyo 1994, p. 36; Collar *et al.* 1992, p. 154). The species is locally known as ''Paujíl de pico azul'' or ''Pavón Colombiano'' and is also referred to in English as the blue-knobbed curassow (United Nations Environment Programme-World Conservation Monitoring Centre (UNEP–WCMC) 2008c, p. 1; Cuervo 2002, p. 138). In older literature, the species is referred to as Prince Albert's curassow (Throp 1964, p. 124). The blue-billed curassow is described as mainly black with blue at the base of its bill. The male has a white-plumaged crissum (the area under the tail), whereas the female has a black and white crest and black and white barring on her wings (BirdLife International (BLI) 2007d, p. 1; Throp 1964, p. 124).

Taxonomy

The blue-billed currassow was first taxonomically described by Fraser in 1852 and placed in the family Cracidae, within the order Galliformes.

Habitat and Life History

Blue-billed curassows prefer undisturbed, heterogeneous primary forests in the humid lowlands of the Sierra Nevada de Santa Marta Mountains at elevations up to 1,200 meters (m) (3,937 feet (ft)) (Salaman *et al.* 2001, p. 183; del Hoyo 1994, p. 361; Collar *et al.* 1992, p. 154). The blue-billed curassow requires a large home range of primary tropical forest (Cuervo 2002, pp. 138–140). The species will rarely cross narrow deforested corridors, such as those caused by roads or oil pipelines, and will not cross large open areas between forest fragments (Cuervo and Salaman 1999, p. 7). The species is described as being trusting of humans (del Hoyo 1994, p. 336).

The blue-billed curassow is terrestrial and feeds mostly on fruit and leaves, and sometimes on worms and carrion. It plays an important role in dispersing seeds and regenerating tropical forests (BLI 2007d, p. 1; Brooks 2006, p. 17; Brooks and Strahl 2000, pp. 5–8; Cuervo and Salaman 1999, p. 8).

Cracids are slow to reproduce, with a replacement rate of at least 6 years (Silva and Strahl 1991, p. 50). Curassows reach sexual maturity in their second year (Throp 1964, p. 130). Blue-billed curassows form monogamous pairs that share responsibilities for young (Todd *et al.* 2008; Cuervo and Salaman 1999, p. 9). The breeding season begins in December and extends through March (Cuervo and Salaman 1999, p. 8). A breeding season also occurs from June through August (Urueña, 2008, p. 71).

During the mating season, the male blue-billed curassows make ''booming'' calls that can be heard 500 m (1,640 ft) away (Ochoa-Quintero *et al.* 2005, pp. 42, 44). Adults build large nests made of sticks and leaves in dense lianas (woody vines) (Cuervo and Salaman 1999, p. 8). The typical blue-billed curassow clutch size is 1–2 large white eggs, which is a small clutch size

relative to other species in the order Galliformes (del Hoyo 1994, p. 336; Throp 1964, p. 130). Young hatch in July after an approximately 29-day incubation period (del Hoyo 1994, p. 361; Hilty and Brown 1986, p. 129; Throp 1964, p. 131). In captivity, curassows are long-lived species (Todd *et al.* 2008, p. 7). Throp (1964, p. 132) recorded a blue-billed curassow still laying eggs at 20 years of age. However, in the wild, one generation is considered to be 10 years (Cuervo 2002, p. 141).

Historical Range and Distribution

The blue-billed curassow historically occurred in northern Colombia, from the base of the Sierra Nevada de Santa Marta (in the northern Departments of Magdalena La Guijaira, and Cesar), west to the Sinú valley (Department of Córdoba), through the Río Magdalena (through the Departments (from south to north) of Huila, Tolima, Caldas, Antioquia, Santander, Bolivar, Magdalena, and La Guajira) (BLI 2007a, p. 1; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361). The species' historic range encompassed an area of approximately 106,700 square kilometers (km^2) (41,197 square miles (mi^2)) (Cuervo 2002, p. 141). There were no confirmed observations of blue-billed curassows between 1978 and 1997 (Brooks and Gonzalez-Garcia 2001, p. 183), and surveys conducted in 1998 failed to locate any males (BLI 2007d, p. 3) (as detailed under Factor B, below), prompting researchers to believe the species to be extinct in the wild (del Hoyo 1994, p. 361). However, a series of reported observations made in 1993 were confirmed in the year 2000 (Cuervo 2002, pp. 136–137).

Current Range and Distribution

The current range of the blue-billed curassow is estimated to be a 2,090-km^2 (807-mi^2) area (BLI 2007d, p. 2) of fragmented, disjunct, and isolated tropical moist and humid lowlands and premontane forested foothills in the Rio Magdalena and lower Cauca Valleys of the Sierra Nevada de Santa Marta Mountains. The species may be found at elevations up to 1,200 m (3,937 ft) (Donegan and Huertas 2005, p. 29; Salaman *et al.* 2001, p. 183; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361; Collar *et al.* 1992, p. 154), but it is more commonly found below 600 m (del Hoyo 1994, p. 361). Little information is available on the size of the forest fragments where the species has been observed. However, researchers conducting fieldwork in the Department of Antioquía in 1999 and 2001 noted that the patch sizes varied from 3 km^2 (1.2 mi^2) to 10 km^2 (3.9 mi^2) in size (Ochoa-Quintero *et al.* 2005, p. 46).

In 1993, sightings were reported in the northern Departments of Córdoba (at La Terretera, near Alto Sinú) and Bolívar (in the Serranía de San Jacinto (San Jacinto Mountains)) (Williams, *in litt.,* as cited in BLI 2007d, p. 2). Additional observations were made in the northernmost Department of La Guajira in 2003 (in the Valle de San Salvador Valley) (Strewe and Navarro 2003, p. 32). More recently, individuals have been observed in the tropical forests of the central Departments of Antioquía (on the slopes of the Serranía de San Lucas and Bajo Cauca-Nechí Regional Reserve area), the Departments of Santander and Boyacá (on the slopes of the Serranía de las Quinchas), and in the southeastern Department of Cauca (in northeastern and lower Cauca Valley) (BLI 2007d, p. 2; Urueña *et al.* 2006, p. 42; Donegan and Huertas 2005, p. 29; Ochoa-Quintero *et al.* 2005, pp. 43–44; Cuervo 2002, pp. 135–138;). Experts consider the most important refuges for this species to be: (1) Serranía de San Lucas (Antioquía); (2) Paramillo National Park (Antioquía and Córdoba Departments); (3) Bajo Cauca-Nechí Regional Reserve (Antioquía and Córdoba Departments); and (4) Serranía de las Quinchas Bird Reserve (Santander and Boyacá Departments) (BLI 2007d, p. 3; Cuervo 2002, p. 139). These refugia are discussed under Factor A, below.

Population Estimates

There is little information on population numbers for the various reported locations of the species, and political instability within the country makes it difficult to know the exact population size of this species (Houston Zoo 2008). In 2002, Cuervo (2002, p. 141) considered the Serranía de las Quinchas and Serranía de San Lucas populations to be the stronghold of the species. However, surveys in 2003 led researchers to believe that Serranía de las Quinchas serves as the species' stronghold (BLI 2007d, pp. 2, 5–6). In 2003, the population at Serranía de las Quinchas (Boyacá Department) location was estimated to be between 250 and 1,000 birds. The only other information on the subpopulation level is a report from Strewe and Navarro (2003, p. 32), based on field studies conducted between 2000 and 2001, that hunting had nearly extirpated the blue-billed curassow from a site in San Salvador (La Guijara) (Factor B).

Using the International Union for Conservation of Nature and Natural Resources (IUCN) categories, the blue-billed curassow population was estimated according to IUCN criteria to be more than 1,000 but fewer than 2,500 in 1994 (BLI 2007d, p. 2). In 2001, Brooks and Gonzalez-Garcia (2001, p. 184) estimated the total population to be much fewer than 2,000 individuals. In 2002, it was estimated that the species had lost 88 percent of its habitat and half of its population within the last three generations, or 30 years (Cuervo 2002, p. 141). Local reports indicate an overall declining trend characterized by recent rapid declines of all subpopulations (BLI 2007d, p. 1; Cuervo 2002, p. 138; Strahl *et al.* 1995, p. 25). For further information on population size, see Factor E, below.

Conservation Status

The blue-billed curassow is identified as a critically endangered species under Colombian law (EcoLex 2002, p. 12). The species is considered one of the most threatened cracids by the IUCN Cracid Specialist Group. The species is categorized by the IUCN as 'Critically Endangered,' with habitat loss as a primary threat (BLI 2004b, p. 1; Cuervo 2002, p. 141; del Hoyo 1994 p. 340; Strahl *et al.* 1995, pp. 4–5; Urueña *et al.* 2006, pp. 41–42).

Summary of Factors Affecting the Blue-Billed Curassow

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Habitat or Range

The blue-billed curassow prefers undisturbed, heterogeneous forests and is rarely found in secondary or even slightly disturbed forests (Cuervo and Salaman 1999, p. 7). The blue-billed curassow occurs today in several disjunct locations along a much-restricted part of its historic distribution (Brooks and Gonzalez-Garcia 2001, p. 183; Collar *et al.* 1992, pp. 61–62; Cuervo and Salaman 1999, p. 7). Researchers note that the blue-billed curassow requires large territories, but there is little information as to the actual size of the remaining forest fragments (Cuervo and Salaman 1999, p. 7). In 1999 and 2001, researchers conducting fieldwork in the Department of Antioquia noted that the patch sizes in which the species were observed or heard varied from 3 km^2 (1.2 mi^2) to 10 km^2 (3.9 mi^2) in size (Ochoa-Quintero *et al.* 2005, p. 46). Since the 1990s, the species has been observed in the Departments of Córdoba (at La Terretera, near Alto Sinú, 1993) and Bolívar (in the Serranía de San Jacinto, 1993) (Williams *in litt.,* as cited in BLI 2007d, p. 2); La Guajira (in the Valle de San Salvador Valley, 2003) (Strewe and

Navarro 2003, p. 32); Antioquía (on the slopes of the Serranía de San Lucas and Bajo Cauca-Nechí Regional Reserve area, 1999 and 2001) (Ochoa-Quintero *et al.* 2005, pp. 43–44); Santander and Boyacá (on the slopes of the Serranía de las Quinchas); and Cauca (in northeastern and lower Cauca Valley) (BLI 2007d, p. 2; Urueña *et al.* 2006, p. 42; Donegan and Huertas 2005, p. 29; Cuervo 2002, pp. 135–138.).

Deforestation

Primary forest habitats throughout Colombia have undergone extensive deforestation. Viña *et al.* (2004, pp. 123–124) used satellite imagery to analyze deforestation rates and patterns along the Colombian-Ecuadorian Border (in the Departments of Putumayo and Sucumbios, respectively), finding that, from 1973 to 1996, a total of 829 km^2 (320 mi^2) of tropical forests within the study area were converted to other uses. This corresponds to a nearly one-third total loss of primary forest habitat, or a nearly 2 percent mean annual rate of deforestation within the study area. During the study, the area within Colombia experienced a three-times-larger annual rate of loss than that in Ecuador, due to more intense pressures from human colonization and illegal crop cultivation (Viña *et al.* 2004, p. 124). The human population within the area increased from approximately 50,000 to over 250,000 people during the 23-year period (Perz *et al.* 2005, pp. 26–28). A similar phenomenon occurred in the Río Magdalena Valley, which coincides with the species' historic range as well as its disjunct and restricted current range. The Río Magdalena runs from south to north approximately 1,540 km (950 mi) through western Colombia and served as the main waterway connecting coffee (*Coffea* spp.) plantations to the ports on the Western Colombian coast in the 1920s, when the river was reportedly plagued by occasional droughts and erosion. In the 1930s, a railway was completed along much of the Río Magdalena Valley; this infrastructural improvement contributed to a growth in several industries, including coffee (throughout the Río Magdalena valley), bananas (*Musa* spp.) (in the Magdalena Department), and oil (in the Santander Department) (Ocampo and Botero 2000, pp. 76–78). Deforestation and habitat loss throughout the lowland forests across northern Colombia over the past 100 years contributed to the increasing rarity of the species, and extirpated the species from a large portion of its previous range by the 1980s (Brooks and Gonzalez-Garcia 2001, p. 183; Cuervo and Salaman 1999, p. 7; Collar *et al.* 1992, pp. 61–62.).

In a similar study specific to the western Andean Amazon area of Colombia (in the Departments of Arauca, Casemere, Meta, Vichada, Amazonas, Caquetá, Guainia, Guaviare, Putumayo, and Vaupés), deforestation between 1980 and 1990 totaled 52,320 km^2 (20,201 mi^2) (Perz *et al.* 2005, pp. 26–28). The most recent reports indicate that habitat loss is ongoing and may be accelerating. Between the years 1990 and 2005, Colombia lost a total of 7,920 km^2 (3,058 mi^2) of primary forest (Butler 2006a, pp. 1–3; Food and Agriculture Organization of the United Nations (FAO) 2003a, p. 1). Researchers have observed that road building and other infrastructure improvements in previously remote forested areas have increased accessibility and facilitated further habitat destruction, exploitation, and human settlement (Álvarez 2005, p. 2042; Cárdenas and Rodríguez Becerra 2004, pp. 125–130; Etter *et al.* 2006, p. 1; Hunter 1996, pp. 158–159; Viña *et al.* 2004, pp. 118–119). In Antioquia, cattle ranches are extensive in areas where the blue-billed curassow occurs; cattle ranching is considered a less labor-intensive land use, meaning that more people need to turn to alternative sources of income generation, such as cultivation or extractive industries (Melo and Ochoa 2004, as cited in Urueña *et al.* 2006, p. 42). In Serranía de las Quinchas, the economy is based principally on timber extraction, agriculture, and cattle ranching (Urueña and Quevedo unpubl. data 2004, as cited in Urueña *et al.* 2006, p. 47). These activities contribute to further habitat fragmentation and reduction. In terms of habitat destruction, an influx of settlers displaced from the Departments of Antioquia, Tolima, and Cundinamarca, due to violence and public disorder in these Departments, are the principal threat to the mountainous regions in these Departments (Urueña *et al.* 2006, p. 42).

The decline in blue-billed curassow population numbers (see Population estimates, above) is inextricably linked to habitat loss. The blue-billed curassow became increasingly rare during the 20th Century, as much of the lower-elevation forests in their historic range of the Río Magdalena and Río Cauca Valleys were deforested, forcing the blue-billed curassow to move to higher elevations (Cuervo and Salaman 1999, p. 8). By the 1980s, the species had disappeared from a large portion of its previous range (Collar *et al.* 1992, pp. 61–62), which historically encompassed approximately 106,700 km^2 (41,197 mi^2) (Cuervo 2002, p. 141). In 2002, it was estimated that, within the three prior generations (30 years), the species had lost 88 percent of its original habitat and that the remaining suitable habitat had been reduced to 13,300 km^2 (5,135 m^2) (Cuervo 2002, p. 141). The current range of the blue-billed curassow is estimated to be 2,090 km^2 (807 mi^2) (BLI 2007d, p. 2) (see also ''Small Population Size,'' Factor E).

Deforestation and fragmentation caused by human encroachment are ongoing throughout the blue-billed curassow's range, including: Antioquía (on the slopes of the Serranía de San Lucas and Bajo Cauca-Nechí Regional Reserve area); Santander and Boyacá Departments (on the slopes of the Serranía de las Quinchas); and in the southeastern Department of Cauca (in northeastern and lower Cauca Valley), where timber extraction and mining continue (Urueña *et al.* 2006, p. 42). Human activities that are contributing to habitat loss include: forest clearing for subsistence agriculture, cash crops (such as coffee), and grazing (BLI 2007d, p. 3; Urueña *et al.* 2006, p. 42; Álvarez 2005, p. 2,042; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12) habitat alteration, human population displacement, and hunting as a result of armed conflict (Álvarez 2003, pp. 51–52; Álvarez 2001, p. 305), habitat destruction and alteration as a result of fire (Moreno *et al.* 2006, p. 1; Álvarez 2005, p. 2,041); habitat loss for dams and reservoir development (Kreger 2005, pp. 5–6; Cuervo 2002, p. 139); illicit crop cultivation (such as the coca plant (*Erythroxylum coca*)) (Álvarez 2007, pp. 133–135; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12; Álvarez 2001, pp. 1086–1087); gold mining activities (Cuervo 2002, p. 139); habitat pollution due to oil development and distribution (Álvarez 2005, p. 2041; Cárdenas and Rodríguez Becerra 2004, p. 355); and increased access and habitat destruction resulting from road development (Cuervo 2002, pp. 139–140). Roads create barriers to animal movements, expose animals to traffic hazards, and increase human access into habitat, thus facilitating further exploitation and habitat destruction (Hunter 1996, pp. 158–159). Local human populations have recently settled in forested areas that previously provided habitat for blue-billed curassows. This human settlement is accelerating habitat loss and fragmentation with only 5 percent of the species' restricted range now covered by forest (Brooks and Gonzalez-Garcia 2001, pp. 183–184), and is leaving only

fragmented, disjunct, and isolated populations in the remaining four or five patches of tropical humid and premontane forests (Donegan and Huertas 2005, p. 29; Álvarez 2003, p. 51; Brooks and Strahl 2000, pp. 14–15; Cuervo and Salaman 1999, p. 7; Collar *et al.* 1994, pp. 61–62).

Illegal Crop Cultivation and Eradication

The cultivation of illegal crops (including coca) poses additional threats to the environment beyond encouraging the destruction of montane forests (Balslev 1993, p. 3). Van Schoik and Schulberg (1993, p. 21) noted that coca crop production destroys the soil quality by causing the soil to become more acidic, which depletes the soil nutrients and ultimately impedes the regrowth of secondary forests in abandoned fields. Although Colombia continues to be the leading coca bush producer (United Nations Office of Drugs and Crime (UNODC) *et al.* 2007, p. 7), since 2003, cocaine cultivation has remained stable at about 800 km^2 (309 mi^2) of land under cultivation (UNODC *et al.* 2007, p. 8). This stabilization of production is partially attributed to alternative development projects that were implemented between 1999 and 2004 to encourage pursuits other than illegal crop cultivation (UNODC *et al.* 2007, p. 77). This sustained level is also attributed to heightened eradication efforts. Between 2002 and 2004, aerial spraying occurred over more than 1,300 km^2 (502 mi^2) annually, peaking in 2004, when 1,360 km^2 (525 mi^2) of illicit crops were sprayed (UNODC and the Government of Colombia (GOC) 2005, p. 11).

In 2006, eradication efforts were undertaken on over 2,130 km^2 (822 mi^2) of land, which included spraying of 1,720 km^2 (664 mi^2) and manual eradication on the remaining land. Eradication efforts undertaken in 2006 occurred over an area 2.7 times greater than the net cultivation area (UNODC *et al.* 2007, p. 8). Drug eradication efforts in Colombia have further degraded and destroyed primary forest habitat by using nonspecific aerial herbicides to destroy illegal crops (BLI 2007d, p. 3; Álvarez 2005, p. 2042; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12). Herbicide spraying has introduced harmful chemicals into blue-billed curassow habitat and has led to further destruction of the habitat by forcing illicit growers to move to new, previously untouched forested areas (Álvarez 2007, pp. 133–143; BLI 2007d, p. 3; Álvarez 2005, p. 2042; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12; Álvarez 2002, pp. 1,088–1,093). Between 1998 and 2002, cultivation of illicit crops increased by 21 percent each year, with a concomitant increase in deforestation of formerly pristine areas of approximately 60 percent (Álvarez 2002, pp. 1,088–1,093).

Effects of Habitat Fragmentation

A study conducted on the effects of habitat fragmentation on Andean birds within western Colombia determined two primary conditions that increased a species' vulnerability to habitat fragmentation and susceptibility to local extirpation and extinction: (1) Species that were located at the upper or lower limit of their altitudinal or geographical distribution (as is the case for the blue-billed curassow, which formerly occupied the now-cleared lower elevation forests and is relegated to isolated forest fragments within its current range), and (2) species that were large fruit-eating birds with limited distributions and narrow habitat preferences (also traits of the blue-billed curassow) (Kattan and Álvarez-Lopez 1996, pp. 5–6). The study also determined that 31 percent of the historical bird populations in western Colombia had become extinct or locally extirpated by 1990, largely as a result of habitat fragmentation from deforestation and human encroachment (Kattan and Álvarez-Lopez 1996, p. 5; Kattan *et al.* 1994, p. 141).

The most direct physical consequence of habitat fragmentation is loss of habitat heterogeneity (the variety, relative abundance, and spatial configuration of differing habitat types); habitat heterogeneity is a characteristic preferred by the blue-billed curassow (see Habitat and Life History, above) (Kattan and Álvarez-Lopez 1996, p. 6). Local reports indicate an overall declining trend, characterized by recent rapid declines of all populations of blue-billed curassows (BLI 2007d, p. 1; Cuervo 2002, p. 138; Strahl *et al.* 1995, p. 25). Moreover, the ability of the blue-billed curassow to repopulate an isolated patch of suitable habitat following decline or extirpation is highly unlikely due to the species' small overall population size, its tendency to avoid degraded habitats, and the large distances between the remaining primary forest fragments, in addition to the species' avoidance of crossing large areas of open habitat (Cuervo and Salaman 1999, p. 7; Hanski 1998, pp. 45–46).

In addition to the direct detrimental effect of habitat loss, blue-billed curassows and other cracids are susceptible to indirect effects of habitat disturbance and fragmentation (Brooks and Strahl 2000, p. 10; Silva and Strahl 1991, p. 38). A study conducted in northwestern Colombia suggests that habitat destruction and fragmentation may increase a species' vulnerability to predation (Arango-Vélez and Kattan 1997, pp. 140–142) (Factor C). Habitat fragmentation, in combination with growing numbers of human settlements, has made the species' habitat more accessible and more vulnerable to hunting (Factor B) and predation (Factor C). Habitat loss also compounds the species' decline in population numbers (estimated to be between 1,000 and 2,500 individuals) (BLI 2004b, p. 1) (see Factor E, Small population size).

Refugia

Several areas within the blue-billed curassow's current range are designated as national parks or other types of preserves, including Tayrona and Sierra Nevada de Santa Marta National Parks (both in Antioquía Department) (Cuervo 2002, p. 140) and the Colorados Sanctuary (Bolívar Department), which protects part of the Serranía de San Jacinto (BLI 2007d, pp. 2–3; Urueña *et al.* 2006, p. 42). Experts consider the most important refuges for this species, containing the largest remaining areas of suitable habitat, to be in the following areas (arranged geographically, from north to south): (1) Serranía de San Lucas, (2) Paramillo National Park, (3) Bajo Cauca-Nechí Regional Reserve, and (4) El Paujíl Bird Reserve (BLI 2007d, p. 3; Cuervo 2002, pp. 139–140; Urueña *et al.* 2006, p. 42), four of the five locations where the species has been observed in the 21st Century (see Current Range, above). The habitat within these refugia underserves the needs of the species for various reasons, including past and ongoing habitat destruction and incomplete habitat inclusion, as enumerated below. In addition, inadequate regulatory mechanisms hamper protection of the species and its habitat (Factor D).

(1) Serranía de San Lucas (Antioquía) is not a protected area, but is one of the largest remaining tracts of forest that is the least disturbed (WWF 2001b, p. 1). Even so, only a few isolated forest patches survive above 1,000 m (3,280 ft) in the northern lowlands (Antioquia Department) (Donegan and Salaman 1999, p. 4). Ongoing pressures on this habitat include human encroachment for natural resources, colonization, ranching, logging, and crop production, as well as pollution of the Magdelena and Cauca Rivers (WWF 2001b, p. 3). In 1996, there was a gold rush that led to deforestation for logging, settlements, conversion to agriculture, and coca production (BLI 2007d, p. 3). Using

satellite imagery and fieldwork, Cuervo (2002, p. 140) determined that deforestation on the eastern slopes of the Serranía de San Lucas was extensive between 1995 and 1996. In 2005, highway construction was underway as part of a national plan to connect the East Andes, the West Andes, and the Pacific ports, including roadbuilding through the Serranía de San Lucas and adjacent lowlands (Álvarez 2005, p. 2,042). Because the species prefers pristine habitat, this ongoing habitat alteration negatively impacts the integrity of this location and the survival of the species therein.

(2) The Paramillo National Park (Antioquía and Córdoba Departments), created in 1977, encompasses an area 4,600 km² (1,776 mi²) in size and includes moist and cloud forest habitats (Corantioquia 2008, p. 1). However, it only protects the upper elevational limit of the habitat occupied by the species, where the species is rarer (Cuervo 2002, p. 140). This Park is inhabited by an indigenous community (Emberá), for whom the Park was created. Farmers also inhabit the interior regions of the Park (BLI 2007a, pp. 1–2). The areas to the south of the Park have undergone intense habitat disturbance from logging, drug crop production, and inundation from flooding caused by the construction of the Urrá Dam (Cuervo 2002, p. 139). Deforestation has occurred throughout a large portion of the Park's buffer zone as well as in the extreme southern reaches within Park boundaries (Cuervo 2002, p. 140). Between 2003 and 2004, the area of cocaine cultivation within the Paramillo National Park increased from 1.1 km² to 4.6 km² (0.42 mi² to 1.8 mi²) (UNODC and GOC 2005, p. 45). The Urrá Dam was constructed on the Sinú River between 1993 and 1998; the Sinú River Valley was part of the blue-billed curassows' historic range (BirdLife International (BLI) 2007a, p. 1; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361). The reservoir flooded the area and led to displacement of human populations and other habitat alterations, including fish kills caused by blocked spawning and migratory routes (NGO Working Group on Export Development Canada 2003, p. 31).

(3) The Bajo Cauca-Nechí Regional Reserve (Antioquía and Córdoba Departments), created in 1999, is located within a large tract (450 km² (174 mi²)) of forested land at an elevation of 800 m (2,625 ft). Bajo Cauca is the second most populated region in the Department of Antioquia. Logging is important in this region, and the Reserve allows commercial exploitation of wood (Fundación Viztaz 2007, p. 2). Surveys are scant in this area, which is believed to be home to many species as yet unidentified by science (Cuervo 2002, p. 137; Donegan and Salaman 1999, p. 12). Although the Reserve provides suitable habitat for the species, and the blue-billed curassow is presumed to inhabit this area, it has not been confirmed within the Reserve (BLI 2007d, p. 3).

(4) El Paujíl Bird Reserve (Santander and Boyacá Departments) is a private reserve established in Serranía de las Quinchas (WorldTwitch Colombia 2004, p. 3). In the early 1990s, the Serranía de las Quinchas (Boyacá Department, central Colombia) was considered one of the last remaining well-preserved cloud forests and the largest tract of lowland wet forest in the region, with up to 500 km² (193 mi²) of forest remaining. Within a decade, the forest had dwindled to 120 km² (46 mi²) (WorldTwitch Colombia 2004, p. 3). In 2002, the largest known subpopulation of blue-billed curassow was located in the Serranía de las Quinchas and became regarded as the stronghold of the species (BLI 2007d, p. 2). El Paujíl Bird Reserve was created in 2004 specifically to protect the blue-billed curassow and its habitat (BLI 2007b, p. 2). Originally comprising 10 km² (3.9 mi²) of lowland tropical forest up to elevations of 700 m (2,297 ft), the Reserve has expanded to 60 km² (23 mi²) (ProAves 2010, p. 1; American Bird Conservancy 2010, p. 1). The Reserve includes suitable habitat for the species. However, collection of eggs and chicks are ongoing within the region (Cuervo 2002, p. 139; Urueña *et al.* 2006, p. 42) (see Factor B), and there are questions as to the effectiveness of this Reserve to protect the species (see Factor D).

Summary of Factor A

The blue-billed curassow prefers undisturbed habitat, and the remaining small populations are limited to four or five small, disjunct, and isolated areas in seven different Departments. Within the past 30 years, or three generations, the species is estimated to have lost 88 percent of its habitat and half of its population. Deforestation and conversion of primary forests for human settlements and agriculture has led to habitat fragmentation throughout the species' range and to isolation of remaining populations. Habitat loss and fragmentation were factors in the species' historical decline (over the past 50 years) and caused localized extirpations, and continue to be factors negatively affecting the blue-billed curassow in the wild. Human encroachment into the species' preferred primary forest habitat has resulted in habitat alteration and disturbance activities that have caused declines in the blue-billed curassow population. Cultivation of illegal drug crops, such as cocaine, leads to further deforestation and alters soil compositions, hindering regeneration of abandoned fields. In addition, drug eradication programs involving the aerial spraying of nonspecific herbicides lead to further environmental degradation and destruction of primary forest habitat.

Three of the four most important refugia continue to undergo habitat destruction, and regulatory mechanisms are inadequate to mitigate the primary threats to this species (Factor D). A private refuge, the El Paujíl Bird Reserve, was formed to protect the blue-billed curassow and its habitat, which includes a large amount of suitable habitat, but may be lacking in its ability to adequately protect the species (Factors B and D). Habitat fragmentation contributes to the species' vulnerability to hunting (Factor B) and predation (Factor C) by increasing human and predator access to the habitat. The species' historic range, which encompassed approximately 106,700 km² (41,197 mi²), has been reduced to 2,090 km² (807 mi²). Experts estimate that 88 percent of this habitat loss has occurred within the last 30 years, or three generations. Habitat destruction and fragmentation of the remaining primary forest habitat is expected to continue, as human encroachment and associated activities continue within the blue-billed curassow's range. Therefore, we find that the present destruction, modification, and curtailment of habitat are threats to the blue-billed curassow throughout all of its range.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Blue-billed curassows are hunted by indigenous people and local residents for subsistence, sport, trade, and entertainment (Brooks and Gonzalez-Garcia 2001, p. 183; Brooks and Strahl 2000, p. 10; Cuervo and Salaman 1999, p. 9; Throp 1964, p. 127; Urueña *et al.* 2006, p. 42). Cracids, including the blue-billed curassow, are considered particularly vulnerable to hunting pressures and are among those species most rapidly depleted by hunting (Redford 1992, p. 419). Several factors contribute to the species' vulnerability to hunting and collection: their large size, ease of location during the breeding season, trusting nature, and low productivity (1–2 eggs) relative to other Galliformes (del Hoyo 1994, p. 336). Cracids are also slow to reproduce,

with a replacement rate of at least 6 years (Silva and Strahl 1991, p. 50), which makes it difficult for the species to rebound from hunting pressures.

Hunting affects the blue-billed curassow in all life stages. In 1999, hunters in Antioquío (where the blue-billed curassow is known on the slopes of the Serranía de San Lucas and Bajo Cauca-Nechí Regional Reserve area) reported killing as many as 20 blue-billed curassows within the prior 20 years (Donegan and Salaman 1999, p. 21). In 2004, it was reported that hunting had abated somewhat, because productive hunting grounds had become too remote from villages and because the communities have access to domestic meat (Melo and Ochoa 2004, as cited in Urueña *et al.* 2006, p. 42). However, both eggs and chicks continue to be collected in some areas (such as Serranía de las Quinchas, where El Paujíl Reserve is located) to be sold at local markets (Cuervo 2002, p. 139; Urueña *et al.* 2006, p. 42), despite measures to protect the species from collection (Factor D). In 1999, live trapped birds (typically chicks) sold for up to US$100 (greater than the average monthly income) (Donegan and Salaman 1999, p. 21). These birds are either consumed or maintained as captive animals. The blue-billed curassow, as well as other cracids (e.g., chachalacas (*Ortalis* spp.) and guans (*Penelope* spp.)) serve as a major source of protein for indigenous people and attract a great deal of ecotourism (Brooks and Strahl 2000, p. 8). People colonizing forested areas capture juvenile birds as pets and hold them in captivity in fenced yards or in cages (Cuervo and Salaman 1999, p. 8; Donegan and Salaman 1999, p. 21). Indigenous people also collect feathers and other body parts of curassows for rituals, ornamentation, arrowheads, and for sale to tourists (Silva and Strahl 1991, p. 38).

Most hunting occurs during the mating season, when males are more easily located by their booming mating calls (Cuervo and Salaman 1999, p. 9; del Hoyo 1994, p. 336), which can be heard from up to 500 m (1,640 ft) away (Ochoa-Quintero *et al.* 2005, pp. 42, 44). The direct take of males leads to disequilibrium of sex ratios for this species, which forms monogamous pairs (Cuervo and Salaman 1999, p. 9; Todd *et al.* 2008), and it also leads to the disruption of mating activities (Cuervo and Salaman 1999, p. 9; del Hoyo 1994, p. 336). Researchers attribute hunting pressure as the cause for the near extinction of the blue-billed curassow population in the San Salvador Valley (Strewe and Navarro 2003, p. 32). Researchers also attribute to hunting the absence of blue-billed curassows from parts of its historical range where suitable habitat (primary forest) still exists (Brooks and Strahl 2000, p. 10). In 1998, for instance, no males were observed during field surveys, prompting researchers to conclude that hunting continued to be a serious risk to the species (BLI 2007d, p. 3).

Habitat fragmentation and concomitant human encroachment (Factor A) have made the species' habitat more accessible, resulting in the species becoming more vulnerable to hunting. A study conducted in French Guiana provided a quantitative estimate of the effect of hunting on a related cracid species, the black curassow (*Crax alector*) (del Hoyo 1994, p. 336). The black curassow has similar habitat requirements (undisturbed primary tropical to subtropical humid forest at 0–1,400 m (0–4,600 ft) elevation) as the blue-billed curassow (BLI 2007e). The estimated population density of black curassows in nonhunted areas was between 7 and 9 birds per 1 km^2 (0.4 mi^2); in areas with intermittent hunting, the numbers fell to between 0.5 and 2.25 birds; and in areas where hunting was regular, numbers fell to between 0.5 and 0.73 birds (del Hoyo 1994, p. 336). We believe that the effects of hunting on the blue-billed curassow would result in similar population reductions based on its similarity of habitat requirements and life-history traits.

In 1988, Colombia listed the blue-billed curassow in Appendix III of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (UNEP–WCMC 2008c). An Appendix III listing requires that the listing range country (in this case, Colombia) must issue an export permit for all exports of the species when the Management Authority of Colombia is satisfied that specimens have been legally obtained and live specimens will be transported such that risk of injury, damage, and cruelty are minimized. Imports require the prior presentation of a certificate of origin and, where the import is from Colombia, an export permit. In the case of rexports, a reexport certificate issued by the country of re-export is required (UNEP–WCMC 2008a). According to the World Conservation Monitoring Centre (WCMC), a total of 12 live birds have been traded internationally since 1990 (UNEP–WCMC 2008e). This trade consisted of imports of two individuals into the United States and five birds into Mexico in the early 1990s, and exports of five captive-bred specimens from the United States to Colombia and Belgium. Therefore, commercial international trade in wild specimens over the past 20 years has not been extensive.

The blue-billed curassow has been collected from the wild for use in zoos and in captive-breeding programs, both domestically and abroad. A small number of birds have been collected by the Cali Zoo and Santa Fe de Medellin Zoo in Colombia (Cuervo 2002, p. 142), and small collections are held in the United States, including the Houston Zoo and San Diego Zoo, as well as in Japan and Mexico (Brooks and Strahl 2000, p. 15; Cuervo 2002, p. 142). The Cali and Houston Zoo collections are being used for captive breeding, which we consider vital to conserving and recovering this species (Factor E). International trade for zoos and captive-breeding purposes does not contribute to the endangerment of the species. We believe that this limited amount of international trade, controlled via CITES, is not a threat to the species.

Summary of Factor B

The blue-billed curassow is hunted and collected from the wild at all life stages throughout its current range. Blue-billed curassow eggs and chicks are collected for food and sale in local markets, or are often captured and held in captivity as pets or as a future food source. Hunting results in the direct removal of eggs, juveniles, and adults from the population. Blue-billed curassows are slow to reproduce, produce a low clutch size, and exhibit a poor replacement rate (see Habitat and Life History). Hunting can destroy pair bonds and remove potentially reproductive adults from the breeding pool. The species is particularly vulnerable to hunting and collection pressures due to the ease in locating this large bird during its breeding season. The majority of hunting occurs during the mating season, when males are heard calling for females, leading to disproportionate hunting of males. Hunting disturbances during the breeding season disrupt breeding activities, further compounding the threats associated with hunting mortalities. There are continued reports of hunting pressures on the species; these pressures have been and continue to be compounded by ongoing human encroachment into previously undisturbed forests (Factor A). Hunting and collection negatively affects the global population of the blue-billed curassow, due to its small population size and fragmented distribution. Hunting, combined with habitat fragmentation (Factor A), increases the possibility of local extirpation since the blue-billed curassow is unlikely to

reoccupy an area that has been depleted through hunting because it avoids crossing large, open areas between habitat fragments (see Factor E, Likelihood to Disperse). Therefore, we find that hunting, collection, and associated disturbances are threats to the blue-billed curassow.

Factor C: Disease or Predation

We are unaware of information regarding disease or the potential for significant disease outbreaks in the blue-billed curassow. As a result, we do not consider disease to be a threat to the species.

According to Delacour and Amadon (1973), predators of cracids include snakes (suborder Serpentes), foxes (family Canidae), wild cats (*Felis silvestris*), feral dogs (*Canus lupus familiaris*), and raptors (order Falconiformes). Arango-Vélez and Kattan (1997, pp. 137–143) studied predation rates on Andean bird nests within fragmented forest habitats of northwestern Colombia. Although not specific to the blue-billed curassow, the study focused on understory nesting birds with similar nesting habits and in forest fragment sizes similar to where the blue-billed curassow is currently found (Arango-Vélez and Kattan 1997, p. 138). The study found that nest predation by generalist predators is more prevalent in smaller, isolated forest patches. However, in the study, increased predation in smaller habitat fragments could not be solely attributed to the ''edge effect,'' whereby smaller patch sizes facilitate predators' access and ability to capture prey throughout the fragments. Rather, reduced habitat patch sizes caused a shift from larger to smaller predators, which tend to prey upon the eggs and juveniles of understory birds, rendering ground-dwelling birds, such as blue-billed curassows, particularly susceptible (Arango-Vélez and Kattan 1997, pp. 140–142).

Other studies concerning the effects of habitat fragmentation on avian predation show similar results (Keyser 2002, p. 186; Renjifo 1999, p. 1,133; Keyser *et al.* 1998, p. 991; Hoover *et al.* 1995, p. 151; Wilcove 1985, p. 1,214). Gibbs (1991, p. 157) found that a larger proportion of ground-nests and elevated nests were predated in patches smaller than 1 km^2 (0.39 mi^2) and that ground-nesting birds were predated more heavily than elevated-nesting birds. In addition to the importance of patch size for influencing the level of predation, the composition of the areas surrounding the patch is also important (Arango-Vélez and Kattan 1997, p. 141). For instance, in lowland Costa Rica, the edge effect (where predation is greater at the edge of forest patches than in the interior of the patch) was greatest in forest patches bordered by secondary growth than by pasture (Gibbs 1991, p. 157).

Summary of Factor C

Snakes, foxes, feral cats, feral dogs, and raptors are all predators of cracids. Predation results in the direct removal of eggs, juveniles, and adults from the population. Blue-billed curassows are slow to reproduce, produce a low clutch size, and exhibit a poor replacement rate (see Habitat and Life History). Predation can destroy pair bonds and remove potentially reproductive adults from the breeding pool. Studies on similar species in similar Andean habitats indicate that vulnerability to predation by generalist predators increases with increased habitat fragmentation and smaller patch sizes. Predation exacerbates the genetic complications associated with the species' small population size (Factor E). Because of the species' small population size and inability to recolonize isolated habitat fragments (Factor E), predation renders the species vulnerable to local extirpation. Therefore, we find that predation, compounded by ongoing habitat destruction (Factor A) and hunting (Factor B), is a threat to the blue-billed curassow.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

Regulatory mechanisms may provide species-specific or habitat-specific protections. An evaluation of the adequacy of regulatory mechanisms within Colombia to mitigate or remove the threats to the blue-billed curassow is provided below, beginning with species-specific and followed by habitat-specific protection mechanisms.

The Colombian Government has enacted and ratified numerous domestic and international laws, decrees, and resolutions for managing and conserving wildlife and flora (Matallana-T 2005, p. 121). Colombian Law No. 99 of 1993 (Creating the Ministry of the Environment and Renewable Natural Resources and organizing the National Environmental System (SINA)) sets out the principles governing environmental policy in Colombia, and provides that the country's biodiversity be protected and used primarily in a sustainable manner (EcoLex 1993, p. 2). Resolution No. 584 of 2002 (Species that are endangered wildlife in the national territory) provides a list of Colombian wildlife and flora that are considered threatened. Threatened is defined as those species whose natural populations are at risk of extinction, as their habitat, range, or ecosystems that support them have been affected by either natural causes or human actions. Threatened species are further categorized as critically endangered, endangered, or vulnerable. A critically endangered species (CR) is one that faces a very high probability of extinction in the wild in the immediate future, based on a drastic reduction of its natural populations and a severe deterioration of its range; an endangered species (EN) is one that has a high probability of extinction in the wild in the near future, based on a declining trend of its natural populations and a deterioration of its range; and a vulnerable species (VU) is one that is not in imminent danger of extinction in the near future, but it could be if natural population trends continue downward and deterioration of its range continues (EcoLex 2002, p. 10).

The blue-billed curassow is considered a critically endangered species under Colombian law pursuant to paragraph 23 of Article 5 of Law No. 99, as outlined in Resolution No. 584 (EcoLex 2002, p. 12). This status confers certain protections upon the species. Resolution No. 849 of 1973 (laws governing commercial hunting of saínos, boas, anacondas, and birds throughout the country) and Resolution No. 787 of 1977 (laws governing sport hunting of mammals, birds, and reptiles of wildlife), regulate and prohibit commercial and sport hunting of all wild bird species, respectively, except those specifically identified by the Ministry of the Environment or otherwise permitted (EcoLex 1973, p. 1; EcoLex 1977, p. 3). The Ministry of the Environment does not permit the blue-billed curassow to be hunted commercially or for sport because of its status as a critically endangered species. Neither Resolution prohibits subsistence hunting. As discussed under Factor B, commercial and sport hunting are not threats to this species, but subsistence hunting continues to threaten the species throughout its range, including within protected areas. Thus, these Resolutions are ineffective at reducing the existing threat of subsistence hunting to the blue-billed curassow.

Additional efforts to protect the species from subsistence hunting are inadequate. Within El Paujíl Reserve, for instance, there are penalties for shooting or trapping the species (BLI 2007d, p. 3). However, as recently as 2006, it was reported that both chicks and eggs continued to be collected in the Serranía de las Quinchas region, where the Reserve is located, for domestic use and for sale at local markets (Cuervo 2002, p. 139; Urueña *et al.* 2006, p. 42) (Factor

B). Thus, private efforts to protect the species from hunting appear to be inadequate within a region where national laws are ineffective at protecting the species from such take.

The blue-billed curassow is listed in Appendix III of CITES (see Factor B). CITES is an international treaty among 177 nations, including Colombia (which became a Party in 1981) and the United States (which became a Party in 1975) (UNEP–WCMC 2008a, p. 1). In the United States, CITES is implemented through the U.S. Endangered Species Act (Act). The Act designates the Secretary of the Interior as the Scientific and Management Authorities to implement the treaty, with all functions carried out by the Service. Under this treaty, countries work together to ensure that international trade in animal and plant species is not detrimental to the survival of wild populations by regulating the import, export, reexport, and introduction from the sea of CITES-listed animal and plant species (USFWS 2008, p. 1). As discussed under Factor B, we do not consider commercial international trade to be a threat impacting the blue-billed curassow.

Colombia has numerous laws and regulations pertaining to forests and forestry management, including: The Forestry Law of 1959 (Law 2—[On] forest economy [of the] nation and conservation [of] renewable natural resources) (EcoLex 1959); the Forestry Code of 1974 (Decree 2,811—National code of renewable natural resources and protection of the environment) (Faolex 1974), and the forest plan of 1996 (Decree 1,791—Forest Improvement Plan) (Faolex 1996). A new forest law was developed and approved in 2006 (Law No. 1,021, General [Forestry] Law). The new law seeks to: (1) Further promote forest plantations and create financial mechanisms for investments, (2) provide for rigorous control and expanded sustainable use of natural forests, (3) and regulate and further develop forest concessions in the country (International Tropical Timber Organization (ITTO) 2006, p. 218). However, the ITTO considers the Colombian forestry sector to be lacking in law enforcement and on-the-ground control of forest resources, with no specific standards for large-scale forestry production, no forestry concession policies, and a lack of transparency in the application of the various laws regulating wildlife and their habitats (ITTO 2006, p. 222).

Resource management in Colombia is highly decentralized. Resources are managed within local municipalities by one of 33 Autonomous Regional Corporations known as CARs (Corporaciones Autónomas Regionales) (Matallana-T 2005, p. 121). CARs are corporate bodies of a public nature, endowed with administrative and financial autonomy to manage the environment and renewable natural resources (Law 99 of 1993). The blue-billed curassow is currently known to occur within seven different Departments, each of which is managed by a separate local entity. These corporations grant concessions, permits, and authorizations for forest harvesting (ITTO 2006, p. 219). Forty percent of Colombia's public resources are managed by local municipalities, making Colombia one of the most decentralized countries in terms of forestry management in Latin America (Matallana-T 2005, p. 121).

Monitoring of resource use and forest development authorized by these corporations is conducted mostly by local nongovernmental organizations. Governmental institutions responsible for oversight appear to be underresourced and unable to maintain an effective presence in the field (ITTO 2006, p. 222). Consequently, there is no vehicle for overall coordination of species management for multijurisdictional species such as the blue-billed curassow. The private Proaves-Colombia Foundation plans to generate a national strategy for the conservation of the blue-billed curassow through the project, ''Saving the Blue-billed Curassow'' (Quevedo *et al.* 2005, as cited in Urueña *et al.* 2006, p. 42). In 2004, this project evaluated and prioritized threats in Serranía de las Quinchas region (Machado 2004, as cited in Urueña *et al.* 2006, p. 42), assessed population density and structure (Arias 2005, as cited in Urueña *et al.* 2006, p. 42), studied habitat use and behavioral aspects in Paujíl de Pico Bird Reserve (Urueña 2005, as cited in Urueña *et al.* 2006, p. 42), and promoted an environmental education campaign and the creation of El Paujíl Bird Reserve (Urueña and Quevedo 2005, as cited in Urueña *et al.* 2006, p. 42). However, despite the increased community environmental education effort, the transitory nature of migrant workers in this region diminishes the program's effect (Urueña, 2009, pers. comm.).

Currently there are approximately 49 nationally recognized protected areas in Colombia (Matallano-T 2005, p. 121). The five most common categories of habitat protection are: (1) National Natural Park (an area whose ecosystems have not been substantially altered by human exploitation or occupation, and where plant and animal species, or complex geomorphological landscapes have historical, cultural, scientific, educational, aesthetic, or recreational value); (2) Wildlife Sanctuary for Fauna and Flora (an area dedicated to preserve species or communities of wildlife, and to conserve genetic resources of wildlife); (3) National Natural Reserve (an area that preserves flora and fauna and is established for the study of its natural wealth); (4) Panoramic Park (a parcel of land of panoramic, cultural, or natural value preserved for education and relaxation); and (5) Unique National Area (a rare or unique ecosystem) (Matallano-T 2005, p. 121). Several areas considered to be important refuges for the blue-billed curassow are protected areas and are managed by autonomous corporations, including: (1) The Paramillo National Natural Park (Antioquía and Córdoba Departments) and (2) The Bajo Cauca–Nechí Regional Natural Reserve (Antioquía and Córdoba Departments) (BLI 2007d, p. 3; Cuervo 2002, p. 139), both of which are managed by Corantioquia (Corantioquia 2008, p. 1).

(1) The Paramillo National Natural Park (Antioquía and Córdoba Departments) is a large Park, but no protective measures have been implemented to curb human impacts on the habitat and species by the indigenous and farming residents within the park (BLI 2007a, pp. 1–2; BLI 2007d, p. 3) (Factor A). Cocaine cultivation is occurring within the Park boundaries (UNODC and GOC 2005, p. 45). Dam construction on the Sinú River, part of the species' historic range (BLI 2007a, p. 1; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361), has caused ongoing flooding in the area since its completion in 1998 (NGO Working Group on Export Development Canada 2003, p. 31; Cuervo 2002, p. 139). Thus, the designation of this area as a Park has not mitigated human-induced habitat destruction (Factor A).

(2) The Bajo Cauca-Nechí Regional Natural Reserve (Antioquía and Córdoba Departments) encompasses suitable habitat for the blue-billed curassow, but the species has not been confirmed within the Reserve (BLI 2007d, p. 3). Nonetheless, it is notable that this Reserve, which is designated to preserve and research flora and fauna, allows logging (Fundación Viztaz 2007, p. 2). Thus, should the species be located therein, this Reserve's designation as a preserve would not mitigate the threat from habitat destruction (Factor A).

The privately owned El Paujíl Bird Preserve, which was established specifically to protect the blue-billed curassow and its habitat (BLI 2007d, p. 2) (Factor A), has measures in place to penalize shooting or trapping the

species (BLI 2007d, p. 3). However, egg and chick collection are ongoing within the Serranía de las Quinchas area, where the private reserve is located (Factor B).

Aside from the Paramillo National Park, which includes habitat in the upper elevational limit of the blue-billed curassow's preferred range (Cuervo 2002, p. 140), no effective protective measures have been undertaken (BLI 2007d, p. 2; Brooks and Gonzalez-Garcia 2001, p. 183) in that the regulatory mechanisms in these protected areas do not mitigate habitat destruction, which is a primary risk factor for this species (Factor A). Thus, these protected areas do not provide sufficient protections to mitigate the effects from habitat loss (Factor A) or reduce threats from hunting and collection (Factor B).

Summary of Factor D

Colombia has numerous laws and regulatory mechanisms intended to protect and manage wildlife and their habitats. The blue-billed curassow is considered critically endangered under Colombian law and lives within several managed forests or protected areas. However, on-the-ground enforcement of existing wildlife protection and forestry laws and oversight of the local jurisdictions implementing and regulating activities are ineffective at mitigating the primary threats to the blue-billed curassow. As discussed in Factor A, habitat destruction, degradation, and fragmentation continue throughout the existing range of the blue-billed curassow. As discussed in Factor B, uncontrolled hunting and commercial use of the blue-billed curassow are ongoing and continue to negatively affect the continued existence of the species. Moreover, the lack of a species conservation strategy and the decentralized management of natural resources in Colombia provide no overall coordination in the conservation efforts for species including the blue-billed curassow, which ranges in multiple jurisdictions. Despite ongoing work toward developing a national conservation strategy for the species, it is not known whether it will be formally adopted by the Government of Colombia, and at this time we are unable to determine whether the strategy will be effective in reducing the threats to this species on a local or rangewide basis. Therefore, we find that the existing regulatory mechanisms currently in place for the blue-billed curassow do not reduce or remove the factors threatening the species, thus we find that Factor D is a threat to the blue-billed curassow.

Factor E: Other Natural or Manmade Factors Affecting the Continued Existence of the Species

Three additional factors affect the blue-billed curassow: Limited ability to disperse to unoccupied habitat; small population size, and unsuccessful captive-breeding programs.

Likelihood To Disperse

The blue-billed curassow exhibits several characteristics that make it unlikely to disperse into isolated habitat fragments in order to repopulate patches of suitable habitat. The blue-billed curassow requires a large home range of primary tropical forest (Cuervo 2002, pp. 138–140). The habitat patches within the blue-billed curassow's current range are described by researchers as fragmented, disjunct, and isolated (Donegan and Huertas 2005, p. 29; Salaman *et al.* 2001, p. 183; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361; Collar *et al.* 1992, p. 154). The species will rarely cross narrow deforested corridors, such as those caused by roads or oil pipelines, and it will not cross large open areas between forest fragments (Cuervo and Salaman 1999, p. 7). In addition to the species' small overall population size (see below), researchers believe it is unlikely that the blue-billed curassow would repopulate an isolated patch of suitable habitat following decline or extirpation of the species from that patch (Cuervo and Salaman 1999, p. 7; Hanski 1998, pp. 45–46) (see Factor E, Captive Breeding Program).

Small Population Size

Deforestation and habitat loss throughout the blue-billed curassow's historic range has resulted in fragmented, disjunct, and isolated populations in the remaining four or five patches of tropical humid and premontane forests and caused regional extirpations of the blue-billed curassow (Brooks and Gonzalez-Garcia 2001, p. 183; Cuervo and Salaman 1999, p. 7; Collar *et al.* 1992, pp. 61–62). It is estimated that the largest subpopulation (in the Serranía de las Quinchas, Boyacá Department) contains between 250 and 999 birds (BLI 2007d, p. 2), and that the total population is much fewer than 2,000 individuals (Brooks and Gonzalez-Garcia 2001, p. 184). Cuervo (2002, p. 141) estimated that the species had lost more than half of its population over the last three generations, or 30 years. Further, it is estimated that, at the current rate of decline, the blue-billed curassow could lose up to 79 percent of its current population within the next 10 years and could be extinct within the next three generations, or 30 years (BLI 2007d, p. 3; Cuervo 2002, p. 141).

The blue-billed curassow's restricted and fragmented range, combined with its small population size (Cuervo 2002, p. 138; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361), makes the species particularly vulnerable to the threat of adverse genetic effects and susceptible to extinction through natural or manmade events that destroy individuals and their habitat (BLI 2007d, pp. 1–2; Cuervo 2002, p. 140; Brooks and Gonzalez-Garcia 2001, pp. 185–190). Meta-population analysis involves the study of the dynamics of an entire population by studying movements within local populations (Hanski 1998, p. 41). ''A meta-population composed of extinction-prone local populations in a small patch network is necessarily more threatened than are meta-populations in large and well connected networks'' (Hanski 1998, p. 42). Considering that not all blue-billed curassow individuals in a population are breeding at any one time, the actual number of individuals contributing to population growth will be a smaller number than the total number of individuals.

Small population sizes render species vulnerable to any of several risks, including loss of genetic variation, inbreeding depression, and accumulation of deleterious genes. Inbreeding can have individual or population-level consequences either by increasing the phenotypic expression (the outward appearance or observable structure, function, or behavior of a living organism) of recessive, deleterious alleles or by reducing the overall fitness of individuals in the population (Charlesworth and Charlesworth 1987, p. 238; Shaffer 1981, p. 131). Small, isolated populations of wildlife species are also susceptible to demographic problems (Shaffer 1981, p. 131), which may include reduced reproductive success of individuals and chance disequilibrium of sex ratios. Chance disequilibrium of sex ratios would be further exacerbated by preferential hunting of male birds (Factor B). This species' risk of extinction is further compounded by ongoing collection of eggs and chicks, and by hunting-related disturbances that may disrupt breeding pairs (Factor B). Once a population is reduced below a certain number of individuals, it tends to rapidly decline towards extinction (Franklin 1980, pp. 147–148; Gilpin and Soulé 1986, p. 25; Holsinger 2000, pp. 64–65; Soulé 1987, p. 181).

Captive-Breeding Program

A captive-breeding program is being developed within the species' range (see Current Range and Distribution, above) by Fundación Ecolombia, based at the Wildlife Rehabilitation Centre in Los Farallones (Antioquía Department, Colombia). The captive-held population includes three males and two females. The program has met with little success because attempts to breed the species in captivity have been unsuccessful to date (two sterile eggs laid in 2003 and none since). The species is historically known to be a poor breeder in captivity (Throp 1964, p. 127). The program is exploring artificial insemination for future breeding (Wildlife Protection Foundation (WPF) 2007, p. 2). The Houston Zoo, however, which has maintained cracids since the 1960s, has bred the species for 30 years and has successfully raised at least 10 blue-billed curassows in captivity (Houston Zoo 2008, p. 2; Todd *et al.* 2008, p. 1). The Houston Zoo also conducts outreach and breeding research. While this has resulted in limited exports of captive-bred birds for scientific purposes (i.e., to zoos; see also Factor B), the number of birds in captivity has dropped worldwide. In addition, the number of specimens originally imported into the United States was small (Houston Zoo 2008, p. 2), which would limit the number of breeding pairs and offspring and, therefore, their conservation value for reintroduction into the wild. Thus, the captive breeding program is not currently contributing to reintroduction, but serves a conservation value by providing specimens for zoos that conduct outreach and breeding research. Further, reintroduction would appear to be important for recovery of this species because the species is not likely to disperse into or repopulate suitable habitat on its own.

Summary of Factor E

The blue-billed curassow's small population size increases its vulnerability to genetic risks associated with small population sizes that negatively impact the species' long-term viability and increase the possibility of localized extirpations of the remaining fragmented populations. Further, the species is unlikely to repopulate areas of suitable habitat from which a subpopulation has been extirpated because it avoids crossing the disturbed areas that separate the remaining suitable habitat for this species. Range-country attempts at captive breeding have been unsuccessful, and the stock in U.S. captive-breeding programs is limited; therefore, the captive-breeding program is not contributing to reintroduction of the species in the wild and so is not currently mitigating the problem of small population size. Therefore, we believe that, in combination with the risks to the species from habitat destruction (Factor A), hunting (Factor B), and predation (Factor C), the blue-billed curassow is vulnerable to localized extirpation or extinction from which the species would be unable to recover, due to its small population size and apparent inability to repopulate fragmented, isolated habitats such as those currently present within this species' range.

Blue-Billed Curassow Status Determination

The five primary factors that threaten the survival of the blue-billed curassow are: (1) Habitat destruction, fragmentation, and degradation (Factor A); (2) overexploitation due to hunting and collecting of eggs and chicks (Factor B); (3) predation (Factor C); (4) inadequacy of regulatory mechanisms to reduce the threats to the species (Factor D); and (5) small population size and isolation of remaining populations (Factor E).

The direct loss of habitat through widespread deforestation and conversion of primary forests to human settlement and agricultural uses has led to the fragmentation of habitat throughout the range of the blue-billed curassow and isolation of the remaining populations (Factor A). The species' historic range, which encompassed approximately 106,700 km^2 (41,197 mi^2), has been reduced to 2,090 km^2 (807 mi^2). Experts estimate that 88 percent of this habitat loss has occurred within the last 30 years, or three generations. The best available information indicates that the species' population was reduced by 50 percent in the 30 years prior to 2002 and that ongoing habitat destruction and degradation are continuing at a rate that would lead to the extinction of the blue-billed curassow within the next 30 years if measures are not taken to ameliorate the loss of habitat. Thus, habitat loss poses an imminent threat of extinction and is a factor that currently endangers the species.

The blue-billed curassow is hunted or collected, whole or in parts, in all life stages (eggs, juveniles, adults, feathers, and other body parts) throughout its current range by both indigenous people and by local settlers for both sustenance and sport; for domestic use in rituals; and for sale to tourists (Factor B). Several life-history traits of the species contribute to its vulnerability to hunting and collection: Its large size, ease of location during breeding season, trusting nature, low productivity (1–2 eggs), and a replacement rate of 6 years (taking an individual of the species an average of 6 years to replace itself). Adults are hunted mainly during the breeding season, when males are most vulnerable and more easily located by their loud mating calls that are audible at long distances. The direct take of males disrupts sex ratios in this species, which forms monogamous pairs, and this take also disrupts mating activities. Hunting pressure has caused severe depletion or near extirpation in portions of its historical range, despite the continued availability of suitable habitat (primary forest). The effects of hunting are exacerbated by ongoing habitat fragmentation (Factor A), which increases accessibility into the species' habitat, rendering it more vulnerable to hunting. Concomitantly, increased conversion of primary forest habitat has encouraged further human settlement within the blue-billed curassow's habitat. Hunting poses an imminent threat of extinction and is a factor that currently endangers the species.

Blue-billed curassows are vulnerable to predation by generalist predators, including snakes, foxes, feral cats, feral dogs, and raptors (Factor C). Habitat fragmentation (Factor A) contributes to this vulnerability, because research indicates that predation increases with increased habitat fragmentation and smaller patch sizes. Predation leads to the direct removal of eggs, juveniles, and adults from the population, exacerbating risks associated with the species' small population size (see below). Predation can destroy pair bonds and remove potentially reproductive adults from the breeding pool. The blue-billed curassow is slow to reproduce and produces a low clutch size, and predation exacerbates this species' already poor replacement rate (see Habitat and Life History).

The threats from habitat destruction, hunting, and predation are compounded by the species' small population size (Factor E). The blue-billed curassow's population has been reduced by 50 percent within the last 30 years. The species' low population estimate of fewer than 2,000 individuals, combined with its restricted, fragmented, and isolated habitat, makes the species particularly vulnerable to numerous human factors (e.g., agricultural development, armed conflict, fire, dams and reservoir development, increased human settlement, illicit drug production and control, mining activities, oil development and distribution, and road development).

Further, the species' reticence to cross large open areas makes it unlikely that the species would repopulate suitable habitat without human intervention in remaining isolated forest patches that are separated by large distances, all of which put the species at a risk of extinction.

Finally, despite numerous laws and regulatory mechanisms (Factor D) to administer and manage wildlife and their habitats, on-the-ground enforcement of these laws and oversight of the local jurisdictions implementing and regulating activities within the species' habitat are inadequate to mitigate the effects of habitat loss (Factor A) and hunting (Factor B). Habitat destruction and hunting continues within the species' range and, aside from El Paujíl Bird Preserve, no other areas provide effective protective measures for protecting the blue-billed curassow from ongoing hunting or its habitat from ongoing destruction.

We have carefully assessed the best available scientific and commercial information regarding the past, present, and potential future threats faced by the blue-billed curassow. We conclude that the ongoing threats to the blue-billed curassow, habitat destruction (Factor A), hunting (Factor B), and predation (Factor C), exacerbated by the species' small population size and limited dispersal ability (Factor E), and compounded by inadequate regulatory mechanisms to mitigate these threats (Factor D), to be equally present and of the same magnitude throughout the species' entire current range. We further conclude, based on the best available scientific and commercial information, that the magnitude of these threats are of an extent that places the species in danger of extinction at this time. Therefore, on the basis of our analysis of the best available scientific and commercial information, we conclude that the blue-billed curassow is endangered throughout its range, and thus should be designated an endangered species under the Act.

Brown-Banded Antpitta (Grallaria Milleri)

Species Description

The brown-banded antpitta is a member of the ground-antbird Family (Formicariidae), is approximately 18 cm (7 in) long from bill to tail, and endemic to the west slope of the central Andes of Colombia (Krabbe and Schulenberg 2003, p. 682; Fjeldså and Krabbe 1990, p. 414; Hilty and Brown 1986, p. 422). The species is locally known as ''Tororoi'' (Beltrán and Kattan 2002). This bird is a uniform dark brown, with a dingy white throat and underbelly.

Taxonomy

The brown-banded antpitta was first taxonomically described by Chapman in 1911 and placed in the Ground-Antbird Family (Formicariidae). The type specimen (the actual specimen that was first described by Chapman) was obtained from Laguneta (Quindío Department) (Beltrán and Kattan 2002, p. 327). Laguneta is, therefore, referred to as the ''type locality.''

Habitat and Life History

The brown-banded antpitta currently inhabits the humid understory and forest floor habitats of mid-montane and cloud forests between 2,400 and 2,600 m (7,874 and 8,530 ft) with high density of herbaceous plants and shrubs (Krabbe and Schulenberg 2003, p. 719; Kattan and Beltrán 1999, p. 272). The species has been observed in older (30-year-old) secondary-growth forest habitats and alder (*Alnus acuminata*) plantations (Cuervo 2002, pp. 326–327; Krabbe and Schulenberg 2003, p. 719).

Researchers consider antpitta life histories to be among the least known of Neotropical bird species (Dobbs *et al.* 2001, p. 225). The brown-banded antpitta, as with other antpittas, is a secretive species, with a low population density and high habitat specificity (Kattan and Beltrán 2002, p. 232). Antpittas are considered to be nearly flightless (Krabbe and Schulenberg 2003, p. 698) and their dispersal capabilities are not well known (Cuervo 2002, p. 327), except that one banded individual traveled a distance of 0.041 km^2 (0.02 mi^2) (Kattan and Beltrán 2002, p. 234). This ground-dwelling species lives either singly or in pairs (Beltrán and Kattan 2002, p. 327) and has a high territorial fidelity (Cuervo 2002, p. 327). It can be seen running along the forest floor picking up prey (Krabbe and Schulenberg 2003, p. 719), which apparently consists of beetles (*Coleoptera* spp.) and earthworms.

Nothing is known about the brown-banded antpitta's reproductive ecology, except that its peak reproductive period is between March and May (Beltrán and Kattan 2002, pp. 326–327) and that both parents feed the young (del Hoyo 2003, p. 719). Drawing from studies on similar species, including the Colombian species, scaled antpitta (*Grallaria guatimalensis*) and chestnut-crowned antpitta (*Grallaria ruficapilla*), the species tend to nest on fallen logs, on the forks of tree trunks, or atop the crowns of low-growing palms, situated at nearly groundlevel to no higher than 3 m (10 ft) off the ground (Dobbs *et al.* 2001, p. 226; Wiedenfeld 1982, p. 581). The typical clutch size for antpittas is considered to be two eggs (Dobbs *et al.* 2001, p. 227; Wiedenfeld 1982, p. 581). Antpitta nests are roughly circular cups, loosely constructed of dead leaves that are generally hard to distinguish from the surroundings (Dobbs *et al.* 2001, p. 227; Wiedenfeld 1982, p. 581). Antpittas appear to rely on camouflage, both to hide the location of their nests (Wiedenfeld 1982, p. 580), as well as in response to disturbance, when birds remain absolutely still to avoid detection by potential predators (Dobbs *et al.* 2001, p. 226).

Historical Range and Distribution

The brown-banded antpitta was historically known from a single location, near Laguneta in the central Andes (centrally located in the Department of Quindío), which ranges in altitude from 1,859 m (6,100 ft) in the surrounding valleys to 3,140 m (10,300 ft) at its highest point (Chapman 1917, pp. 35–36, 396). In 1917, the valley leading to Laguneta was described as gently rising until about 2,530 m (8,300 ft), when the terrain rose steeply up to 2,896 ft (9,500 ft). The vegetation was described as open, with scattered palms and little other vegetation until about 2,835 m (9,300 ft), where the forest began (Chapman 1917, p. 36). At 3,140 m (10,300 ft), the forest was described as dense with little undergrowth, except in occasional clearings dominated by dense shrubs so thick as to be impenetrable without a knife (Chapman 1917, p. 35). Eleven specimens were collected between 1911 and 1942; the species was last observed and collections were made at the type locality at Laguneta in 1942 (Beltrán and Kattan 2002, p. 325; Collar *et al.* 1992, p. 698).

Chapman (1917, p. 36) described the practice of slash-and-burn agriculture around Laguneta in 1917, noting that much of the hillside between 2,530 and 2,835 m (8,300–9,300 ft) was bare and close-cropped, having been burned and cleared. By 1994, the forested area providing habitat for the brown-banded antpitta in and around the type locality near Laguneta had been mostly destroyed (Collar *et al.* 1994, p. 136), and despite subsequent surveys (in 1986, 1988, and 1991), the species was not observed. In 1992, researchers considered the brown-banded antpitta to be locally extirpated, if not extinct throughout its range (Cuervo 2002, pp. 326–327; Kattan and Beltrán 1997, pp. 367–369; Collar *et al.* 1992, p. 689). Although the brown-banded antpitta was rediscovered in 1994 (Kattan and Beltrán 1997, pp. 367–369), researchers

continue to consider the species to be locally extinct (extirpated) from its type locality of Laguneta (Quindío Department) (Beltrán 2002 *in litt.,* as cited in Beltrán and Kattan, p. 327) due to extensive deforestation (Beltrán and Kattan 2002, p. 327).

Current Range and Distribution

The current range of the brown-banded antpitta is described as humid understory and forest floors of mid-montane and cloud forests, preferring altitudes between 2,400 and 2,600 m (7,874 and 8,530 ft), in areas with a high density of herbs and shrubs (Krabbe and Schulenberg 2003, p. 719; Kattan and Beltrán 1999, p. 272). The current range is estimated to be 300 km² (116 mi²) (BLI 2007f, p. 1). The species is known today from only three areas in the upper Río Magdalena valley. The first area is the humid forests in the Central Andes of Colombia's Ucumarí Regional Park (Risaralda Department), where it was first sighted in 1994 (Kattan and Beltrán 1997, pp. 369–370) and recently observed in 2000 (Beltrán and Kattan 2002, p. 326). The site is approximately 44 km² (17 mi²) in the Otún River watershed (Kattan and Beltrán 1999, p. 273). The second area is the southeastern slope of Volcán Tolima in the Río Toche Valley on private land (the house of La Carbonera) (Tolima Department), where it was first observed in 1998 and recently observed in 2000 (Beltrán and Kattan 2002, p. 325). This location is 0.05 km² (0.02 mi²) in size at elevations ranging from 2,750 to 2,900 m (9,022 to 9,514 ft) (Beltrán and Kattan 2002, p. 326). The third area is the Río Blanco river basin (Caldas Department), where it was most recently observed in 2000 (Beltrán and Kattan 2002, p. 326). This site is a strip of land less than 200 linear km (124 linear mi) on the Central Cordilla, between 2,300 and 3,100 m (7,546 and 10,171 ft) in elevation (BLI 2004c, p. 2; Kattan and Beltrán 2002, p. 238). Experts consider the most important refuges for this species to be: (1) The Ucumarí Regional Park (Risaralda Department), (2) the Río Toche Valley (Tolima), (3) the Río Blanco river basin (Caldas Department), and (4) the Reserve of Cañon and Quindío Departments, where suitable habitat exists but the species may be extirpated. These refugia are further discussed under Factor A, below.

Population Estimates

There have been few quantitative surveys of the brown-banded antpitta. Available population information is provided for the four areas considered to be important refugia for the species (as discussed in Factor A). The population located within the Ucumarí Regional Park has been surveyed twice. In the first survey, conducted from 1994 to 1997, 11 brown-banded antpittas were captured and banded. In a subsequent survey of a 0.17–1 km² (0.07–0.62 mi²) area within the Ucumarí Regional Park during 1995 to 2000, Kattan and Beltrán (2002, pp. 232–233) captured and banded 36 brown-banded antpittas. Based on these surveys, the subpopulation within the 0.63 km² (0.24 mi²) Park was estimated to include up to 106 individuals, averaging approximately 1.3 individuals per 0.01 km² (0.004 mi²) (Kattan and Beltrán 1999, p. 276; Kattan and Beltrán 1997, pp. 367–369). Thus, this subpopulation contains at least 36, and possibly as many as 106 individuals.

Qualitative surveys conducted from 1998 to 2000 in the Río Toche Valley determined that the brown-banded antpitta is uncommon and local (Beltrán and Kattan 2002, p. 326). One individual was observed in 1999 (Cuervo *in litt.,* as cited in Beltrán (2002 p. 326). There is no information on the estimated population size of brown-banded antpitta within the Río Toche. Thus, this subpopulation contains at least one individual, but there is no estimate of the upper limit of the population.

A census of the population in the Río Blanco river basin was undertaken in June 2000, within an approximately 5 km (3 mi) transect. Researchers inferred the presence of at least 30 individuals, based on vocalizations they elicited in response to recordings of the species' alarm call (Beltrán and Kattan 2002, p. 326). There is no information on the estimated population size of brown-banded antpitta within the Río Blanco area. Thus, this population may contain 30 individuals, but the upper limit of the population estimate is unknown.

The species is not currently known to inhabit the Reserve del Cañon del Quindío. Although the species was observed there in 1911 and 1942 (Beltrán and Kattan 2002, p. 325; Collar *et al.* 1992, p. 698) and the area contains suitable habitat, the species has not been observed there since 1942 (Beltrán and Kattan 2002, p. 235).

The IUCN estimates that the largest subpopulation contains 424 individuals (BLI 2007f, p. 4), but it is unclear as to which subpopulation this estimate refers. The global population of brown-banded antpitta is estimated by the IUCN to be larger than 250 individuals, but not more than 999 birds (BLI 2007f, p. 1), equating to approximately 338 to 756 individuals (BLI 2007f, p. 4). It is estimated that the species has lost up to 9 percent of its population in the last 10 years, or 3 generations, and that this rate of decline will continue over the next 10 years (BLI 2007f, p. 4). Additional information on the population size of this species is provided in the discussion of Factor E, below.

Conservation Status

The brown-banded antpitta is identified as an endangered species under Colombian law pursuant to paragraph 23 of Article 5 of the Law 99 of 1993, as outlined in Resolution No. 584 of 2002 (EcoLex 2002, p. 12). The IUCN has classified the species as 'Endangered' since 1994 because it is known from very few locations and occupies a very small range (BLI 2004c, p. 1).

Summary of Factors Affecting the Brown-Banded Antpitta

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Habitat or Range

The brown-banded antpitta inhabits the humid understory and forest floor habitats of mid-montane and cloud forests between 1,800 and 2,600 m (5,905 and 8,530 ft) that have a high density of herbs and shrubs (Krabbe and Schulenberg 2003, p. 719; Kattan and Beltrán 1999, p. 272). The current range is estimated to be 300 km² (116 mi²) (BLI 2007f, p. 1), and the species is known today in only three locations: (1) Ucumarí Regional Park (Kattan and Beltrán 1997, pp. 369–370) (Risaralda Department), (2) the southeastern slope of Volcán Tolima in the Río Toche Valley (Tolima Department), and (3) the Río Blanco catchment (Caldas Department). These locations are discussed further under Refugia, below.

Deforestation

Colombia has experienced extensive deforestation in the last half of the 20th Century as a result of habitat conversion for human settlements, road building, agriculture, and timber extraction. A 23-year study, from 1973 to 1996, demonstrated that these activities reduced the amount of primary forest cover in Colombia by approximately 3,605 hectares (ha) (8,908 acres (ac)) annually, representing a nearly one-third total loss of primary forest habitat (Viña *et al.* 2004, pp. 123–124). Beginning in the 1980s, habitat loss increased dramatically as a result of influxes of people settling in formerly pristine areas (Perz *et al.* 2005, pp. 26–28; Viña *et al.* 2004, p. 124). More recent studies indicate that the rate of habitat destruction is accelerating. Between the years 1990 and 2005, Colombia lost approximately 52,800 ha (130,471 ac) of

primary forest annually (Butler 2006a, pp. 1–3; FAO 2003a, p. 1). Human activities, such as encroachment, cultivation, grazing, and infrastructural development, have resulted in extensive deforestation and environmental degradation of primary forests in the Río Magdalena valley, part of the brown-banded antpitta's range (Cuervo and Salaman 1999, p. 8; Ocampo and Botero 2000, pp. 76–78). These studies and activities in Colombia are described in greater detail under Factor A for the blue-billed curassow, above.

A study conducted on the effects of habitat fragmentation on Andean birds within western Colombia determined that 31 percent of the historical bird populations in western Colombia had become extinct or locally extirpated by 1990, largely as a result of habitat fragmentation from deforestation and human encroachment (Kattan and Álvarez-Lopez 1996, p. 5; Kattan *et al.* 1994, p. 141). Deforestation has led to local extirpation of the brown-banded antpitta in its type locality, near Laguneta in the central Andes (Quindío Department), where the natural vegetation has been reduced to 10 percent of its former area (Beltrán 2002 *in litt.,* as cited in Beltrán and Kattan, p. 327). Deforestation continues in mid-montane and cloud forests in the Departments Caldas and Risaralda, where this species has been observed (Dolphijn 2005, p. 2). Human encroachment and ongoing deforestation throughout this species' current range are discussed under Refugia, below.

In addition to the direct detrimental effect of habitat loss, there are several indirect effects of habitat disturbance and fragmentation (Brooks and Strahl 2000, p. 10; Silva and Strahl 1991, p. 38). Roads create barriers to animal movement, expose animals to traffic hazards, and increase human access to habitat, facilitating further exploitation and habitat destruction (Hunter 1996, pp. 158–159). Researchers have observed that road building and other infrastructure improvements in previously remote forested areas have increased accessibility and facilitated further habitat destruction, exploitation, and human settlement (Etter *et al.* 2006, p. 1; Álvarez 2005, p. 2,042; Cárdenas and Rodríguez Becerra 2004, pp. 125–130; Viña *et al.* 2004, pp. 118–119; Hunter 1996, pp. 158–159).

Illegal Crops and Their Eradication

Illegal drug crops are cultivated within the brown-banded antpitta's range. In 2003, nearly 80 percent of the heroin entering the United States came from opium (*Papaver somniferum*) farms in the Department of Tolima (Forero and Weiner 2003, p. 1). Cocaine cultivation occurs in other parts of the species' range. In 2003, authorities first detected cocaine cultivation in Caldas, traditionally the center of the Colombian coffee-growing industry; it was estimated that less than 1 km^2 of land was under cocaine cultivation (0.54 km^2 (0.21 mi^2)). By 2004, cultivation had risen 563 percent, covering a 36-km^2 (14-mi^2) area (UNODC and GOC 2005, p. 27). Coca crops deplete the soil of nutrients, which hampers regeneration following abandonment of fields (Van Schoik and Schulberg 1993, p. 21). Drug eradication efforts in Colombia have further degraded and destroyed primary forest habitat by using nonspecific aerial herbicides to destroy illegal crops (Álvarez 2005, p. 2,042; BLI 2007d, p. 3; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12). Herbicide spraying has introduced harmful chemicals into brown-banded antpitta habitat and has led to further destruction of the habitat by forcing illicit growers to move to new, previously untouched forested areas (Álvarez 2007, pp. 133–143; BLI 2007d, p. 3; Álvarez 2005, p. 2,042; Cárdenas and Rodríguez Becerra 2004, p. 355; Álvarez 2002, pp. 1,088–1,093; Oldham and Massey 2002, pp. 9–12). Between 1998 and 2002, cultivation of illicit crops increased by 21 percent each year, with a concomitant increase in deforestation of formerly pristine areas of approximately 60 percent (Álvarez 2002, pp. 1,088–1,093).

Refugia

The most important refugia for the brown-banded antpitta include: (1) Ucumarí Regional Park, (2) the Río Toche Valley, (3) the Río Blanco catchment, and (4) Reserva Departamental del Cañon del Quindío. These refugia are discussed below.

(1) Ucumarí Regional Park (Risaralda Department) covers an area of approximately 44 km^2 (17 mi^2) in the Otún River watershed, with elevations ranging from 1,700 to 2,600 m (5,577 to 8,530 ft) (Beltrán and Kattan 2002, pp. 325–326; Kattan *et al.* 2006, pp. 301–302; Kattan and Beltrán 1999, p. 273). The brown-banded antpitta prefers habitat within the upper range limits of this Park, at altitudes between 2,400 and 2,600 m (7,874 and 8,530 ft) (Krabbe and Schulenberg 2003, p. 719; Kattan and Beltrán 1999, p. 272). Most of the forested habitat within the park was cleared in the 1960s for cattle ranching, leaving the remaining natural forests only on the steepest slopes (Kattan and Beltrán 1999, p. 273). Much of the Park has been allowed to naturally regenerate, and plantations of alder (*Alnus acuminata*) and ash (*Fraxinus chinensis)* are overgrown with natural vegetation (Kattan and Beltrán 1997, p. 369). The Park also contains a small area of private pasturelands (Kattan and Beltrán 1997, p. 369), and agricultural expansion, selective logging, and firewood collection are ongoing in the region (BLI 2008a, p. 1).

(2) In Río Toche Valley (Tolima Department), on the southeastern slope of Volcán Tolima, the brown-banded antpitta is considered uncommon and local (Beltrán and Kattan 2002, p. 326; BLI 2004c, p. 2; Kattan and Beltrán 2002, p. 238). This habitat is described as fragmented, and it is estimated that the natural cover has been reduced by 15 percent at elevations between 1,900 and 3,200 m (6,234 and 10,499 ft). The majority of suitable habitat is above 2,200 m (7,218 ft) in elevation, and Kattan and Beltrán (2002, p. 238) consider it to be of sufficient size to support a population of brown-banded antpitta, making this an important area of suitable habitat for the species (p. 327).

(3) Río Blanco catchment (Caldas Department) comprises a strip less than 200 km (124 mi) long on the Central Cordilla, between 2,300 and 3,100 m (7,546 and 10,171 ft) (BLI 2004c, p. 2; Beltrán and Kattan 2002, pp. 325, 238). The area is considered to be of sufficient size to support the species (Kattan and Beltrán 2002, p. 238). However, the species has been observed at this location only once, in the year 2000 (Beltrán and Kattan 2002, p. 328).

(4) Reserva Departamental del Cañon del Quindío (Quindío Department): The Department of Conservation and Management of Alto Quindío owns and manages this 56 km^2 (22 mi^2) reserve, which ranges in elevation from 2,600 to 4,000 m (ft) (8,530 to 13,123 ft) (Corporación Autónoma Regional del Quindío 2008). The type locality for the brown-banded antpitta (Laguneta) is located in the Department of Quindío (Beltrán and Kattan 2002, p. 325). Beltrán and Kattan (2002, pp. 238, 327) believe that this Reserve comprises habitat suitable for the brown-banded antpitta (as described under Current Range, above) and represents an important habitat conservation area for the species (Beltrán and Kattan 2002, p. 327). However, the species has not been observed in Quindío since 1942 (Beltrán and Kattan 2002, p. 325; Collar *et al.* 1992, p. 698) and is considered to be locally extinct there (Beltrán 2002 *in litt.,* as cited in Beltrán and Kattan 2002, p. 327).

Nearly all the other forested habitat below 3,300 m (10,827 ft) in the Central Andes where the brown-banded antpitta occurred historically has been deforested and cleared for agricultural land use (BLI 2004c, p. 2). The remaining forests providing suitable habitat for the brown-banded antpitta have become fragmented and isolated, and are surrounded by or being converted to pasture and agricultural crops (e.g., coffee plantations, potatoes, and beans) (BLI 2004c, p. 2). Approximately 85 percent of forested habitat at altitudes between 1,900 m (6,234 ft) and 3,200 m (10,499 ft) has been converted to other land uses (BLI 2004c, p. 2; Cuervo 2002, p. 327; Stattersfield *et al.* 1998, p. 205). In 1998, forest conversion within the range of the brown-banded antpitta was projected to continue (Stattersfield *et al.* 1998, p. 205). Cuervo (2002, p. 328) estimated that the available suitable habitat for this species totals no more than 500 km^2 (310 mi^2); BirdLife International estimated that the species currently occupies an area 300 km^2 (116 mi^2) in size (BLI 2007f, p. 1).

Deforestation has greatly affected the current population size and distributional range of the brown-banded antpitta (Kattan and Beltrán 1997, p. 367; Collar *et al.* 1992, p. 698). The species was thought to be extinct or on the verge of extinction (Beltrán and Kattan 2002, pp. 326–327; Kattan and Beltrán 1997, pp. 367–369; Collar *et al.* 1992, p. 689), until its rediscovery in 1994 (Kattan and Beltrán 1997, pp. 367–369). The brown-banded antpitta is now confirmed within three localities, including the Ucumarí Regional Park, the Río Toche Valley, and the Río Blanco basin. These habitats are characterized as heterogeneous and fragmented (Beltrán and Kattan 2002, p. 327; Kattan and Beltrán 2002, p. 237). The species is considered extirpated from its type locality (Beltrán 2002 *in litt.,* as cited in Beltrán and Kattan, p. 327), despite the existence of suitable habitat (Beltrán and Kattan 2002, p. 328), suggesting that the species is unable to recolonize areas from which it has been extirpated.

Summary of Factor A

The brown-banded antpitta prefers the humid understory and forest floor habitats of midmontane and cloud forests between 2,400 and 2,600 m (7,874 and 8,530 ft) and has been observed in older (30-year-old) secondary-growth forest habitats and alder plantations. Habitat destruction, alteration, conversion, and fragmentation continue to be factors affecting the brown-banded antpitta. The direct loss of habitat through widespread deforestation and conversion of primary forests for human settlement and agricultural uses has led to the habitat fragmentation throughout the brown-banded antpitta's range. Cultivation of illegal drug crops, such as cocaine, leads to further deforestation and alters soil compositions, hindering regeneration of abandoned fields. In addition, drug eradication programs involving the aerial spraying of nonspecific herbicides lead to further environmental degradation and destruction of primary forest habitat. The current populations are small, very localized, and limited to a narrow elevational band that contains fragmented, disjunct, and isolated habitat. The species does not appear capable of recolonizing areas of suitable habitat that are isolated from extant locations (see Factor E, Likelihood to Disperse).

Historically, the species was known only in one location, near Laguneta, which had been reduced to 10 percent of its original vegetative cover by 1994. Currently, the species' range is estimated to be 300 km^2. The destruction and fragmentation of the remaining primary forested habitat is expected to continue, with ongoing human encroachment bringing increased population pressures and drug crop production, along with infrastructural improvements that facilitate encroachment into previously inaccessible areas. Therefore, we find that the present destruction, modification, and curtailment of habitat are a threat to the brown-banded antpitta throughout all of its range.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We are not aware of any information currently available that addresses the occurrence of overutilization that may be causing a decline of the brown-banded antpitta. Therefore, we do not consider overutilization for commercial, recreational, scientific, or educational purposes to be a threat to the brown-banded antpitta.

Factor C: Disease or Predation

We are unaware of information regarding disease or the potential for significant disease outbreaks in the brown-banded antpitta. As a result, we do not consider disease to be impacting the status of the species in the wild.

Both terrestrial and avian predators prey upon antpittas, including the mountain coati (*Nasuella olivacea*), tayra (*Eira barbara*—in the weasel family), squirrel cuckoo (*Piaya cayana*), and crimson-rumped toucanet (*Aulacorhynchus haematopygus*) (Dobbs *et al.* 2001, p. 231). Brown-banded antpittas are a ground-dwelling, nearly flightless species (Krabbe and Schulenberg 2003, p. 719; Beltrán and Kattan 2002, p. 327). Antpittas generally react nonconfrontationally in response to potential predators, relying on camouflage as a defense mechanism. Nesting birds rarely call from atop their nests (Wiedenfeld 1982, p. 580); they rely on their cryptic plumage and remain still to avoid detection when potential predators approach (Dobbs *et al.* 2001, pp. 226, 230). As discussed in detail above for the blue-billed curassow (Factor C, Predation), research on Andean understory nesting birds that are similar to the ground-dwelling brown-banded antpitta (Beltrán and Kattan 2002, p. 327) indicated that predation rates increase in isolated and fragmented forest habitats, especially smaller forest patches that facilitate predator access to the understory (Keyser 2002, p. 186; Renjifo 1999, p. 1,133; Wilcove 1985, p. 1,214; Keyser *et al.* 1998, p. 991; Arango-Vélez and Kattan 1997, p. 138; Hoover *et al.* 1995, p. 151; Gibbs 1991, p. 157).

Summary of Factor C

Mountain coatis, tayras, squirrel cuckoos, and crimson-rumped toucanets are known antpitta predators. Predation results in the direct removal of eggs, juveniles, and adults from the population. The brown-banded antpitta produces a low clutch size (see Habitat and Life History), and predation can remove potentially reproductive adults from the breeding pool. Moreover, habitat fragmentation has occurred and is ongoing throughout the brown-banded antpitta's range (Factor A). Studies on similar species in similar Andean habitats indicate that vulnerability to predation increases with increased habitat fragmentation and smaller patch sizes. The brown-banded antpitta does not have sophisticated antipredator response mechanisms, making this species particularly vulnerable to an increased risk of predation. Predation exacerbates the genetic complications associated with the species' small population size (Factor E). Because of the species' small population size and inability to recolonize isolated habitat fragments (Factor E), predation renders the species vulnerable to local extirpation. Therefore, we find that predation, exacerbated by ongoing habitat destruction (Factor A), is a threat to the brown-banded antpitta.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

Regulatory mechanisms may provide species-specific or habitat-specific protections. An evaluation of the adequacy of regulatory mechanisms within Colombia to mitigate or remove the threats to the brown-banded antpitta is provided below, beginning with species-specific and followed by habitat-specific protection mechanisms.

Colombia has enacted numerous laws to protect species and their habitats (Matallana-T 2005, p. 121). The brown-banded antpitta is listed as an endangered species under Colombian Law 99 of 1993 (EcoLex 1993, p. 2) and Resolution No. 584 of 2002 (EcoLex 2002, pp. 10, 12). A full description of these laws and the categorization of threatened species in Colombia were provided above, as part of the Factor D analysis for the blue-billed curassow. This threat status confers protections upon the species, including protection from commercial take under Resolution No. 849 of 1973 and Resolution No. 787 of 1977 (EcoLex 1977, p. 3; EcoLex 1973, p. 1). Hunting is not a threat to this species. Therefore, this law is not effective at reducing the primary threat to the species—habitat destruction.

Colombia has enacted numerous forestry laws and forestry management practices (Law No. 2 (EcoLex 1959); Decree No. 2,811 (Faolex 1974); Decree No. 1,791 (Faolex 1996); Law No. 1,021 (EcoLex 2006)). Weaknesses in the implementation of these laws and the decentralized nature of Colombian resource management are described in detail above for the blue-billed curassow (Factor D) (ITTO 2006, pp. 218–219, 222; Matallana-T 2005, pp. 121–122). The brown-banded antpitta ranges in multiple Departments (currently known in Risaralda, Caldas, and Tolima), all of which are administered by different autonomous corporations. Habitat destruction, the primary threat to the brown-banded antpitta, is ongoing throughout the species' range (Factor A). The lack of a national conservation strategy for the brown-banded antpitta, combined with decentralized natural resource management in Colombia, may hamper conservation of the brown-banded antpitta. The existing laws and the decentralized nature of forestry management are ineffective at protecting the brown-banded antpitta and its habitat even within protected areas (Brooks and Gonzalez-Garcia 2001, p. 183).

Colombia has several categories of national habitat protection (Matallana-T 2005, pp. 121–122), which were described above, as part of the Factor D analysis for the blue-billed curassow (Matallana-T 2005, pp. 121–122). Of the four areas identified as refugia for the brown-banded antpitta, two are considered protected areas under Colombian law: (1) The Ucumarí Regional Park and (2) Reserva del Cañon del Quindío.

(1) The Ucumarí Regional Park (Risaralda Department) is managed by the Corporación Autónoma Regional de Risaralda (CARDER) (BLI 2008a, p. 3), with the primary goals of conservation and ecotourism. The Park is managed for multiple uses, including agriculture and cattle grazing (BLI 2008a, p. 1), and includes recreation and commercial areas for activities such as camping and freshwater fishing (CARDER 1995, pp. 3–4). According to the management plan for the Park that was instituted in 1995, recreational and commercial activities are permitted only when they do not significantly alter the environment (CARDER 1995, pp. 3–4). However, according to BirdLife International (2008a, p. 3), there has been little in the way of conservation planning, and the habitat within the protected area continues to undergo pressures from agricultural expansion, firewood collection, and selective cutting. Consequently, the threat from habitat destruction (Factor A) is not reduced or ameliorated.

(2) Reserva del Cañon del Quindío (Quindío Department) is managed by the Corporación Autónoma Regional del Quindío (2008, p. 1). According to the management plan for the Department of Quindío (*www.crq.gov.co/documentos/PAT_CRQ_2007_2009.pdf*), between 2007 and 2009, forestry planning commenced for the entire Department with the goal of completing forest plans for four different areas within the Department by the end of 2009. However we are unaware of any information indicating that this planning process has been completed, or what protections may exist for brown-banded antpitta habitat within this Reserve. Moreover, as discussed under Factor A, although this Reserve contains suitable habitat for the brown-banded antpitta (Beltrán and Kattan 2002, p. 328), there are no known populations of the brown-banded antpitta within this Reserve (Beltrán and Kattan 2002, p. 325; Collar *et al.* 1992, p. 698). Therefore, the threat from habitat destruction (Factor A) is not reduced or ameliorated within this area.

Summary of Factor D

Colombia has numerous laws and regulatory mechanisms to administer and manage wildlife and their habitats. The brown-banded antpitta is listed as endangered under Colombian law and lives within forested or protected areas that are regulated by law. However, on-the-ground enforcement of existing wildlife protection and forestry laws and oversight of the local jurisdictions implementing and regulating activities are ineffective at mitigating the primary threat to the brown-banded antpitta. As discussed for Factor A, habitat destruction, degradation, and fragmentation continue throughout the existing range of the brown-banded antpitta. Under Colombian law, there are two protected areas containing suitable habitat for the brown-banded antpitta. The species is known to occur in only one of these areas, wherein resources are managed for commercial and recreational uses. Conservation planning within both areas is lacking, so that the existence of these protected areas does not mitigate the threat of habitat loss. Therefore, we find that the existing regulatory mechanisms currently in place are inadequate to mitigate the primary threats to the brown-banded antpitta.

Factor E: Other Natural or Manmade Factors Affecting the Continued Existence of the Species

Two additional factors affect the brown-banded antpitta: Its likelihood to disperse and small population size.

Likelihood To Disperse

The brown-banded antpitta exhibits several characteristics indicative of its vulnerability to local extirpation and inability to recolonize previously inhabited locations, despite the presence of suitable habitat. This ground-dwelling species (Beltrán and Kattan 2002, p. 327) has a high territorial fidelity and, although dispersal capabilities are not well-known (Cuervo 2002, p. 327), except those in the banding study by Kattan and Beltrán (2002, p. 234), the farthest known distance traveled by any one individual bird was 0.041 km^2 (0.02 mi^2). This suggests that the brown-banded antpitta is unable to repopulate an isolated patch of suitable habitat following decline or local extirpation of that patch (Cuervo and Salaman 1999, p. 7; Hanski 1998, pp. 45–46). The local extirpation of this species from its type locality in Laguneta, Quindío (Beltrán and Kattan 2002, p. 327), and the lack of recolonization despite the existence of suitable habitat in the Cañon del Quindío Reserve, support the hypothesis that the species may be incapable of dispersing to suitable habitat fragments without human intervention. To the best of our knowledge, there are no recovery or

reintroduction programs in place for this species.

Small Population Size

There have been few quantitative studies of brown-banded antpitta populations. A total of 48 individuals have been directly observed at 2 locations (Ucumarí Regional Park and Río Toche) (Cuervo *in litt.,* as cited in Beltrán 2002 p. 326; Kattan and Beltrán 2002, pp. 232–233; Kattan and Beltrán 1999, p. 276; Kattan and Beltrán 1997, pp. 367–369), 30 have been inferred at 1 location (Río Blanco) (Beltrán and Kattan 2002, p. 326), and up to 106 have been predicted to occur in 1 subpopulation within the brown-banded antpitta's current range (Ucumarí Regional Park) (Kattan and Beltrán 2002, pp. 232–233; Kattan and Beltrán 1999, p. 276; Kattan and Beltrán 1997, pp. 367–369). From work at Ucumarí Regional Park, Kattan and Beltrán (Kattan and Beltrán 1999, p. 276; Kattan and Beltrán 1997, pp. 367–369) predicted a population density of approximately 1.3 individuals per .01 km^2 (0.004 mi^2).

The IUCN has estimated the brown-banded antpitta's total population size to be more than 250 and fewer than 999 adult individuals in a 300-km^2 (116-mi^2) area (BLI 2007f, p. 1). However, this is a categorical approximation based on the following extrapolation: An expected average of 2.5 to 5.6 individuals per square kilometer multiplied by 45 percent of the extent of occurrence (300 km^2) (116 mi^2) (BLI 2007f, p. 1), leading to estimated population numbers between 338 and 756 individuals (BLI 2007f, p. 4). While this density is well within Kattan and Beltrán's (Kattan and Beltrán 1999, p. 276; Kattan and Beltrán 1997, pp. 367–369) predicted population density of 1.3 individuals per .01 km^2 (116 mi^2), it should be noted that extrapolating population sizes based on the availability of suitable habitat may result in an overestimate for the brown-banded antpitta for several reasons: (1) The species may not be randomly distributed within the given habitat; (2) extrapolation does not take into account human-induced threats, such as disturbance or hunting; and (3) not all individuals within the population are breeding at any one time, so that the actual number of individuals contributing to population growth will be a smaller number than the total number of individuals.

In a review by Jetz *et al.* (2008, p. 110) of 1,158 well-studied bird species in Australia, North America, and southern Africa, Jetz *et al.* (2008, p. 115) found that most species occurred in only 40–70 percent of the predicted range. They further noted that narrow-ranging species, such as the brown-banded antpitta, are particularly subject to population size overestimation, because they are unlikely to be randomly distributed within the habitat (Jetz *et al.* 2008, p. 116). Moreover, at-risk species, existing in declining, fragmented populations (as is the case for the brown-banded antpitta), are often absent from suitable but suboptimal habitat, thus exacerbating range overestimates (Jetz *et al.* 2008, p. 115). For instance, although suitable habitat exists in the species' type locality (Laguneta) in the Cañon del Quindío Reserve, the species has not been observed there since 1942 and is considered extirpated from this locality (Beltrán and Kattan 2002, p. 327; Collar *et al.* 1992, p. 698). Thus, the species appears to be incapable of repopulating suitable habitat on its own accord (Jetz *et al.* 2008, p. 115; Beltrán and Kattan 2002, p. 328) and the existence of suitable habitat does not connote the presence of the species.

This conclusion is supported by Beltrán and Kattan (2002, p. 328), who noted that, out of a potential habitat of 855 km^2 (330 mi^2), the species did not occupy two of the seven historical localities, prompting them to reduce the estimated area of occupancy to no more than 500 km^2. Thus, ground-truthing is essential to accurate population-size estimations. The IUCN is reviewing this situation to improve upon conservation assessments (Jetz *et al.* 2008, p. 117), and although it may be an overestimate, the figure ranging from 338 to 756 individuals represents the best information on population size.

Based on genetic considerations, in the absence of quantitative studies specific to this species, a generally accepted approximation of minimum viable population size is described by the 50/500 rule (Shaffer 1981, p. 133; Soulé 1980, pp. 160–162). According to this rule, the minimum viable population size is defined as the minimum number of individuals that is sufficient to respond over time to unexpected environmental conditions within the species' habitat (Shaffer 1981, pp. 132–133; Soulé 1980, pp. 160–162). This rule states that an effective population size (N_e) of 50 individuals is the minimum size required to avoid imminent risks from inbreeding. N_e represents the number of animals in a population that actually contribute to reproduction, and is often much smaller than the census, or total number of individuals in the population (N). Furthermore, the rule states that the long-term fitness of a population requires a N_e of at least 500 individuals, so that it will not lose its genetic diversity over time and will maintain an enhanced capacity to adapt to changing conditions. Therefore, an analysis of the fitness of this population would be a good indicator of the species' overall survivability. The available information for 2007 indicates that the total global population of the brown-banded antpitta may range between 338 and 756 individuals (BLI 2007f, p. 4); 338 is above the minimum effective population size required to avoid risks from inbreeding (N_e = 50), and 756 is above the upper threshold for long-term fitness (N_e = 500).

Given that the global population size is a qualitative assessment that may be an overestimate, that the actual number of breeding pairs is unknown but smaller than this number, and that the species exists in subpopulations that are unlikely to disperse into other locations, it is beneficial to analyze the fitness of the subpopulations that have been quantitatively assessed. The best-studied subpopulation is located within the Ucumarí Regional Park. A total of 47 individuals have been directly observed, and researchers estimate that the area may support as many as 106 individuals (Kattan and Beltrán 2002, pp. 232–233; Kattan and Beltrán 1999, p. 276; Kattan and Beltrán 1997, pp. 367–369). Forty-seven is just below the minimum effective population size required to avoid risks from inbreeding (N_e = 50 individuals). Moreover, the upper estimate of 106 individuals (not all of which will be reproducing) is approximately one-fifth of the upper threshold (N_e = 500 individuals) required for long-term fitness of a population that will not lose its genetic diversity over time and will maintain an enhanced capacity to adapt to changing conditions. Therefore, we currently consider the species to be at risk due to the lack of near- and long-term viability.

Small population sizes render species vulnerable to genetic risks that can have individual or population-level consequences on the genetic level and can increase the species' susceptibility to demographic problems, as explained in more detail above for the blue-billed curassow (Factor E, Small Population Size) (Charlesworth and Charlesworth 1987, p. 238; Shaffer 1981, p. 131). Once a population is reduced below a certain number of individuals, it tends to rapidly decline toward extinction (Holsinger 2000, pp. 64–65; Soulé 1987, p. 181; Gilpin and Soulé 1986, p. 25; Franklin 1980, pp. 147–148).

The brown-banded antpitta's restricted range, combined with its small population size (Cuervo 2002, p. 138; Cuervo and Salaman 1999, p. 7; del

Hoyo 1994, p. 361) and low prospect for dispersal (BLI 2004c, p. 2; Beltrán and Kattan 2002, p. 326; Kattan and Beltrán 2002, p. 238; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361; Kattan and Beltrán 1997, pp. 369–370; Kattan and Beltrán 1999, p. 273) makes the species particularly vulnerable to the threat of adverse natural (e.g., genetic, demographic, or stochastic) and manmade (e.g., habitat alteration and destruction) events that destroy individuals and their habitats (Brooks and Gonzalez-Garcia 2001, pp. 185–190; Holsinger 2000, pp. 64–65; Young and Clarke 2000, pp. 361–366; Primack 1998, pp. 279–308;).

Summary of Factor E

The brown-banded antpitta's small population size increases its vulnerability to genetic risks associated with small population sizes that negatively impact the species' long-term viability and increase the possibility of localized extirpations of the remaining fragmented populations. Further, the species is unlikely to repopulate areas of suitable habitat from which it has been locally extirpated because it exhibits high territorial fidelity and has never repopulated suitable existing habitat within the Department of Quindío, where the species' type locality (Laguneta) is located and the species has not been observed since 1942. Consequently, we believe that, in combination with the risks to the species from habitat destruction (Factor A) and predation (Factor C), the brown-banded antpitta is vulnerable to localized extirpation or extinction from which the species would be unable to recover, due to its small population size and apparent inability to repopulate fragmented, isolated habitats such as that currently present within this species' range.

Brown-Banded Antpitta Status Determination

The four primary factors that threaten the survival of the brown-banded antpitta are: (1) Habitat destruction, fragmentation, and degradation (Factor A); (2) predation (Factor C); (3) inadequacy of regulatory mechanisms to reduce the threats to the species (Factor D); and (4) small population size and isolation of remaining populations (Factor E).

The direct loss of habitat through widespread deforestation and conversion of primary forests to human settlement and agricultural uses has led to the fragmentation of habitat throughout the range of the brown-banded antpitta and isolation of the remaining populations. The species has been locally extirpated in its type locality and has experienced a 55 percent reduction of suitable habitat, and its range is estimated to be 300 km^2 (116 mi^2).

Brown-banded antpittas are vulnerable to predation by mountain coatis, tayras, squirrel cuckoos, and crimson-rumped toucanets (Factor C). Habitat fragmentation (Factor A) contributes to this vulnerability, because research indicates that predation increases with increased habitat fragmentation and smaller patch sizes. Predation leads to the direct removal of eggs, juveniles, and adults from the population, exacerbating risks associated with the species' small population size and the risk of local extirpation (Factor E). Brown-banded antpittas, as with other antpittas, produce a low clutch size (see Habitat and Life History), and predation can destroy pair bonds and remove potentially reproductive adults from the breeding pool.

The threats from habitat destruction (Factor A) and predation (Factor C) are compounded by the species' small population size (Factor E). The brown-banded antpitta has undergone a population decline that is closely associated with a reduction in range caused by habitat destruction (Factor A). The brown-banded antpitta's small population size of between 338 and 756 individuals is likely to be an overestimate based on the fact that population sizes for narrow-ranging species are typically overestimated when based on extent of occurrence. The species' subpopulations, one of which is estimated to include only 46 to 106 individuals, are isolated from each other. The species' confirmed absence from suitable habitat within its historic range, combined with the species' high territorial fidelity, suggests that the species is incapable of repopulating suitable habitat without human intervention. We are unaware of any reintroduction or recovery programs for this species. The species' small population size increases its vulnerability to natural and human factors (e.g., genetic isolation, agricultural development, increased human settlement, and road development) that could lead to local extirpation, which the species has already experienced in its type locality due to habitat destruction. Within the last three generations, or 10 years, the brown-banded antpitta has undergone up to a 9 percent reduction in population size and, at the current level of habitat destruction, this rate of decline is projected to continue over the next 10 years. Below a certain number, species' populations are unable to recover and, given the small number and isolated nature of existing brown-banded antpitta populations, such reductions in numbers could lead to extinction of the brown-banded antpitta.

Although Colombia has adopted numerous laws and regulatory mechanisms to administer and manage wildlife and their habitats, on-the-ground enforcement of these laws and oversight of the local jurisdictions implementing and regulating activities are inadequate to address the primary threat to this species, which is habitat loss (Factor A). Several populations of brown-banded antpitta are within sanctuaries or preserves; however, habitat destruction and hunting continues within these areas, and regulations are not uniformly enforced, monitoring is limited, and management plans are not developed or implemented, resulting in ineffective protective measures for conservation of the species.

We have carefully assessed the best available scientific and commercial information regarding the past, present, and potential future threats faced by the brown-banded antpitta. We consider the ongoing threats to the brown-banded antpitta, habitat destruction (Factor A) and predation (Factor C), exacerbated by the species' small population size and limited dispersal ability (Factor E), and compounded by inadequate regulatory mechanisms to mitigate these threats (Factor D), to be equally present and of the same magnitude throughout the species' entire current range. Based on this information, we find that the brown-banded antpitta is in danger of extinction throughout all of its range.

Cauca Guan (Penelope perspicax) Biology and Distribution

Species Description

The Cauca guan, a member of the Cracid family, is endemic to the central and western slopes of the Andes of Colombia (Delacour and Amadon 2004, pp. 133–135; Brooks and Strahl 2000, p. 13; Hilty and Brown 1986, p. 125). It is a large bird, measuring approximately 76 cm (30 in) in length (Hilty and Brown 1986, p. 125). The species is locally known as ''Pava Caucana'' (Rios *et al.* 2006, p. 17; Renjifo 2002, p. 124). The Cauca guan is described as a ''drab'' brown-gray, with a chestnut-colored rear part and tail, and a bright red dewlap (a flap of skin hanging beneath its lower jaw) (BLI 2007h, p. 1).

Taxonomy

The Cauca guan was first taxonomically described by Bangs in

1911 and placed in the Cracidae family (BLI 2007h, p. 1).

Habitat and Life History

The Cauca guan has been observed in mature tropical humid forests and in fragmented secondary forests, forest edges, and plantations of the exotic Chinese ash (*Fraxinus chinensis*) trees that are located within 1 km (0.62 mi) of primary forest (Kattan *et al.* 2006, p. 299; Rios *et al.* 2006, pp. 17–18; Renjifo 2002, p. 127). Older reports indicate that the species once inhabited dry forests in the Cauca, Patía, and Dagua River valleys (Renjifo 2002, p. 126). The Cauca guan requires large territories for foraging (Kattan 2004, p. 11), but today is relegated mostly to small forest fragments (Kattan *et al.* 2006, p. 301). This species, as with other guans, tends to aggregate within its habitat, generally based on resource availability. For instance, Cauca guans tend to congregate around fruit trees at certain times of year. Thus, depending on the time of year, improper sampling might tend to overestimate or underestimate the population (Kattan *et al.* 2006, p. 305). Cauca guans are reportedly timid in the presence of humans (Rios *et al.* 2006, p. 21).

Cauca guans feed mostly on fruit and leaves (including those of the nonnative Chinese ash trees) and occasionally on invertebrates and flowers (Muñoz *et al.* 2006, p. 49; Rios *et al.* 2006, pp. 17–18; Renjifo 2002, p. 127). Although primarily terrestrial, the species is occasionally found in the upper stories of forests obtaining food. Because fruit availability within a forest is spatially and temporally variable, guans must undergo regional movements in pursuit of fruiting plants. The species is usually found singly, in pairs, or in groups of up to six individuals. The largest recorded gathering of Cauca guans was 30 individuals (Rios *et al.* 2006, p. 16). There are two breeding seasons coinciding with the rainy seasons, one at the beginning of the year and another in August (Rios *et al.* 2006, p. 17). Nests are circular cups made of leaves and small branches (Renjifo 2002, p. 127), and the typical clutch size is two eggs, which is considered low. Guans remain paired during the breeding period and until chicks are 1 year in age; this is considered a long fledging period (Rios *et al.* 2006, p. 17). Cracids are also slow to reproduce, with a replacement rate of at least 6 years (Silva and Strahl 1991, p. 50).

Historical Range and Distribution

The Cauca guan's historical distribution included the east slopes of the West Andes and the Cauca, Patía, and Dagua Valleys, in the Departments of Cauca, Quindío, Risaralda, and Valle de Cauca. The historic range is estimated to have been approximately 24,900 km² (9,614 mi²) (Renjifo 2002, p. 128). In the early part of the 20th Century, the Cauca guan inhabited the dry forests of the Cauca, Dagua, and Patía Valleys (Renjifo 2002, p. 128). The Cauca Valley lies between the central and western Andes and spans the Departments of Cauca, Valle de Cauca, Quindío, and Risaralda (WWF 2001a, p. 1). The Dagua Valley lies on the Pacific side of the western Andes, in Valle de Cauca; it is described as an isolated valley of dry forest that changes in elevation from 400 to 2,000 m (1,312 to 6,562 ft) and is surrounded at upper elevations by humid forest to the west and cloud forest to the north, south, and east (Silva 2003, p. 4). The Patía Valley lies between the central and western Andes in the Department of Cauca, in southwestern Colombia; it has a mean altitude of 600–900 m (1,969–2,953 ft) (WWF 2001c, p. 1). This area was once covered in wetlands, humid forests, and dry forests. Today, most of the dry forests have been eliminated and highly fragmented, such that continuous forest exists only above 2,000 m (6,562 ft) (Renjifo 2002, p. 128).

From the beginning of the 20th Century through the 1950s, the species was considered common (BLI 2007h, p. 1; Renjifo 2002, p. 126). Between the 1970s and 1980s, there was extensive deforestation in the Cauca Valley, and the species went unobserved during this time, leading researchers to suspect that the Cauca guan was either extinct or on the verge of extinction (Brooks and Strahl 2000, p. 14; del Hoyo 1994, pp. 337, 349; Hilty and Brown 1986, p. 125; Hilty 1985, p. 1,004). The species was rediscovered in 1987 (Renjifo 2002, p. 124).

Current Range and Distribution

Today, the Cauca guan inhabits the eastern and western slopes of the West and Central Andes Mountain ranges, in the Departments of Cauca, Quindío, Risaralda, and Valle de Cauca (BLI 2007h, p. 1; Kattan *et al.* 2006, pp. 299, 301; Renjifo 2002, pp. 124–126). Since 1987, most observations of this species have been at elevations ranging from 1,400 to 2,000 m (4,593 to 6,562 ft) (Renjifo 2002, pp. 124–125), with an occasional sighting at altitudes well below (i.e., 816 m (2,677 ft)) or well above (i.e., 2,690 m (8,825 ft)) this altitudinal range (Muñoz *et al.* 2006, p. 54; Rios *et al.* 2006, p. 17; Renjifo 2002, pp. 124–125). The Ucumarí Regional Park is considered the stronghold of the species (BLI 2007h, p. 1) (see Population Estimates).

The habitat consists primarily of forest fragments, and although continuous cover remains at elevations above 2,000 m (6,562 ft) (Kattan *et al.* 2006, p. 303), researchers have not ascertained whether the species inhabits these higher-altitude contiguous forest areas (Renjifo 2002, p. 129). The current range of the species totals less than 750 km² (290 mi²), of which only 560 km² (216 mi²) is considered suitable habitat (BLI 2007h, p. 1; Kattan *et al.* 2006, p. 299; Rios *et al.* 2006, p. 17).

Population Estimates

Cauca guan populations are characterized as small, ranging from only tens of individuals or, in rare instances, hundreds (Renjifo 2002, p. 12). BirdLife International reported that the largest subpopulation contained an estimated 50 to 249 individuals; however, they do not specify to which population this refers, and these figures are not found in any of the other literature regarding population surveys of the Cauca guan. Ucumarí Regional Park has been considered the stronghold of the species (BLI 2007h, p. 1). Sixteen individuals were counted in 1990, and the species was characterized as ''common'' in plantations in 1994–1995 (Wege and Long 1995, p. 141). Since then, there have been scant sightings of Cauca guan there (Renjifo 2002, p. 125; Wege and Long 1995, p. 141), including the observation of one individual in the Park in 2004 (Scanlon 2004, pp. 1–3). There have been no population surveys within the Park to determine the species' current population size therein.

Munchique National Natural Park (Cauca) is considered to be the most important locality for this species in the southern portion of its range because of the extensive remaining forest habitat, although habitat destruction is ongoing there (see Factor A). The species was last recorded in Munchique in 1987, but has not been confirmed there since (Kattan *et al.* 2006, p. 305; Muñoz *et al.* 2006, p. 54; Salaman *in litt.* 1999, 2000, as cited in BLI 2007h, p. 2).

Kattan *et al.* (2006, p. 302) conducted the only two population surveys in 2000 and 2001 (Muñoz *et al.* 2006 p. 55). They estimated population densities at two locations, Otún-Quimbaya Flora and Fauna Sanctuary (Risaralda) and Reserva Forestal de Yotoco (Valle de Cauca), to be 144–264 individuals and 35–61 individuals, respectively (Kattan *et al.* 2006, p. 304). Kattan *et al.* (2006, p. 302) also examined 10 additional localities, based on locality data reported by Renjifo (2002, pp. 124–125). Visual confirmations were made at only

2 of the 10 localities (Reserva La Sirena and Chorro de Plata, both in the Department of Valle de Cauca), where the extent and occurrence of the populations have yet to be determined (Kattan *et al.* 2006, p. 303). Auditory confirmations were made at 5 of the 10 localities, including: La Zulia, Chicoral, Las Brisas, San Antonio, and Planes de San Rafael (Kattan *et al.* 2006, p. 302).

In 2006, Kattan (*in litt.,* as cited in Muñoz *et al.* 2006 p. 55) estimated the global population to be between 196 and 342 individuals. The IUCN has placed the Cauca guan in the population category ranging from 250 to no more than 1,000 (BLI 2007h, pp. 1, 3). Overall, the population is considered to be in decline (BLI 2007h, p. 2; Kattan 2004, p. 6; Renjifo 2002, p. 129).

Conservation Status

The Cauca guan is listed as endangered under Colombian law (EcoLex 2002, p. 12). The IUCN categorizes the species as 'Endangered' due to its small, contracted range composed of widely fragmented patches of habitat (BLI 2004e, p. 1).

Summary of Factors Affecting the Cauca Guan

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Habitat or Range

Historically, Cauca guans were considered common (BLI 2007h, p. 1; Renjifo 2002, p. 126). They inhabited the eastern slopes of the west Andes and the dry forests of the Cauca, Dagua, and Patía Valleys, in the Departments of Cauca, Quindío, and Valle del Cauca (Renjifo 2002, p. 124) (see Historical Distribution, above), in a range extending over approximately 24,900 km² (9,614 mi²). Extensive habitat destruction and fragmentation since the 1950s has resulted in an estimated 95 percent range reduction (Chapman 1917, p. 195; Collar *et al.* 1992, p. 126; Kattan *et al.* 2006, p. 299; Renjifo 2002, pp. 126–127; Rios *et al.* 2006, p. 17). As a result, although it prefers mature tropical humid forests, the Cauca guan exists primarily in fragmented and isolated secondary forest remnants, forest edges, and in feral plantations of the exotic Chinese ash trees that are located within 1 km (0.62 mi) of primary forest (Kattan *et al.* 2006, p. 299; Renjifo 2002, p. 127; Rios *et al.* 2006, pp. 17–18). Its current range is estimated to be less than 750 km² (290 mi²), of which only 560 km² (216 mi²) is considered suitable habitat (BLI 2007h, p. 2; Kattan *et al.* 2006, p. 299; Rios *et al.* 2006, p. 17). It is estimated that more than 30 percent of this loss of habitat has occurred within the last three generations, or 30 years (Renjifo 2002, p. 129).

Deforestation

Colombia has experienced extensive deforestation in the last half of the 20th Century as a result of habitat conversion for human settlements, road building, agriculture, and timber extraction. A 23-year study, from 1973 to 1996, demonstrated that these activities reduced the amount of primary forest cover in Colombia by approximately 3,605 ha (8,908 ac) annually, representing a nearly one-third total loss of primary forest habitat (Viña *et al.* 2004, pp. 123–124). Beginning in the 1980s, habitat loss increased dramatically as a result of influxes of people settling in formerly pristine areas (Perz *et al.* 2005, pp. 26–28; Viña *et al.* 2004, p. 124). More recent studies indicate that the rate of habitat destruction is accelerating. During the period 1990–2005, Colombia lost approximately 52,800 ha (130,471 ac) of primary forest annually (Butler 2006a, pp. 1–3; FAO 2003a, p. 1). These studies and activities are described in greater detail under Factor A for the blue-billed curassow, above.

Human-induced deforestation and environmental degradation have caused the Cauca guan to shift its range and elevational distribution to the few remaining forest remnants. The Cauca guan was once considered to occur only on the eastern slopes of the West Andes and Cauca, Patía, and Dagua Valleys (Renjifo 2002, p. 128). Today, the species occurs on the western slopes of the central and western Andes of Colombia (BLI 2007h, p. 1; Kattan *et al.* 2006, p. 299; Delacour and Amadon 2004, p. 135; Renjifo 2002, p. 124). During the latter half of the 20th Century, much of the lower-elevation forests in the Río Cauca Valley, where the species was observed most often between 1937 and 1963, were deforested (Renjifo 2002, p. 124). Habitat destruction and alteration in the sub-Andean slopes around the Cauca, Dagua, and Patía Valleys has left only a few hundred hectares (100 hectares = 1 km² = 0.39 mi²) of isolated, small, fragmented forest remnants, and the Cauca guan is absent from most of these fragments (Renjifo 2002, p. 128). The species has been extirpated from the Cauca and Dagua Valleys, but may still exist in patches within the Patía Valley (Renjifo 2002, p. 128). Beginning in 1989, the species was observed several times in the Department of Risaralda, in an area and at elevations that were not part of the species' historic range, but represent the extreme fringe of its former range (Renjifo 2002, pp. 124–125).

Habitat destruction and alteration, in addition to shifting the species to the fringes of its former range, have caused the Cauca guan to shift in its altitudinal distribution (Cuervo and Salaman 1999, p. 8). Nearly all the forested habitat below 3,300 m (10,827 ft) in the Central Andes, where the Cauca guan occurs today, has been deforested and cleared for agricultural land use, such as pasture, coffee plantations, potatoes, and beans (BLI 2004c, p. 2). Approximately 85 percent of forested habitat at altitudes between 1,900 m (6,234 ft) and 3,200 m (10,499 ft) has been converted to other land uses (BLI 2004c, p. 2; Cuervo 2002, p. 327; Stattersfield *et al.* 1998, p. 205). By 1994, in Quindío, extensive deforestation at elevations between 1,800 and 2,600 m (5,905 and 8,530 ft) led to the destruction of much of the Cauca guan's preferred habitat of mature humid forests (Collar *et al.* 1994, p. 136). Prior to the species' rediscovery in 1987, its altitudinal range was between 1,300 and 2,100 m (4,265 and 6,890 ft) (del Hoyo 1994, p. 349; Hilty and Brown 1986, p. 125), with occasional sightings at lower elevations in the Patía Valley (between 642 and 650 m (2,106 and 2,133 ft) (Renjifo 2002, pp. 124–125; Hilty and Brown 1986, p. 125).

Since 1987, the Cauca guan has been observed only in the remaining and much-restricted forest remnants of the following Departments: Cauca (in the years 1987, 1989, and 1992), Quindío (1995–1997), Risaralda (1989, 1995–1997, 2000, 2001), and Valle de Cauca (1988, 1999, 2000) (Delacour and Amadon 2004, p. 135; Kattan *et al.* 2006, p. 299; Renjifo 2002, pp. 124–125). Renjifo (2002, pp. 124–125) provided detailed observation records indicating that reports since 1987 ranged in altitude between one sighting at 900 m (2,953 ft) in the Patía Valley in 1992, and the rest between 1,350 and 2,690 m (4,429 and 8,825 ft). In 2006, Muñoz *et al.* (2006, p. 54) reported the species' range as being between 1,200 and 2,600 m (3,937 and 8,530 ft), and Rios *et al.* (2006, p. 17) reported the species' range as 1,000–2,500 m (3,281–8,202 ft). These ranges are consistent with recent observations of the species. Kattan *et al.* (2006, pp. 299, 301) reported its range as 1,000–2,000 m (3,281–6,562 ft), noting that recent sightings at higher elevations demonstrated that the species has shifted its altitudinal range, as deforestation throughout much of Cauca, Dagua, and Patía Valley has left only isolated forest fragments remaining at elevations below 2,000 m (6,562 ft).

Although continuous cover remains in some locations above 2,000 m (6,562 ft) (Kattan *et al.* 2006, p. 303), researchers are uncertain whether the species inhabits these areas (Renjifo 2002, p. 129). The midmontane and cloud forests in the Department of Risaralda, where this species was observed as recently as the year 2000 (Renjifo 2002, p. 124), continue to undergo deforestation (Dolphijn 2005, p. 2). In Cauca, timber extraction and mining are ongoing (Urueña *et al.* 2006, p. 42). Deforestation and habitat alteration are ongoing throughout the Cauca guan's limited range of 560 km² (216 mi²).

Illegal Crops and Their Eradication

Cocaine and opium have been cultivated throughout the Cauca guan's range. The cultivation of illegal crops (including coca and opium) in Colombia destroys montane forests (Balslev 1993, p. 3). Coca production destroys the soil quality by causing the soil to become more acidic, which depletes the soil nutrients and ultimately impedes the regrowth of secondary forests in abandoned fields (Van Schoik and Schulberg 1993, p. 21). As of 2004, the estimated total amount of land under cultivation for cocaine equaled 80,000 ha (197,683 ac); 4,000 ha (9,884 ac) of land are under opium cultivation (UNODC *et al.* 2007, pp. 7–8). These figures include habitat within the Cauca guan's range. Between 2003 and 2004, cocaine cultivation areas decreased from 1,445 to 1,266 ha (3,571 to 3,128 ac) in Cauca, and increased 22 percent from 37 ha (91 ac) to 45 ha (111 ac) in Valle de Cauca (UNODC and GOC 2005, p. 15). At the same time, opium cultivation decreased in Cauca from 600 ha (1,483 ac) to 450 ha (1,112 ac) (UNODC 2005, p. 50).

Colombia continues to be the leading coca bush producer (UNODC *et al.* 2007, p. 7). However, since 2003, cocaine cultivation has remained stable at about 800 km² (309 mi²) of land under cultivation (UNODC *et al.* 2007, p. 8). This is attributed, in part, to the implementation of alternative development projects, which encourage people to pursue alternative vocations to planting illegal crops (UNODC *et al.* 2007, p. 77). In 2004, the United Nations Office on Drugs and Crime and the Government of Colombia reported that no coca had been cultivated in the Departments of Quindío and Risaralda since the year 2000 (UNODC and GOC 2005, p. 48). This was attributed to alternative development programs being implemented between 1999 and 2007, for which US$200,000 was provided to Quindío and US$800,000 to Risaralda (UNODC and GOC 2005, p. 48). During the same period, at least US$12.1 million was spent in alternative development programs in Cauca, where coca production decreased, and another 1.6 million was spent in Valle de Cauca, where coca production increased (UNODC and GOC 2005, p. 48).

This stabilization of the amount of land under cultivation for illegal drug crops is also attributed to heightened eradication efforts. Between 2002 and 2004, aerial spraying occurred over more than 1,300 km² (502 mi²) annually, peaking in 2004, when 1,360 km² (525 mi²) of illicit crops were sprayed (UNODC and GOC 2005, p. 11). In 2006, eradication efforts were undertaken on over 2,130 km² (822 mi²) of land, consisting of 1,720 km² (664 mi²) of land being sprayed and manual eradication being used on the remaining land. Eradication efforts undertaken in 2006 occurred over an area representing 2.7 times more land than the net cultivation area (UNODC *et al.* 2007, p. 8). In Cauca alone, 1,811 ha (4,475 ac) of coca fields and 435 ha (1,075 ac) of opium fields were sprayed or manually eradicated in 2004 (UNODC 2005, p. 66).

Drug eradication efforts in Colombia have further degraded and destroyed primary forest habitat by using nonspecific aerial herbicides to destroy illegal crops (BLI 2007d, p. 3; Álvarez 2005, p. 2,042; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12). Herbicide spraying has introduced harmful chemicals into Cauca guan habitat and has led to further destruction of the habitat by forcing illicit growers to move to new, previously untouched forested areas (Álvarez 2007, pp. 133–143; BLI 2007d, p. 3; Álvarez 2005, p. 2,042; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12; Álvarez 2002, pp. 1,088–1,093). Between 1998 and 2002, cultivation of illicit crops increased 21 percent each year, with a concomitant increase in deforestation of formerly pristine areas of approximately 60 percent (Álvarez 2002, pp. 1,088–1,093).

Effects of Habitat Fragmentation

The Cauca guan requires large territories for foraging (Kattan 2004, p. 11), but today is relegated mostly to small forest fragments (Kattan *et al.* 2006, p. 301), making it more susceptible to habitat disturbance, further fragmentation, and destruction from human activity (Brooks and Strahl 2000, p. 10; Silva and Strahl 1991, p. 38).

An analysis of the effects of habitat fragmentation on Andean birds within western Colombia established that 31 percent of the historical bird populations in western Colombia had become extinct or locally extirpated by 1990, largely as a result of habitat fragmentation from deforestation caused by human encroachment (Kattan and Álvarez-Lopez 1996, p. 5; Kattan *et al.* 1994, p. 141). Kattan and Álvarez-Lopez (1996, pp. 5–6) also identified two conditions that increase a species' vulnerability to extinction or local extirpation as a result of habitat fragmentation: (1) Species at the upper or lower limit of their altitudinal distribution (which is the case for the Cauca guan) are more susceptible to local extirpation and extinction, and (2) large fruit-eating birds with limited distributions and narrow habitat preferences were most vulnerable to extinction (also the case for the Cauca guan). Deforestation has eradicated the Cauca guan from much of its historic range and has led to local extirpation (Kattan *et al.* 2006, p. 299; Collar *et al.* 1994, pp. 61–62) in the Cauca and Dagua Valleys (Renjifo 2002, p. 128), such as in San Antonio (Valle de Cauca), where the species has not been observed since 1917 (Renjifo 2002, p. 124). Moreover, in light of the species' characteristics, the Cauca guan is unlikely to repopulate an isolated patch of suitable habitat following decline or local extirpation (see Factor E, Likelihood to Disperse).

The Cauca guan, as with other cracids, is susceptible to indirect effects of habitat disturbance and fragmentation (Brooks and Strahl 2000, p. 10; Silva and Strahl 1991, p. 38). A study conducted in northwestern Colombia demonstrated that habitat destruction and fragmentation may increase a species' vulnerability to predation (Arango-Vélez and Kattan 1997, pp. 140–142) (Factor C). In addition, habitat fragmentation, combined with continuing human encroachment, increases the species' vulnerability to hunting (Factor B). Habitat fragmentation may affect population densities by shifting the availability of resources, such as food (Kattan *et al.* 2006, p. 305). Habitat fragmentation also compounds problems for species with small population sizes, such as the Cauca guan, which has an estimated population between 196 and 342 individuals (Kattan *in litt.,* as cited in Muñoz *et al.* 2006 p. 55) (Factor E).

Refugia

The Cauca guan has recently been confirmed in the following locations: (1) Otún-Quimbaya Flora and Fauna Sanctuary; (2) Reserva La Sirena; (3) Reserva Forestal de Yotoco; (4) Chorro

de Plata; and (5) Munchique National Natural Park (Kattan *et al.* 2006, pp. 299, 305; Delacour and Amadon 2004, p. 135; Renjifo 2002, pp. 124–125). These locations are discussed below.

(1) Otún-Quimbaya Flora and Fauna Sanctuary (Department of Risaralda), a 4.9-km² (1.9-mi²) reserve in the Department of Risaralda, contains a habitat mosaic of old-growth fragments and regenerating secondary forests, including abandoned ash plantations that cover 0.18 km² (0.07 mi²) (Kattan *et al.* 2006, p. 303; CARDER 2000, p. 1; Kattan and Beltrán 1997, p. 369). Most of the forested habitat in the area was cleared in the 1960s for cattle ranching, leaving the remaining natural forests only on the steepest slopes (Kattan and Beltrán 1999, p. 273). In population surveys conducted by Kattan *et al.* (2006, p. 304) in 2000 and 2001, this subpopulation was estimated to include between 144 and 264 individuals. Kattan (2004, pp. 12–13) also advised that the Otún-Quimbaya Sanctuary was not large enough to provide the space and resources needed to sustain a viable Cauca guan population.

This Sanctuary is adjacent to the Ucumarí Regional Park (Kattan *et al.* 2006, p. 302), which covers an area of approximately 44 km² (17 mi²), with elevations ranging from 1,700 to 2,600 m (5,577 to 8,530 ft) (Kattan and Beltrán 1999, p. 273; Kattan *et al.* 2006, pp. 301–302). Ucumarí Regional Park has been considered the stronghold of the species since the late 1990s (BLI 2007h, p. 1) (see Population Estimates, above). The largest number of Cauca guan individuals observed at this site was 16 in 1990 (Wege and Long 1995, p. 141), and a single individual was sighted in 2004 (Scanlon 2004, pp. 1–3); however, there have been no population surveys within the Park to determine the current population size. Subsistence hunting was reportedly prevalent within the Park in the late 1990s (Strahl *et al.* 1995, p. 81; del Hoyo 1994, p. 349; Collar *et al.* 1992, p. 60) (Factors B and D).

(2) Reserva La Sirena (Valle de Cauca) is located above 2,000 m (6,562 ft) and consists of fragmented riparian forest in various stages of succession (Kattan *et al.* 2006, pp. 302–303). Reserva La Sirena has an environmental education center, around which are located some protected areas as well as continuous forest above 2,000 m (6,562 ft). Visual confirmation of the Cauca guan was made in this locality in surveys conducted in 2000 and 2001, but the extent and occurrence of the population have yet to be determined (Kattan *et al.* 2006, p. 303).

(3) Reserva Forestal de Yotoco (Valle de Cauca) is an isolated 5.6-km² (2.16-mi²) reserve on the eastern slopes of the Western Andes, ranging in altitude from 1,400 to 1,600 m (4,593 to 5,249 ft) (Kattan *et al.* 2006, p. 302). In population surveys conducted by Kattan *et al.* (2006, p. 304) in 2000 and 2001, this subpopulation was estimated to include between 35 and 61 individuals. One of the last remaining humid tropical forests in the Valle de Cauca, the forest is mostly well-conserved, but human impacts are evidenced by an asphalt highway running through the middle of the Reserve and numerous footpaths crossing the Reserve to connect to coffee plantations, which, along with pasturelands, surround the forest (BLI 2007h, p. 13).

(4) Chorro de Plata (Valle de Cauca) is a 2-km² (0.77-mi²) forest located at 1,200 m (3,937 ft) (Kattan *et al.* 2006, p. 299; Renjifo 2002, p. 302). Visual confirmation of the Cauca guan was made in this locality in surveys conducted in 2000 and 2001, but the extent and occurrence of the population have yet to be determined (Kattan *et al.* 2006, p. 303).

(5) Munchique National Natural Park (Cauca) is considered an important locality in the southern portion of the species' range, because the species was historically seen there several times and because suitable habitat still exists there (Kattan *et al.* 2006, pp. 305–306). However, the Cauca guan has not been confirmed there since 1987 (Kattan *et al.* 2006, p. 305; Muñoz *et al.* 2006, p. 54; Salaman *in litt.* 1999, 2000, as cited in BLI 2007h, p. 2) (see Population Estimates, above). Moreover, the location of this park within the Pacific Region makes it particularly accessible and vulnerable to exploitation because of the numerous rivers in this part of the country, which facilitate movement of people and products through the region (Ojeda *et al.* 2001, pp. 308–309). In the 1960s and 1970s, the harvest of native ''naranjilla'' or ''lulo'' fruits (*Solanum quitoense*) became an important part of the local economy, which deterred logging. However, logging resumed in the 1980s after a fungal pathogen—anthracnose (*Colletotrichum acutatum*) (Caicedo and Higuera 2007, p. 41)—and invasion by a lepidopteran pest—tomato fruit borer (*Neoleucinodes elegantalis*) (Eiras and Blackmer 2003, p. 1)—destroyed the crops (BLI 2006, p. 2). Human pressures in the Pacific Region include unsustainable logging, colonization, and cash crop cultivation (Ojeda *et al.* 2001, pp. 308–309). Efforts are underway to replant lulo fruit trees to encourage a sustainable local economy, enhance local involvement in conservation, and provide technical skills for integrated pest management. However, logging is ongoing within the park, and human population pressures and associated deforestation, as well as dam construction, are ongoing in the area (BLI 2007h, p. 2).

There are several areas of suitable habitat in which the Cauca guan has not been observed, but that could serve as important potential habitat for the species (see Factor E, Likelihood to Disperse), including: (1) Bosques del Oriente del Risaralda, (2) Cañon del Rio Barbas y Bremen, (3) Finca la Betulia Reserva la Patasola,and (4) Reserva Natural Cajibío. These areas are described below.

(1) Bosques del Oriente del Risaralda (Risaralda): This 23-km² (8.9-mi²) forest is located on the western slopes of the Central Andes, in eastern Risaralda. It ranges in altitude between 1,300 and 3,800 m (5,905 and 12,467 ft). This high-altitude forest is important for the hydrology in lower-elevation areas, including the Otún-Quimbaya Flora and Fauna Sanctuary (Department of Risaralda), where the Cauca guan has been observed. The forest has been recovering from deforestation for the past 30 years and includes a contiguous patch of montane and premontane forest over 85 percent of the area. About 15 percent of the land is zoned for grazing and agriculture, leading to ongoing degradation of these deforested areas, along with conversion for human settlements within the forest (BLI 2007h, p. 6).

(2) Cañon del Rio Barbas y Bremen (Risaralda): This 51-km² (20-mi²) forest is located on the western slopes of the Central Andes. It ranges in altitude between 1,600 and 2,100 m (5,249 and 6,890 ft). This area includes most of the Reserva Forestal Bremen (BLI 2007h, p. 9), where the Cauca guan was observed several times between 1995 and 1997 (Renjifo 2002, pp. 124–125). The Bremen Forest Reserve was established in the 1970s to protect important waterways and is protected within the regional system of protected areas in the coffee-growing region. Today, the Bremen forest comprises 3.4 km² (1.31 mi²) of natural forest and 4.2 km² (1.62 mi²) of exotic plantation forests, which are now being allowed to regenerate to natural forest. A sustainable forestry management plan was implemented in 1996, and plans are underway to connect the isolated forest patches within the Cañon. Currently, the forest patches within the Cañon del Rio Barbas y Bremen are surrounded by cattle ranches and tree plantations, primarily including eucalyptus (*Eucalyptus* spp.) and Mexican weeping pine (*Pinus patula*). There is no further information on the progress of this project.

Currently, the forests located within the Cañon are isolated from each other, and urbanization, agricultural activities, and deforestation are ongoing within the area. The forest is also in close proximity to a main highway in the region—the highway between Armenia and Pereira. A survey of the Cañon in 2003 did not reconfirm the presence of the Cauca guan within this area (BLI 2007h, p. 9).

(3) Finca la Betulia Reserva la Patasola (Quindío): This 17-km² (7-mi²) forest is located on the western slopes of the Central Andes. It ranges in altitude between 2,050 and 2,600 m (6,726 and 8,530 ft). Most of this Reserve is covered by primary forest interspersed with scrub forest and streams. As of 2003, the Cauca guan has been reported but not confirmed within this Reserve. The western border of this Reserve abuts the Otún-Quimbaya Flora and Fauna Sanctuary (BLI 2007h, p. 12), where the population is estimated to be between 144 and 264 individuals (Kattan *et al.* 2006, p. 304).

(4) Reserva Natural Cajibío (Cauca): This 0.52-km² (0.2-mi²) reserve is located on the slopes of the West Andes. It ranges in altitude between 1,100 and 1,250 m (3,609 and 4,101 ft). The habitat is mainly secondary forest, interspersed with agricultural fields (sugarcane (*Saccharum officinarum*), coffee, bananas, and corn (*Zea mays*)) and cattle ranching. This Reserve has been altered by human encroachment and indiscriminate logging. The Cauca guan was not confirmed in this location in a 2003 survey (BLI 2007h, p. 15).

These refugia are limited in size, isolated from each other, and undergoing varying levels of human encroachment and deforestation (Kattan *et al.* 2006, p. 301; Renjifo 2002, p. 128; Brooks and Strahl 2000, pp. 13–14; Collar *et al.* 1994, pp. 61–62; del Hoyo 1994, pp. 337, 349). In addition, regulatory mechanisms within these areas are inadequate to protect the species from ongoing habitat destruction (Factor D).

Summary of Factor A

The habitat preferred by the Cauca guan—humid forests or secondary forests, forest edges, and plantations in proximity to humid forests—has been largely destroyed by cultivation, grazing, human settlements, road building, and other human activities. The species' range has been reduced from 24,900 km² (9,614 mi²) to approximately 560 km² (216 mi²), much of this within the past 30 years. Habitat fragmentation has isolated remaining populations, relegated the species to the edges of its former range, and led to a shift in the species' altitudinal range. Habitat destruction, alteration, conversion, and fragmentation have been factors in the Cauca guan's historical decline (which commenced in the second half of the 20th Century) and continue to be factors in the species' decline, even in areas designated as protected (see also Factor E). Therefore, we find that the present destruction, modification, and curtailment of habitat are a threat to the Cauca guan throughout all of its range.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Cracids are considered particularly vulnerable to hunting pressures and are among those species most rapidly depleted by hunting (Redford 1992, p. 419). Several factors contribute to the sensitivity of Cauca guans to hunting, including: their large size, ease of locating them during their breeding season, their trusting nature, their low productivity (1–2 eggs) relative to other Galliformes, their long generation time, their dependence upon specific habitat, and their poor dispersal qualities (Brooks 1999, p. 43; del Hoyo 1994, p. 336; Silva and Strahl 1991, p. 38). This species, as with other guans, tends to aggregate within its habitat, generally based on resource availability. For instance, Cauca guans tend to congregate around fruit trees at certain times of year (Kattan *et al.* 2006, p. 305). This aggregation of individuals may facilitate hunters in catching larger numbers of the species. Cracids are also slow to reproduce, with a replacement rate of at least 6 years (Silva and Strahl 1991, p. 50).

Cauca guans, and other cracids (e.g., chachalacas (*Ortalis* sp.), serve as major sources of protein for indigenous people (Brooks and Strahl 2000, p. 8). The Cauca guan is hunted by local residents for sustenance, although this activity is illegal (Muñoz *et al.* 2006, p. 50; Rios *et al.* 2006, pp. 22–23; Renjifo 2002, p. 128; del Hoyo 1994, p. 337) (Factor D). The species is sought after by hunters because it is the largest bird in its area of distribution (Renjifo 2002, p. 128). Rios *et al.* (2006, pp. 22–23) interviewed local settlers near the Otún-Quimbaya Flora and Fauna Sanctuary (in Risaralda), where the population is estimated to be between 144 and 264 individuals (Kattan *et al.* 2006, p. 304), who admitted to hunting the Cauca guan within the Sanctuary, claiming to take between 2 and 4 birds per month. This equates to approximately 100 Cauca guans per year (Rios *et al.* 2006, p. 23).

Subsistence hunting may play a role in the decline or possible local extirpation of the species from at least two locations. In the late 1990s, subsistence hunting was widespread in the Ucumarí Regional Park and Munchique National Natural Park (Strahl *et al.* 1995, p. 81; del Hoyo 1994, p. 349; Collar *et al.* 1992, p. 60). The Cauca guan may have been locally extirpated from the Munchique National Natural Park (Cauca) (BLI 2007h, p. 2: Renjifo 2002, p. 124), where the species was last observed in 1987 (Renjifo 2002, p. 124). Despite subsequent searches of the area (Wege and Long 1995, p. 149), there have been no recent confirmations at this locality (Kattan *et al.* 2006, p. 305; Muñoz *et al.* 2006, p. 54; Salaman *in litt.* 1999, 2000, as cited in BLI 2007h, p. 2). Ucumarí Regional Park is considered the stronghold of the Cauca guan (BLI 2007h, p. 1). Although Renjifo (2002, p. 128) notes that the species has recovered within this Park, there have only been scant reports of Cauca guan sightings there between 1994 and 2004 (Scanlon 2004, pp. 1–3; Renjifo 2002, p. 125; Wege and Long 1995, p. 141), and no population surveys have been undertaken there (see Population Estimates, above).

Habitat fragmentation and concomitant human encroachment (Factor A) have made the species' habitat more accessible and the species more vulnerable to hunting. A study conducted in French Guiana provided a quantitative estimate of the effect of hunting on a related cracid species, the black curassow (*Crax alector*) (del Hoyo 1994, p. 336). The black curassow has similar habitat requirements (undisturbed primary tropical to subtropical humid forest at 0–1,400 m (0–4,600 ft) elevation) as the Cauca guan (BLI 2007e). The estimated population density of black curassows in nonhunted areas was between 7 and 9 birds per 1 km² (0.4 mi²); in areas with intermittent hunting, the numbers fell to between 0.5 and 2.25 birds; and in areas where hunting was regular, numbers fell to between 0.5 and 0.73 birds (del Hoyo 1994, p. 336). We believe that the effects of hunting on the Cauca guan would result in similar population declines based on similarities of habitat and species characteristics.

Summary of Factor B

Cracids serve as a major food source in Colombia, and the Cauca guan, as the largest cracid living within its area of distribution, is sought after by locals. Hunting results in the direct removal of eggs, juveniles, and adults from the population. Cauca guans are slow to reproduce, produce a low clutch size,

require a long fledging period, and exhibit a poor replacement rate (see Habitat and Life History, above). Hunting can destroy pair bonds and remove potentially reproductive adults from the breeding pool. Hunting is facilitated by habitat fragmentation (Factor A), which increases access to the forest by hunters. The Cauca guan is hunted throughout its current range, including within protected areas, and hunting may be responsible for a decline or local extirpation of the species from at least two of these protected areas (Ucumarí Regional Park and Munchique National Natural Park). Therefore, we find that subsistence hunting for domestic consumption is a threat to the Cauca guan throughout its range.

Factor C: Disease or Predation

We are unaware of any information regarding disease or the potential for significant disease outbreaks in the Cauca guan populations. As a result, we do not consider disease to be a threat to the species.

Predators of cracids include snakes, foxes, feral cats, feral dogs, and raptors (Delacour and Amadon 1973). Cauca guans are also slow to reproduce, with a long fledging period (up to 1 year) and a replacement rate of at least 6 years (Rios *et al.* 2006, p. 17; Silva and Strahl 1991, p. 50). Cauca guans require large territories for foraging (Kattan 2004, p. 11), but today are relegated mostly to small forest fragments (Kattan *et al.* 2006, p. 301). As discussed in detail above for the blue-billed curassow (Factor C), studies have shown that habitat fragmentation increases the potential predation pressure within habitat fragments by facilitating the predators' access throughout the fragment and because smaller fragments support smaller predators, which tend to depredate on the more vulnerable life-history stages of the Cauca guan, eggs and juveniles (Keyser *et al.* 2002, p. 186; Renjifo 1999, p. 1,133; Keyser *et al.* 1998, p. 991; Arango-Vélez and Kattan 1997, pp. 137–143; Hoover *et al.* 1995, p. 151; Gibbs 1991, p. 157; Wilcove 1985, p. 1,214).

Summary of Factor C

Snakes, foxes, feral cats, feral dogs, and raptors are all predators of cracids. Predation results in the direct removal of eggs, juveniles, and adults from the population. Cauca guans are slow to reproduce, produce a low clutch size, require a long fledging period, and exhibit a poor replacement rate (see Habitat and Life History, above). Predation can destroy pair bonds and remove potentially reproductive adults from the breeding pool. Cauca guan habitat is fragmented and small (Factor A), and studies on similar species in similar Andean habitats indicate that vulnerability to predation by generalist predators increases with increased habitat fragmentation and smaller patch sizes. Predation exacerbates the genetic complications associated with the species' small population size (Factor E). Because of the species' small population size and inability to recolonize isolated habitat fragments (Factor E), predation renders the species vulnerable to local extirpation. Therefore, we find that predation, exacerbated by ongoing habitat destruction (Factor A) and hunting (Factor B), is a threat to the Cauca guan.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

Regulatory mechanisms may provide species-specific or habitat-specific protections. An evaluation of the adequacy of regulatory mechanisms within Colombia to mitigate or remove the threats to the Cauca guan is provided below, beginning with species-specific and followed by habitat-specific protection mechanisms.

Colombia has enacted numerous laws to protect species and their habitats (Matallana-T 2005, p. 121). The Cauca guan is listed as an endangered species under Colombian Law 99 of 1993 (EcoLex 1993, p. 2) and Resolution No. 584 of 2002 (EcoLex 2002, pp. 10, 12). A full description of these laws and the categorization of threatened species in Colombia were provided above, as part of the Factor D analysis for the blue-billed curassow. This threat status confers protections upon the species, including protection from commercial take under Resolution No. 849 of 1973 and Resolution No. 787 of 1977 (EcoLex 1973, p. 1; EcoLex 1977, p. 3). Neither Resolution prohibits subsistence hunting. As discussed under Factor B, commercial and sport hunting are not threats to this species, but subsistence hunting continues to threaten the species throughout its range, including within protected areas.

Hunting may play a role in the decline or possible local extirpation of the species from two protected areas, Munchique National Natural Park and Ucumarí Regional Park, where subsistence hunting was widespread in the 1990s (Strahl *et al.* 1995, p. 81; del Hoyo 1994, p. 349; Collar *et al.* 1992, p. 60) (Factor B). Cauca guans have not been observed in Munchique National Natural Park since 1987 (BLI 2007h, p. 2: Renjifo 2002, p. 124), despite subsequent searches of the area (Wege and Long 1995, p. 149). Similarly, since 1994, there have been only scant sightings of Cauca guans in the Ucumarí Regional Park (Scanlon 2004, pp. 1–3; Renjifo 2002, p. 125; Wege and Long 1995, p. 141) (see Population Estimates, above). Researchers have indicated that local residents continue to hunt the Cauca guan despite the illegality of this activity (Muñoz *et al.* 2006, p. 50; Rios *et al.* 2006, pp. 22–23; Renjifo 2002, p. 128; del Hoyo 1994, p. 337), even within areas designated as ''protected'' under Colombian law (see also next paragraph). For instance, settlers in the Otún-Quimbaya Flora and Fauna Sanctuary admit to taking between 24 and 48 Cauca guans a year (Rios *et al.* 2006, pp. 22–23) (Factor B). Thus, these Resolutions are ineffective at reducing the existing threat of subsistence hunting to the Cauca guan.

Colombia has enacted numerous forestry laws and forestry management practices (Law No. 2 (EcoLex 1959); Decree No. 2,811 (Faolex 1974); Decree No. 1,791 (Faolex 1996); Law No. 1,021 (EcoLex 2006)). Weaknesses in the implementation of these laws and the decentralized nature of Colombian resource management are described in detail above for the blue-billed curassow (Factor D) (ITTO 2006, pp. 218–219, 222; Matallana-T 2005, pp. 121–122). Experts consider these decentralized management mechanisms ineffective at protecting the Cauca guan from habitat destruction (Factor A) or hunting (Factor B) (Muñoz *et al.* 2006, p. 50). Habitat destruction and hunting are ongoing throughout the species' range, indicating that forestry regulations are ineffective at mitigating the threats to the Cauca guan from habitat destruction (Factor A) or hunting (Factor B).

Colombia has several categories of national habitat protection (Matallana-T 2005, pp. 121–122), which were described above, as part of the Factor D analysis for the blue-billed curassow (Matallana-T 2005, pp. 121–122). The Cauca guan occurs within national parks (including the Ucumarí Regional Park, last confirmed Cauca guan sighting in 2004 (Scanlon 2004, pp. 1–3), and Munchique National Natural Park, confirmed in 1987 (Salaman *in litt.* 1999, 2000, as cited in BLI 2007h, p. 2; Kattan *et al.* 2006, p. 305; Muñoz *et al.* 2006, p. 54); reserves (Reserva Forestal de Bremen, confirmed in 1997 (Renjifo 2002, pp. 124–125), Reserva Forestal de Yotoco, confirmed in 2000–2001 (Renjifo 2002, pp. 124–125), and Reserva La Sirena, confirmed in 2000–2001 (Kattan *et al.* 2006, p. 302)); and sanctuaries (Otún-Quimbaya Flora and Fauna Sanctuary, confirmed in 2000–2001 (Kattan *et al.* 2006, p. 302)). Within the last 20 years, the Cauca guan

population may have declined or been extirpated from at least two Parks, the Munchique National Natural Park and the Ucumarí Regional Park, where the species has not been observed since 1987 (Renjifo 2002, pp. 124–125) and 2004 (Scanlon 2004, pp. 1–3), respectively. These Parks were subject to subsistence hunting in the late 1990s (Strahl *et al.* 1995, p. 81; del Hoyo 1994, p. 349; Collar *et al.* 1992, p. 60), and subsistence hunting of Cauca guan continues in these and other protected areas, such as Otún-Quimbaya Flora and Fauna Sanctuary (Rios *et al.* 2006, pp. 22–23) (Factor B). In addition, logging, population pressure, and agriculture are ongoing within these Parks. Ucumarí Regional Park, considered the stronghold for the species (BLI 2007h, p. 2), continues to be managed for multiple uses (including pasture land and other commercial ventures) (Factor A). In light of the multiple land uses allowed within the Park, and the ongoing human-induced habitat destruction, the park provides little or no protection to the species from the threat of habitat destruction (Factor A).

The Cauca guan ranges in multiple Departments (currently known in Cauca, Quindío, Risaralda, Valle de Cauca), each of which administers their own natural resources under different autonomous corporations (ITTO 2006, p. 219; Law 99 of 1993). We are unaware of any coordinated species management plan. Therefore, in view of the decentralized resource management structure, the absence of a conservation strategy for the species, the threats to the Cauca guan from habitat destruction (Factor A) and hunting (Factor B) are not mitigated.

Summary of Factor D

Colombia has numerous laws and regulatory mechanisms to administer and manage wildlife and their habitats. The Cauca guan is listed as endangered under Colombian law and occurs within several protected areas. However, on-the-ground enforcement of existing wildlife protection and forestry laws and oversight of the local jurisdictions implementing and regulating activities are ineffective at mitigating the primary threats to the Cauca guan. As discussed for Factor A, habitat destruction, degradation, and fragmentation continue throughout the existing range of the Cauca guan. As discussed for Factor B, uncontrolled subsistence hunting of the Cauca guan is ongoing and continues to negatively affect the continued existence of the species. Moreover, the lack of a species conservation strategy and the decentralized management of natural resources in Colombia provide no overall coordination in the conservation of species such as Cauca guans, which range in multiple jurisdictions. Therefore, we find that the existing regulatory mechanisms currently in place are inadequate to mitigate the primary threats to the Cauca guan.

Factor E: Other Natural or Manmade Factors Affecting the Continued Existence of the Species

Two additional factors affect the Cauca guan: Its minimal likelihood for dispersal and the species' small population size.

Likelihood To Disperse

The Cauca guan exhibits characteristics indicative of an inability to disperse into isolated habitat fragments and recolonize patches of suitable habitat that have undergone a localized extirpation. The Cauca guan prefers habitat of mature humid forests (Collar *et al.* 1994, p. 136), has generally been found only in secondary habitats that are situated within 1 km (0.62 mi) of primary forest (Renjifo 2002, p. 127), and is reported as timid in the presence of humans (Rios *et al.* 2006, p. 21). The remaining suitable habitat available to the Cauca guan is limited to a few disjunct and isolated forest fragments only a few hundred hectares (100 hectares = 1 km^2 = 0.39 mi^2) in size (Kattan *et al.* 2006, p. 301; Kattan 2004, p. 6; Renjifo 2002, p. 128).

Existing habitat for the Cauca guan is fragmented, with large distances between the remaining primary forest fragments (Cuervo and Salaman 1999, p. 7; Hanski 1998, pp. 45–46) and an ever-growing human presence in and around the species' existing habitat (BLI 2004c, p. 2; Cuervo 2002, p. 327; Renjifo 2002, pp. 124–128; Cuervo and Salaman 1999, p. 8; Stattersfield *et al.* 1998, p. 205). Without human intervention, the Cauca guan is unlikely to repopulate an isolated patch of suitable habitat following decline or local extirpation. Evidence for the Cauca guan's inability to disperse across fragmented habitat patches is provided by the fact that there are several areas of suitable habitat, located near previously reported localities for the species, in which the Cauca guan has not been observed (see Factor A, Refugia).

Small Population Size

Habitat destruction (Factor A) and hunting (Factor B) have affected the current population size and distributional range of the Cauca guan (Collar *et al.* 1994, p. 60; Collar *et al.* 1992, pp. 126–127). By the 1980s, the species was believed extinct or on the verge of extinction (Brooks and Strahl 2000, p. 14; del Hoyo 1994, pp. 337, 349; Hilty and Brown 1986, p. 125; Hilty 1985, p. 1,004). The Cauca guan is now confirmed only in several isolated locations. Overall, the population is considered to be in decline, with the current isolated populations ranging from tens of individuals to a few hundred individuals at best (BLI 2007h, p. 2; Kattan 2004, p. 6; Renjifo 2002, p. 129), but there have been few population surveys of the Cauca guan. In 2006, Kattan (*in litt.,* as cited in Muñoz *et al.* 2006, p. 55) estimated the global population to be between 196 and 342 individuals. Kattan *et al.* (2006, p. 302) conducted the only two population surveys, in 2000 and 2001 (Muñoz *et al.* 2006, p. 55). They estimated population densities at two locations, Otún-Quimbaya Flora and Fauna Sanctuary (Risaralda) and Reserva Forestal de Yotoco (Valle de Cauca), to be between 144 and 264 individuals, and 35 to 61 individuals, respectively (Kattan *et al.* 2006, p. 304).

Small population sizes render species vulnerable to genetic risks that can have individual or population-level consequences on the genetic level and can increase the species' susceptibility to demographic problems, as explained in more detail above for the blue-billed curassow (Factor E, Small Population Size) (Charlesworth and Charlesworth 1987, p. 238; Shaffer 1981, p. 131). Once a population is reduced below a certain number of individuals, it tends to rapidly decline towards extinction (Holsinger 2000, pp. 64–65; Soulé 1987, p. 181; Gilpin and Soulé 1986, p. 25; Franklin 1980, pp. 147–148).

In the absence of quantitative studies specific to this species, a general approximation of minimum viable population size is the 50/500 rule, as described above as part of the Factor E analysis for the brown-banded antpitta (Shaffer 1981, pp. 132–133; Soulé 1980, pp. 160–162). The total population size of the Cauca guan is estimated to be between 196 and 342 individuals. While 196 individuals is above the minimum population size required to avoid short-term genetic consequences, 342 falls below the threshold minimum number of 500 individuals required for long-term fitness of a population.

Moreover, because the Cauca guan exists in isolated forest fragments and is unlikely or incapable of dispersing to disjunct patches, each disjunct locality likely acts as a subpopulation. Therefore, the resiliency of each of these subpopulations will be lower than that of the global population. The largest reported subpopulation, in Otún-Quimbaya Flora and Fauna Sanctuary,

contains between 144 and 264 individuals (Kattan *et al.* 2006, p. 304). The lower figure, 144 individuals, is above the minimum effective population size required to avoid imminent risks from inbreeding (N_e = 50). The upper limit of the subpopulation, 264 birds, represents the maximum number of individuals in the subpopulation, but does not take into account that not all members of the population will be reproductive. This figure is well below the upper threshold (N_e = 500 individuals) required for long-term fitness of a population to ensure that the species will not lose its genetic diversity over time and will maintain an enhanced capacity to adapt to changing conditions. The only other subpopulation figures are for Reserva Forestal de Yotoco, with an estimated 35 to 61 individuals (Kattan *et al.* 2006, p. 304). Both of these figures are well below the 50/500 threshold. Therefore, we currently consider these subpopulations (and the species as a whole) to be at risk from genetic complications due to the lack of short- and long-term viability.

The Cauca guan's small population size, combined with its restricted range and inability to repopulate suitable habitat following local extirpations (Renjifo 2002, p. 138; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361), makes the species particularly vulnerable to the threat of adverse natural (e.g., genetic, demographic, or environmental) and manmade (e.g., hunting or deforestation) events that destroy individuals and their habitat (BLI 2007, pp. 1–2; Renjifo 2002, p. 140; Holsinger 2000, pp. 64–65; Young and Clarke 2000, pp. 361–366).

Summary of Factor E

The Cauca guan is now confirmed only in several isolated locations. The Cauca guan is unlikely or incapable of dispersing into suitable habitat that is isolated from extant populations, and the species' overall small population size makes it vulnerable to genetic and demographic risks that negatively impact the species' short- and long-term viability. The Cauca guan's small population size, restricted range, and inability to repopulate suitable habitat following local extirpations expose the species to threats associated with adverse natural (e.g., genetic, demographic, or environmental) and manmade (e.g., hunting or deforestation) events that destroy individuals and their habitat. Therefore, we believe that, in combination with the risks to the species from habitat destruction (Factor A), hunting (Factor B), and predation (Factor C), the Cauca guan is vulnerable to localized extirpation or extinction from which the species would be unable to recover, due to its small population size and apparent inability to repopulate fragmented, isolated habitats such as those currently present within this species' range.

Cauca Guan Status Determination

The five primary factors that threaten the survival of the Cauca guan are: (1) Habitat destruction, fragmentation, and degradation (Factor A); (2) overexploitation due to hunting; (3) predation (Factor C); (4) inadequacy of regulatory mechanisms to reduce the threats to the species (Factor D); and (5) small population size and isolation of remaining populations (Factor E). The Cauca guan, a large, primarily terrestrial bird, prefers humid forests or secondary forests, forest edges, and plantations that are in close proximity (within 1 km (0.62 mi)) to humid forests.

Habitat destruction, alteration, conversion, and fragmentation were factors in the Cauca guan's historical decline. The species has experienced a 95 percent range reduction since the 1950s, such that the estimated suitable habitat available to the species is approximately 560 km^2 (216 mi^2). Experts estimate that more than 30 percent of this loss of habitat has occurred within the last three generations, or 30 years. Fifty years ago, the species' historic range was estimated to have been an approximately 24,900-km^2 (9,614-mi^2) area, encompassing humid forests on the eastern slopes of the West Andes and the dry forests of the Cauca, Patía, and Dagua Valleys, in the Departments of Cauca, Quindío, Risaralda, and Valle de Cauca. Today, the species has been locally extirpated from the Cauca and Dagua Valleys. The Cauca guan inhabits the western slopes of the central and western Andes in the few remaining upper-elevation forest remnants at altitudes exceeding those reported in the first half of the 20th Century. These shifts to the extremes of its range and shifts in elevational distribution have resulted from extensive habitat destruction throughout the species' range. The dry forests of the Cauca, Dauga, and Patía Valleys and the humid forests on the slopes of these valleys up to 2,000 m have been largely destroyed for cultivation, grazing, human settlements, road building, and other human-induced habitat alterations. Cultivation of illegal drug crops, such as cocaine, has led to further deforestation and altered soil compositions, hindering regeneration of abandoned fields. In addition, drug eradication programs involving the aerial spraying of nonspecific herbicides have led to further environmental degradation and habitat destruction (Factor A).

Although the Cauca guan, which is listed in Colombia as endangered, occurs on lands designated by the Colombian Government as ''protected areas,'' and it is illegal to commercially hunt the species, the existing laws and their enforcement are inadequate (Factor D) to mitigate the effects of ongoing habitat destruction (Factor A) and subsistence hunting (Factor B). Moreover, natural resource management within Colombia is highly decentralized, each district managing their resources autonomously. Thus, there is no overall coordination for the conservation and recovery of the Cauca guan, which ranges in several autonomous districts.

Widespread deforestation and conversion of primary forests has led to the fragmentation of habitat throughout the Cauca guan's range. The remaining suitable habitat is limited to a few disjunct and isolated forest fragments, only a few hundred hectares (100 hectares = 1 km^2 = 0.39 mi^2) in size. Habitat fragmentation affects resource availability for the Cauca guan, which requires large territories for foraging on its preferred food source: Seasonally available fruits. Experts believe that remaining refugia, such as the Otún-Quimbaya Sanctuary, may not be large enough to support viable populations, lacking sufficient space and resources needed for this large, terrestrial bird.

Habitat fragmentation also increases the species' susceptibility to hunting (Factor B). The Cauca guan is hunted throughout its current range. As the largest cracid living within its area of distribution, the Cauca guan is sought after by locals as a major food source. Despite being illegal (Factor D), subsistence hunting of Cauca guans continues throughout its range, including within protected areas. Hunting may be responsible for the species' local extirpation from the Ucumarí Regional Park, considered the stronghold for the species in the 1990s, and the Munchique National Natural Park.

Habitat fragmentation exposes the species to greater risk of extinction caused by adverse natural (e.g., genetic, demographic, or environmental) and manmade (e.g., hunting or deforestation) events (Factor E). At the beginning of the 20th Century through the 1950s, the species was considered common. Habitat fragmentation has led to the isolation of remaining subpopulations, which are estimated to range from tens of individuals or a few hundred individuals at most, thus affecting the

species' resiliency. The total population estimate of 196–342 individuals falls below the threshold minimum number of 500 individuals required for long-term fitness of a population. It is estimated that the species has lost up to 9 percent of its population in the last 10 years. Given that the Cauca guan is likely to interact as subpopulations and its inability to disperse between fragmented habitat patches, the species' effective population size is actually much less than the global population estimate would imply. The fitness of the subpopulations is vital to understanding the viability of the species. The largest subpopulation, estimated to contain between 144 and 264 individuals, falls below the threshold for long-term viability. The other subpopulation for which there is an estimate contains between 35 and 61 individuals, which figures are below the thresholds for both short-term and long-term viability.

Thus, the Cauca guan is at risk from both near-term genetic complications (such as inbreeding and demographic shifts) and the lack of long-term fitness (such as the ability to adapt to changing conditions). Because the species exists in isolated subpopulations, the risk from near-term genetic consequences, such as inbreeding and demographic shifts, is further magnified. These potential genetic problems are exacerbated by ongoing human-induced threats, such as habitat destruction (Factor A) and hunting (Factor B), factors which are not being mitigated by existing regulations (Factor D), and are further magnified by the species' inability to repopulate isolated, fragmented patches of suitable habitat, where Cauca guan populations have undergone decline or local extirpation (Factor E).

We have carefully assessed the best available scientific and commercial information regarding the past, present, and potential future threats faced by the Cauca guan. We consider the ongoing threats to the Cauca guan, habitat destruction (Factor A), hunting (Factor B), and predation (Factor C), exacerbated by the species' small population size and limited dispersal ability (Factor E), and compounded by inadequate regulatory mechanisms to mitigate these threats (Factor D), to be equally present and of the same magnitude throughout the species' entire current range. Based on this information, we find that the Cauca guan is in danger of extinction throughout all of its range.

Gorgeted Wood-Quail (Odontophorus strophium) Biology and Distribution

Species Description

The gorgeted wood-quail, endemic to Colombia and a member of the New World Quail Family (Odontophoridae), is approximately 25 cm (10 in) long (del Hoyo 1994, p. 431; Fjeldså and Krabbe 1990, p. 141; Hilty and Brown 1986, p. 133). The species is locally known as ''perdiz Santandereana'' or ''perdiz de monte'' (Sarria and Álvarez 2002, p. 158), and may be referred to by the more general term ''forest partridge'' in English (BLI 2007g, p. 1). Mainly dark brown with black spots on upper parts, the male has a speckled black and white face, and a white collar on his throat surrounded on the upper and lower side by a band of black. Underparts are rufous-chestnut colored with white spotting. The female appears similar to the male; however, the female has a black collar surrounded by white bands on her throat (BLI 2007g, p. 1).

Taxonomy

The gorgeted wood-quail was first taxonomically described in 1844 by Gould, who placed the species in the Odontophoridae family, also known as the New World Quails (BLI 2007g, p. 1). The type specimen (the actual specimen that was first described by Gould) was obtained in the Colombian Department of Cundinamarca (Hilty and Brown 1986, p. 133), although details on the location were not provided with the description (Warren 1966, p. 318). Therefore, we will refer to the Department of Cundinamarca as the ''type locality.''

Habitat and Life History

The gorgeted wood-quail prefers montane temperate and humid subtropical forests dominated by roble, *Tabebuia rosea,* and secondary-growth forests in proximity to mature forests (Sarria and Álvarez 2002, p. 159), especially those dominated by oak (*Quercus humboldtii*). The species is most often found at elevations between 1,750 and 2,050 m (5,741 and 6,726 ft) (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27; Sarria and Álvarez 2002, pp. 158–159; Wege and Long 1995, pp. 143–144). Fuller *et al.* (2000, pp. 27–28) suggested that the species' range may be up to 2,500 m (8,202 ft) in elevation. However, Sarria and Álvarez (2002, p. 160) noted that, despite the availability of suitable habitat adjacent to the species' current locations, these areas are above the elevational range of the species and are not used. Moreover, in the most recent population surveys in the Yarguíes Mountains (Serranía de los Yarguíes), which range up to 3,200 m (10,498 ft), researchers heard the species vocalizing primarily at elevations between 1,800 and 1,900 m (5,905 and 6,234 ft), and none were heard above 1,950–2,000 m (6,398–6,562 ft) (Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 29; Donegan *et al.* 2004, p. 19). There are no recorded observations of this species at ranges above 2,050 m (6,726 ft) (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27; Sarria and Álvarez 2002, p. 160; Wege and Long 1995, pp. 143–144). Therefore, we conclude that the species' preferred range remains at elevations between 1,750 and 2,050 m (5,741 and 6,726 ft).

The gorgeted wood-quail is primarily terrestrial (Fuller *et al.* 2000, p. 2), living on the forest floor and feeding on fruit, seeds, and arthropods (Fuller *et al.* 2000, pp. 27–28; del Hoyo 1994, p. 431; Collar *et al.* 1992, pp. 171–172). There appear to be two breeding seasons per year, coinciding with the rainy seasons from March through May and September through November (BLI 2007g, p. 3). Gorgeted wood-quails are ground-nesting birds, laying their eggs in a small depression lined with vegetation and almost always covered with brush from the understory (Sarria and Álvarez 2002, p. 159). Similar to other wood-quails, gorgeted wood-quails associate in small groups and call to other groups by chorusing—singing together (Donegan *et al.* 2003, p. 29). Researchers consider this species to be dependent on primary forest for at least part of its life cycle (BLI 2007g, p. 3; Sarria and Álvarez 2002, p. 159).

Historical Range and Distribution

The gorgeted wood-quail historically occurred on the western slope of the East Andes, in the Departments of Santander and Cundinamarca in Colombia (del Hoyo 1994, p. 431; Fjeldså and Krabbe 1990, p. 141; Hilty and Brown 1986, p. 133). Since the 17th Century, extensive logging and land conversion in Cundimarca to agricultural uses nearly denuded all the forests of this area below 2,500 m (8,202 ft) (BLI 2007g, p. 3; Hilty and Brown 1986, p. 133). Habitat destruction is considered the primary factor that led to the historical decline and extirpation of this species from Cundinamarca (Fuller *et al.* 2000, pp. 4–5; Wege and Long 1995, p. 146).

For many years, the species was known only from two specimens collected in 1915 from its type locality in Cundinamarca (Hilty and Brown 1986, p. 133). Although the species was

reported at this site again in 1923 and 1954, it has not been seen there since that time (Wege and Long 1995, p. 146). The species was believed extinct until a record of a male bird and chicks was reported in 1970 in Santander Department in the Cuchilla del Ramo forest (Collar *et al.* 1992, p. 171; Fuller *et al.* 2000, p. 27).

Current Range and Distribution

The gorgeted wood-quail is endemic to the west slope of the East Andes, in the Magdalena Valley (Donegan and Huertas 2005, p. 29), and is known only in the central Colombian Department of Santander (del Hoyo 1994, p. 431; Fjeldså and Krabbe 1990, p. 141; Hilty and Brown 1986, p. 133). The current range of this species is between 10 km^2 (4 mi^2) (Sarria and Álvarez 2002, p. 160) and 27 km^2 (10.42 mi^2) (BLI 2007g, pp. 2, 5).

Since 1970, the species has only been reported in the central Colombian Department of Santander, with fewer than 10 sightings. Visual observations of this species have been scant; most reports have been inferred from auditory detections (Sarria and Álvarez 2002, pp. 158–159). In 1970, the species was observed in Cuchilla del Ramo forest (Wege and Long 1995, p. 143), but has not been confirmed there since that time (BLI 2007g, p. 2) (see also Factor A). The species has been observed and most recently confirmed in three locations: (1) Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary, (2) Cachalú Biological Reserve, and (3) Serranía de los Yarguíes. These confirmed sightings are briefly described below.

(1) Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary (Santander Department): The gorgeted wood-quail was confirmed at this location in 1979 (BLI 2007g, p. 2) and again in 1988 (Sarria and Álvarez 2002, p. 160; Wege and Long 1995, p. 144). In 2004, the species was reported in the oak forests within the Province of Guanentá (BLI 2007g, p. 2), but it is unclear whether these observations occurred within the Sanctuary.

(2) Cachalú Biological Reserve (Santander Department): The gorgeted wood-quail was confirmed in this Reserve in 1999, 2000, and 2001 (BLI 2007g, p. 2; Sarria and Álvarez 2002, pp. 158–159; Fuller *et al.* 2000, p. 27).

(3) Serranía de los Yarguíes (Santander Department): The species has also been confirmed at this location in 2003 and 2004 (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27). The Serranía de los Yarguíes locale reportedly harbors the largest known population and is the stronghold for the species (Turner 2006, p. 22; Donegan and Huertas 2005, p. 29) (see Population Estimates, below).

Generally speaking, these localities are in two disjunct locations within the Department of Santander. Serranía de los Yarguíes is in northern Santander and the other two localities are adjacent to each other in southern Santander (Rainforest Alliance 2008, p. 2; Donegan and Huertas 2005, p. 30). These habitats are described more fully under Factor A (Refugia).

Population Estimates

To the best of our knowledge, there have been no quantitative studies to determine the species' population size. The population estimates for the gorgeted wood-quail are based on qualitative surveys and extrapolations using suitable habitat estimates (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27; Sarria and Álvarez 2002, pp. 158–159; Fuller *et al.* 2000, p. 27;). As noted above (see Current Range), a total of three adults and two chicks were observed between 1923 and 1970 (Sarria and Álvarez 2002, p. 158; Wege and Long 1995, p. 143). The largest number of visual confirmations of individual birds has been reported in the Reserva Biológico Cachalú. In 1999, two groups of seven to nine individuals were observed. Between 2001 and 2002, six groups of 5–11 individuals were observed (Sarria *in litt.,* as cited in Sarria and Álvarez 2002, p. 159). Based on these direct observations, the population in the Reserva Biológico Cachalú may consist of between 30 and 66 individuals.

All other population estimates have been inferred from auditory calls or suitable habitat extrapolations. It is not unusual to infer population estimates for elusive, ground-dwelling species, such as the gorgeted wood-quail, for which direct observation is difficult. However, extrapolating population estimates based on suitable habitat can lead to overestimations of population sizes, especially for narrow-ranging species, such as the gorgeted wood-quail. The potential for overestimation was discussed above, in the analysis of the brown-banded antpitta (Factor E, Small Population Size). For instance, researchers recently estimated that the Serranía de los Yarguíes population may hold a significantly greater number of birds than ever known. Given the inferred density of the species (based on auditory observation) and the extent of forest cover in the Serranía de los Yarguíes, researchers predicted that an excess of 250 individuals was present at the site (Donegan and Huertas 2005, p. 30; Donegan *et al.* 2004, p. 19).

Turner (2006, p. 22) extrapolated the population size, based on satellite images of the area, which indicated that 30,000 ha (74,131 ac) of forest at elevations between 1,500 and 2,200 m (4,921 and 7,218 ft) on the western slope and 2,700 and 2,900 m (8,858 and 9,514 ft) on the eastern slope were available to the species. This yielded a predicted population size of between 1,800 and 3,300 individuals. However, we believe that this population estimate, based on the availability of suitable habitat, may be an overestimate for this species for two reasons: (1) The population may not be randomly distributed throughout the suitable habitat, as assumed by these researchers, and (2) the extrapolation does not take into account human-induced threats, such as hunting (Sarria and Álavarez 2002, pp. 160–161) (Factor B). Therefore, until Turner's (2006, p. 22) predictions have been ground-truthed, we are unable to consider the predicted population estimate of between 1,800 and 3,300 individuals to be a reliable reflection of the current population size. Consequently, we consider the population estimate of between 189 to 486 individuals (BLI 2007g, p. 1) to be the best available estimate of the gorgeted wood-quail.

Conservation Status

The gorgeted wood-quail is identified as a critically endangered species under Colombian law (EcoLex 2002, p. 12). The species is classified as 'Critically Endangered' on the IUCN Red List, due to its small and highly fragmented range, with recent population records from only two areas (BLI 2004d; BLI 2007g, pp. 1, 5).

Summary of Factors Affecting the Gorgeted Wood-Quail

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Habitat or Range

In the early part of the 20th Century, the gorgeted wood-quail was known only in the oak forests in the Department of Cundinamarca. However, extensive deforestation and habitat conversion for agricultural use nearly denuded all the oak forests in Cundinamarca below 2,500 m (8,202 ft) (BLI 2007g, p. 3; Hilty and Brown 1986, p. 133). Deforestation left little remaining suitable habitat for the gorgeted wood-quail, which prefers primary forests and tolerates secondary-growth forests near primary forests (BLI 2007g, p. 3; Sarria and Álvarez 2002, p. 159) at altitudes from 1,500 to 2,500 m (4,921 to 8,202 ft) (Fuller *et al.* 2000, pp.

27–28; del Hoyo 1994, p. 431; Hilty and Brown 1986, p. 133). Subsequent surveys have not located the species in the Department of Cundinamarca since 1954 (Sarria and Álvarez 2002, p. 158; Fuller *et al.* 2000, p. 27; Collar *et al.* 1992, p. 171), and researchers consider the gorgeted wood-quail to be locally extirpated from Cundinamarca (BLI 2007g, p. 3; Sarria and Álvarez 2002, pp. 160–161; Fuller *et al.* 2000, pp. 4–5; Wege and Long 1995, p. 146).

Deforestation, in combination with hunting (Factor B), may have led to the local extirpation of the gorgeted wood-quail from another location. After no confirmed reports of the species in nearly 20 years (Sarria and Álvarez 2002, pp. 158–159), the species was rediscovered in Cuchilla del Ramo forest (in the Department of Santander) in 1970 (Sarria and Álvarez 2002, pp. 158–159; Wege and Long 1995, p. 143) and last confirmed there in 1988 (Collar *et al.* 1992, p. 172). However the species has not been confirmed at that location since that time (BLI 2007g, p. 2; Sarria and Álvarez 2002, pp. 158–159). According to Wege and Long (1995, p. 143), Cuchilla del Ramo, an unprotected area on the western slopes of the East Andes, has been largely cleared of its forest such that only fragments remain. Thus, it is possible that deforestation within the past 30 years has led to the extirpation of the gorgeted wood-quail from this location.

Today, the gorgeted wood-quail is endemic to the western slopes of the East Andes in the Department of Santander, Colombia (Collar *et al.* 1994, p. 70; del Hoyo 1994, p. 431; Fjeldså and Krabbe 1990, p. 141; Hilty and Brown 1986, p. 133). The gorgeted wood-quail is currently confirmed in three locations (see Refugia, below), and its current range is between 10 km² (4 mi²) (Sarria and Álvarez 2002, p. 160) and 27 km² (10.42 mi²) (BLI 2007g, pp. 2, 5). The species has lost 92 percent of its former habitat (Sarria and Álvarez 2002, p. 160), and habitat loss continues throughout its range (BLI 2007g, p. 2; Donegan *et al.* 2003, p. 26; Sarria and Álvarez 2002, pp. 159–160; Collar *et al.* 1994, p. 70; Collar *et al.* 1992, p. 172; Hilty and Brown 1986, p. 133).

Deforestation

Colombian forests have undergone extensive alteration during the 20th Century to establish human settlements, build roads, extract timber, and pursue agriculture. Between 1973 and 1996, these activities reduced the amount of primary forest cover in Colombia by approximately 3,605 ha (8,908 ac) annually, representing a nearly one-third total loss of primary forest habitat (Viña *et al.* 2004, pp. 123–124). Habitat loss accelerated dramatically in the 1980s as an influx of people settled in formerly pristine forests (Perz *et al.* 2005, pp. 26–28; Viña *et al.* 2004, p. 124). Recent studies indicate that the rate of habitat destruction is accelerating. Between the years 1990 and 2005, Colombia lost approximately 52,800 ha (130,471 ac) of primary forest annually (Butler 2006a, pp. 1–3; FAO 2003a, p. 1). These studies and activities were described in greater detail under Factor A for the blue-billed curassow, above. Logging is especially common in the flat lower-elevation areas and areas below 2,500 m (8,202 ft), where deforestation is nearly complete. Logging continues in steeper-sloped areas, where commercially valuable trees are still being extracted, and forested areas are being cleared for agricultural purposes (Fuller *et al.* 2000, p. 4; Stattersfield *et al.* 1998, p. 192).

Human-induced deforestation and environmental degradation have caused the gorgeted wood-quail to shift its range from the Department of Cundinamarca to the Department of Santander. The species was first observed in Santander within Cuchilla del Ramo forest in 1970 (Wege and Long 1995, p. 143), but has not been confirmed there since then (BLI 2007g, p. 2). The presence of the species has been documented only about 10 times, and most of these are based on auditory detections. The species has been most recently confirmed in the following three locations: (1) Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary (BLI 2007g, p. 2; Sarria and Álvarez 2002, p. 160; Wege and Long 1995, p. 144), (2) Cachalú Biological Reserve (BLI 2007g, p. 2; Sarria and Álvarez 2002, pp. 158–159; Fuller *et al.* 2000, p. 27), and (3) the Serranía de los Yarguíes (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27).

Illegal Crops and Their Eradication

Cocaine and opium has been cultivated throughout the gorgeted wood-quail's range. The cultivation of illegal crops (including coca and opium) in Colombia destroys montane forests (Balslev 1993, p. 3). Coca crops also destroy the soil quality by causing the soil to become more acidic, which depletes the soil nutrients and ultimately impedes the regrowth of secondary forests in abandoned fields (Van Schoik and Schulberg 1993, p. 21). As of 2004, an estimated 80,000 ha (197,683 ac) were under cocaine cultivation and 4,000 ha (9,884 ac) were under opium cultivation (UNODC *et al.* 2007, pp. 7–8). These figures include habitat within the gorgeted wood-quail's range. Between 2003 and 2004, cocaine cultivation areas increased 25 percent in Cundinamarca, from 57 to 71 ha (140 to 175 ac), and by 78 percent in Santander, from 632 to 1,124 ha (1,562 to 2,777 ac) (UNODC and GOC 2005, p. 15).

Colombia continues to be the leading coca bush producer (UNODC *et al.* 2007, p. 7). However, since 2003, cocaine cultivation has remained stable, with about 800 km² (309 mi²) of land under cultivation (UNODC *et al.* 2007, p. 8). This stabilization of production is, in part, attributed to alternative development projects implemented between 1999 and 2004, to encourage pursuits other than illegal crop cultivation (UNODC *et al.* 2007, p. 77). This stabilization of production area is also attributed to heightened eradication efforts. Between 2002 and 2004, aerial spraying occurred over more than 1,300 km² (502 mi²) of land annually, peaking in 2004, when 1,360 km² (525 mi²) of illicit crops were sprayed (UNODC and GOC 2005, p. 11). In 2006, eradication efforts were undertaken on over 2,130 km² (822 mi²) of land, consisting of 1,720 km² (664 mi²) of land being sprayed and manual eradication being used on the remaining land. Eradication efforts undertaken in 2006 occurred over an area representing 2.7 times more land than the net cultivation area (UNODC *et al.* 2007, p. 8). In Santander alone, 1,855 ha (4,583 ac) of coca fields were sprayed or manually eradicated in 2004 (UNODC 2005, p. 66).

Drug eradication efforts in Colombia have further degraded and destroyed primary forest habitat by using nonspecific aerial herbicides to destroy illegal crops (BLI 2007d, p. 3; Álvarez 2005, p. 2042; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12). Herbicide spraying has introduced harmful chemicals into gorgeted wood-quail habitat and has led to further destruction of the habitat by forcing illicit growers to move to new, previously untouched forested areas (Álvarez 2007, pp. 133–143; BLI 2007d, p. 3; Álvarez 2005, p. 2,042; Cárdenas and Rodríguez Becerra 2004, p. 355; Oldham and Massey 2002, pp. 9–12 Álvarez 2002, pp. 1088–1093). Between 1998 and 2002, cultivation of illicit crops increased by 21 percent each year, with a concomitant increase in deforestation of formerly pristine areas of approximately 60 percent (Álvarez 2002, pp. 1,088–1,093).

Effects of Habitat Fragmentation

An analysis of the effects of habitat fragmentation on Andean birds within western Colombia determined that 31

percent of the historical bird populations have become extinct, or were locally extirpated by 1990, largely as a result of habitat fragmentation from deforestation and human encroachment (Kattan and Álvarez-Lopez 1996, p. 5; Kattan *et al.* 1994, p. 141). The gorgeted wood-quail, which depends on primary forest for at least part of its life cycle (BLI 2007g, p. 3; Sarria and Álvarez 2002, p. 159), has been extirpated from its type locality in Cundinaramaca (Fuller *et al.* 2000, pp. 4–5; Wege and Long 1995, p. 146). The study also noted that species at the upper or lower limit of their altitudinal distribution are more susceptible to local extirpation and extinction (Kattan and Álvarez-Lopez 1996, pp. 5–6). This is the case for the gorgeted wood-quail; the species prefers habitat at 1,750–2,050 m (5,741–6,726 ft), most of which has been destroyed (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27; Sarria and Álvarez 2002, pp. 158–159; Wege and Long 1995, pp. 143–144), and it has not been documented at higher elevations, despite the availability of suitable habitat (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27; Sarria and Álvarez 2002, pp. 158–160; Wege and Long 1995, pp. 143–144). Another study on the effects of habitat fragmentation in Colombia found that habitat fragmentation facilitates predation and hunting pressure (Arango-Vélez and Kattan 1997, pp. 140–142) (Factors B and C).

Refugia

The gorgeted wood-quail has been observed, and most recently confirmed, in the following three locations: (1) Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary, (2) Cachalú Biological Reserve, and (3) the Serranía de los Yarguíes.

(1) Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary (Santander Department): This 10,420-ha (25,748-ac) humid subtropical and temperate oak forest on the western slope of the East Andes was declared a protected natural area in 1993 (Rainforest Alliance, 2008 p. 2; The Nature Conservancy (TNC) 2008, p. 1; Andrade and Repizzo 1994, p. 43). This area has long been considered the largest remaining sizeable oak forest tract remaining in the northern area of the East Andes, even as recently as the year 2005 (Donegan and Huertas 2005, p. 11; Sarria and Álvarez 2002, p. 160; Stattersfield *et al.* 1998, p. 193; Wege and Long 1995, p. 144). The gorgeted wood-quail was first observed in the Sanctuary in 1979 (BLI 2007g, p. 2) and again 1988 (Sarria and Álvarez 2002, p. 160; Wege and Long 1995, p. 144). In 2004, the species was reported in the oak forests within the Province of Guanentá (BLI 2007g, p. 2), but it is unclear whether these observations occurred within the Sanctuary.

Beginning in the 1960s, habitat conversion accelerated in the East Andes (Stattersfield *et al.* 1998, p. 192). The forests of the Colombian East Andes have been extensively degraded (Stattersfield *et al.* 1998, p. 192; Collar *et al.,* 1992, p. 172; Fjeldså and Krabbe 1990; Hilty and Brown 1986, p. 133). The western slopes have been largely converted to agricultural use and to pastureland for cattle (Stattersfield *et al.* 1998, p. 192), and deforestation continues on the lower slopes of the East Andes (Wege and Long 1995, p. 143). Selective logging affects birds in the lower part of the Guanenta Alto Rio Fonce (Sarria and Álvarez 2002, p. 160; Fuller *et al.* 2000, p. 28), including the gorgeted wood-quail. Stattersfield *et al.* (1998, p. 192) reported that forest loss below 2,500 m (8,202 ft) has been almost complete, although Fuller *et al.* (2000, p. 28) noted that the forest was ''largely intact'' above 1,950–2,200 m (6,398–7,218 ft). However, elevations above this altitude would not serve the needs of the gorgeted wood-quail, because this species is found most often at 1,750–2,050 m (5,741–6,726 ft) in altitude (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27; Sarria and Álvarez 2002, pp. 158–159; Wege and Long 1995, pp. 143–144) (see discussion under Habitat and Life History for the gorgeted wood-quail).

(2) Cachalú Biological Reserve: This 1,300-ha (3,212-ac) Reserve (TNC 2008, p. 1) was established in 1997 adjacent to Guanentá Alto Rio Fonce Flora and Fauna Sanctuary (Rainforest Alliance 2008, p. 2). It encompasses primarily mature oak forests and secondary areas (regenerating pastureland) at altitudes between 1,850 and 2,750 m (6,070 and 9,022 ft). Most of the secondary areas within the Reserve have been regenerating for 20 years. About 4 percent of land formerly used for pastureland and slash-and-burn agriculture has been left to regenerate within the last 8 years (BLI 2007g, p. 10). The species was first observed at this location in 1999 and again in 2000 and 2001 (BLI 2007g, p. 2; Sarria and Álvarez 2002, pp. 158–159; Fuller *et al.* 2000, p. 27).

While human population pressures in northern Santander have not been as great as in other parts of the Andes, 70 percent of the subsistence population living locally has had a major influence on the upper montane forest system. Slash-and-burn agriculture (clearing small plots of land for agriculture and settlement) and subsistence extractive activities (such as harvesting wood, plant fibers, and animals) have turned the upper montane forests into extraction forests (Rainforest Alliance 2008, p. 2). Ongoing slashing and burning on the outskirts of the Reserve could further degrade the integrity of the habitat within the Reserve (BLI 2007g, p. 11).

(3) Serranía de los Yarguíes (Yarguíes Mountains): This 175,000-ha (432,425-ac) forest is located in southern Santander and ranges in altitude between 200 and 3,200 m (656 and 10,499 ft) (BLI 2007g, p. 12; Donegan and Huertas 2005, p. 30). This area was previously unsurveyed for birds, due to political instability and occupation by revolutionary armed forces (Donegan and Huertas 2005, pp. 11, 29–30; Donegan *et al.* 2004, p. 19; Sarria and Álvarez 2002, p. 160). The gorgeted wood-quail was first observed in Yarguíes in 2003 and again in 2004 (BLI 2007g, p. 2; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, p. 27). This site is now considered to be the stronghold for the species (Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2004, p. 19) (see Population Estimates, above). This forest does not have protected status (BLI 2007g, p. 13) and land clearing for slash-and-burn agriculture continues to be a problem within the Serranía de los Yarguíes (BLI 2007g, p. 13; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29).

Summary of Factor A

Habitat destruction, alteration, conversion, and fragmentation were factors in the species' historical decline and continue to be factors affecting the gorgeted wood-quail. The direct loss of habitat through widespread deforestation and conversion of primary forests for agricultural uses has led to a 95 percent range reduction for the species, leading to extirpation of the species in its type locality (in Cundinamarca) and an apparent shift in the species' range (to Santander). The species is known only in three locations, where habitat conversion and poaching of the gorgeted wood-quail are ongoing. Deforestation, habitat conversion, and drug eradication efforts have reduced the amount of suitable habitat at elevations preferred by the species, such that its current range is between 10 and 27 km^2 (4 and 10 mi^2). The destruction and fragmentation of the remaining primary forested habitat are ongoing throughout the species' range and are expected to continue.

Therefore, we find that the present destruction, modification, and curtailment of habitat are threats to the gorgeted wood-quail throughout all of its range.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Galliformes such as the gorgeted wood-quail are chiefly terrestrial birds that are easily hunted or trapped, and they have been closely associated with humans throughout history as a source for food, ornamental collection, commercial trade, and recreational hunting (Fuller *et al.* 2000, p. 2). Hunting the gorgeted wood-quail is illegal in Colombia (Factor D) and is considered poaching. Poaching for subsistence use and for local food trade is ongoing throughout the species' range (BLI 2007g, pp. 7, 11–13; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29) (BLI 2007g, p. 7). Hunting affects birds in the lower part of the Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary (Sarria and Álvarez 2002, p. 160; Fuller *et al.* 2000, p. 28), including the gorgeted wood-quail. Illegal hunting is an ongoing problem on the outskirts of the Cachalú Biological Reserve, where the species has been observed within the past decade (BLI 2007g, p. 10; Sarria and Álvarez 2002, p. 158). Poaching of the gorgeted wood-quail continues to be a problem within the Serranía de los Yarguíes, considered the stronghold for the species (BLI 2007g, p. 13; Turner 2006, p. 22; Donegan and Huertas 2005, p. 29). The IUCN Partridge, Quail, and Francolin Specialist Group (PQF Specialist Group) considers unregulated hunting to be a factor affecting gorgeted wood-quail populations throughout the species' range (Fuller *et al.* 2000, p. 28).

Hunting, in combination with deforestation, may have led to the local extirpation of this species from Cuchilla del Ramo (Department of Santander), where the species was first observed in 1970 (Sarria and Álvarez 2002, pp. 158–159; Wege and Long 1995, p. 143) and last confirmed in 1988 (Collar *et al.* 1992, p. 172). The gorgeted wood-quail has not been confirmed at this location again (BLI 2007g, p. 2; Sarria and Álvarez 2002, pp. 158–159), which may be due to a combination of habitat destruction and hunting pressures. This unprotected area on the western slopes of the East Andes is severely fragmented due to deforestation (Factor A). In addition, active hunting was reported in this location in the late 1980s. Collar *et al.* (1992, p. 172) interpreted this level of hunting to imply that the species was capable of withstanding some hunting pressure. Andrade (*in litt.,* Collar *et al.* 1992, p. 172) noted that this would be the case only where the species is capable of retreating into suitable adjacent habitat. However, little suitable habitat is located in this area. Thus, hunting, in combination with deforestation, may have led to the extirpation of the gorgeted wood-quail from Cuchilla del Ramo.

In addition, Arango-Vélez and Kattan (1997, pp. 140–142) conducted a study on the effect of habitat fragmentation on birds in Colombia and found that habitat fragmentation facilitates hunting because smaller habitat patches allow hunters to more easily penetrate the entire plot (Arango-Vélez and Kattan 1997, pp. 140–142).

Summary of Factor B

The gorgeted wood-quail is hunted (poached) throughout its current range for local consumption or local food trade. Hunting results in the direct removal of individuals from the population and can remove potentially reproductive adults from the breeding pool. This primarily terrestrial species is particularly vulnerable to hunting pressures due to its small population size (Factor E) and fragmented distribution (Factor A). Researchers believe that the gorgeted wood-quail is only capable of escaping hunting pressures when adjacent suitable habitat exists. There are continued reports of hunting pressures on the species; these pressures have been and continue to be exacerbated by ongoing human encroachment into previously undisturbed forests (Factor A). Hunting, combined with habitat fragmentation (Factor A), increases the possibility of local extirpation since the gorgeted wood-quail is unlikely to reoccupy an area that has been depleted through hunting (Factor E, Likelihood to Disperse). Hunting may have led to the local extirpation of the species in a portion of its range. Hunting pressures are ongoing and affect the entire population of gorgeted wood-quail. Therefore, we find that hunting is a threat to the gorgeted wood-quail throughout its range.

Factor C: Disease or Predation

We are not aware of any information regarding disease or the potential for significant disease outbreaks in gorgeted wood-quail populations. As a result, we do not consider disease to be a threat to the species.

Potential quail predators include feral dogs, tayras, dwarf squirrels (*Microsciurus* sp.), tree squirrels (*Sciurus granatensis*), common opossums (*Didelphis marsupialis*), kinkajous (*Potos flavus*), Central American agoutis (*Dasyprocta punctata*), and South American coatis (*Nasua nasua*) (Arango-Vélez and Kattan 1997, p. 141). A predation study conducted in the Colombian Andes demonstrated that habitat fragmentation increased predation pressure on the eggs of the common quail (*Coturnix coturnix*) when situated within smaller, isolated habitat fragments (Arango-Vélez and Kattan 1997, pp. 137–143). Similar studies have found that nest predation is more prevalent in smaller, isolated forest patches because the small size of the patch facilitated predators' access to prey throughout the entire plot (Keyser *et al.* 2002, p. 186; Renjifo 1999, p. 1,133; Keyser *et al.* 1998, p. 991; Hoover *et al.* 1995, p. 151; Gibbs 1991, p. 157; Wilcove 1985, p. 1,214). Arango-Vélez and Kattan (1997, pp. 140–142) also found that smaller fragments support smaller predators, which tend to depredate on eggs and juveniles, rendering understory nesting birds, such as the gorgeted wood-quail, particularly vulnerable to predation during these life-history stages (Arango-Vélez and Kattan 1997, pp. 140–142). These studies were described in more detail above, as part of the Factor C analysis for the blue-billed curassow.

Summary of Factor C

Feral dogs, tayras, dwarf squirrels, tree squirrels, common opossums, kinkajous, Central American agoutis, and South American coatis are potential gorgeted wood-quail predators. Predation results in the direct removal of individuals from the population and can remove potentially reproductive adults from the breeding pool. This primarily terrestrial species is particularly vulnerable to predation pressures due to its small population size (Factor E) and fragmented distribution (Factor A). Habitat fragmentation has occurred and is ongoing throughout the species' range. Studies on similar species in similar Andean habitats indicate that vulnerability to predation increases with increased habitat fragmentation and smaller patch sizes. Predation exacerbates the genetic complications associated with the species' small population size (Factor E). Because of the species' small population size and inability to recolonize isolated habitat fragments (Factor E), predation renders the species vulnerable to local extirpation. Therefore, we find that predation, exacerbated by ongoing habitat destruction (Factor A) and hunting (Factor B), is a threat to the gorgeted wood-quail.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

Regulatory mechanisms may provide species-specific or habitat-specific protections. An evaluation of the adequacy of regulatory mechanisms within Colombia to mitigate or remove the threats to the gorgeted wood-quail is provided below, beginning with species-specific and followed by habitat-specific protection mechanisms.

Colombia has enacted numerous laws to protect species and their habitats (Matallana-T 2005, p. 121). The gorgeted wood-quail is listed as a critically endangered species under Colombian Law 99 of 1993 (EcoLex 1993, p. 2) and Resolution No. 584 of 2002 (EcoLex 2002, pp. 10, 12). A full description of these laws and the categorization of threatened species in Colombia were provided above, as part of the Factor D analysis for the blue-billed curassow. Under Resolution No. 849 of 1973 and Resolution No. 787 of 1977, the Ministry of the Environment does not permit the gorgeted wood-quail to be hunted commercially or for sport because of its status as a critically endangered species (EcoLex 1973, p. 1; EcoLex 1977, p. 3). Neither Resolution prohibits subsistence hunting, which is a threat to the species throughout its range (Factor B). Gorgeted wood-quail is hunted within the Serranía de los Yarguíes, which has no protected status (BLI 2007g, p. 13), despite being considered the stronghold for the species (Turner 2006, p. 22; Donegan and Huertas 2005, p. 29). Thus, these Resolutions are ineffective at reducing the existing threat of subsistence hunting to the gorgeted wood-quail (Factor B).

Colombia has enacted numerous forestry laws and forestry management practices (Law No. 2 (EcoLex 1959); Decree No. 2,811 (Faolex 1974); Decree No. 1,791 (Faolex 1996); Law No. 1,021 (EcoLex 2006)). Weaknesses in the implementation of these laws and the decentralized nature of Colombian resource management are described in detail above for the blue-billed curassow (Factor D) (ITTO 2006, pp. 218–219, 222; Matallana-T 2005, pp. 121–122). These regulatory mechanisms are ineffective at protecting the gorgeted wood-quail (BLI 2007g, p. 13; ITTO 2006, p. 222). Habitat destruction continues to be a problem within the unprotected forests of Serranía de los Yarguíes (BLI 2007g, p. 13), considered the stronghold of the species (Turner 2006, p. 22; Donegan and Huertas 2005, p. 29), and on the outskirts of the Reserva Biológica Cachalú, where the species has also been observed (BLI 2007g, p. 10). Therefore, we determine that forestry regulations are not effective in mitigating the threats to the gorgeted wood-quail from habitat destruction (Factor A).

Colombia has several categories of national habitat protection (Matallana-T 2005, pp. 121–122), which were more fully described above, as part of the Factor D analysis for the blue-billed curassow (Matallana-T 2005, pp. 121–122). The gorgeted wood-quail occurs within two protected areas: the Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary (Sarria and Álvarez 2002, p. 160; Fuller *et al.* 2000, p. 28) and the Cachalú Biological Reserve (BLI 2007g, p. 10; Sarria and Álvarez 2002, p. 158). Habitat destruction and subsistence hunting (poaching) are ongoing within these protected areas, despite being illegal (BLI 2007g, p. 10). Therefore, these sanctuaries and reserves provide little or no protection to the species from the threats of habitat destruction (Factor A) or poaching (Factor B).

Summary of Factor D

Colombia has adopted numerous laws and regulatory mechanisms to administer and manage wildlife and their habitats. The gorgeted wood-quail is considered critically endangered under Colombian law and lives within two protected areas. However, on-the-ground enforcement of existing wildlife protection and forestry laws and oversight of the local jurisdictions implementing and regulating activities are ineffective at mitigating the primary threats to the gorgeted wood-quail. As discussed for Factor A, habitat destruction, degradation, and fragmentation continue throughout the existing range of the gorgeted wood-quail. As discussed for Factor B, uncontrolled hunting of the gorgeted wood-quail is ongoing and negatively affects the continued existence of the species. Therefore, we find that the existing regulatory mechanisms currently in place are inadequate to mitigate the primary threats of habitat destruction (Factor A) and hunting (Factor B) to the gorgeted wood-quail.

Factor E: Other Natural or Manmade Factors Affecting the Continued Existence of the Species

Two additional factors affect the gorgeted wood-quail: its minimal likelihood for dispersal and the species' small population size.

Likelihood To Disperse

The gorgeted wood-quail is currently known in three localities in two disjunct locations within the Department of Santander: Serranía de los Yarguíes, in northern Santander, and Cachalú Biological Reserve and Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary, in southern Santander (Rainforest Alliance 2008, p. 2; TNC 2008, p. 1; Donegan and Huertas 2005, p. 30). Although there is little information on the species' dispersal capabilities, the isolated, fragmented nature of the remaining suitable habitat is considered by researchers to be a hindrance to its ability to disperse because: (1) The gorgeted wood-quail is primarily a terrestrial species that is found at mid-to-upper-elevation forests (1,750–2,050 m (5,741–6,726 ft)) on the western slopes of the East Andes (BLI 2007g, p. 2; Sarria and Turner 2006, p. 22; Donegan and Huertas 2005, p. 29; Donegan *et al.* 2003, Álvarez 2002, pp. 158–159; Fuller *et al.* 2000, pp. 2, 27–28; del Hoyo 1994, p. 431; Wege and Long 1995, pp. 143–144; Collar *et al.* 1992, pp. 171–172; Wege and Long 1995, pp. 143–144); (2) the species is dependent on mature forest for at least part of its life cycle and is not found in secondary habitats that are not adjacent to primary forests (BLI 2007g, p. 3; Sarria and Álvarez 2002, p. 159); (3) researchers believe that the species is capable of escaping hunting pressures only when adjacent to suitable habitat (Andrade *in litt.,* as cited in Collar *et al.* 1992, p. 172); (4) the species is currently located in two disjunct areas, one in northern Santander and the other in southern Santander; and (5) most of the habitat below 1,950–2,500 m (6,398–8,202 ft) in the East Andes has been destroyed, leaving only isolated, fragmented habitat patches (Fuller *et al.* 2000, p. 28; Stattersfield *et al.* 1998, p. 192). Because the species has not demonstrated an aptitude to disperse into secondary-growth areas that are not adjacent to primary forest, and given the isolated, disjunct nature of remaining forest fragments, the gorgeted wood-quail, as with other narrow-ranging species found in fragmented habitat (Hanski 1998, pp. 45–46), is unlikely or incapable of dispersing to suitable habitat that is not adjacent to existing locales.

Small Population Size

Deforestation (Factor A) and overutilization (Factor B) have greatly affected the current population size and distributional range of the gorgeted wood-quail (Collar *et al.* 1994, p. 60; Collar *et al.* 1992, pp. 126–127). The species was thought to be extinct or on the verge of extinction until its rediscovery in 1970 (Fuller *et al.* 2000, pp. 4–5, 27; Wege and Long 1995, p. 146; Collar *et al.* 1992, p. 171). The gorgeted wood-quail is now confirmed

in three isolated areas: the Sanctuary of Fauna and Flora Guanentá-Alto Río Fonce, the Natural Reserve Cachalú, and the Serranía de los Yariguíes (Donegan and Huertas 2005, pp. 11, 29–30; Donegan *et al.* 2004, p. 19; Sarria and Álvarez 2002, p. 160). The population of the gorgeted wood-quail is currently estimated to include 189 to 486 individuals, with a declining population trend (BLI 2007g, pp. 1, 5).

The gorgeted wood-quail's restricted range, combined with its small population size (Sarria and Álvarez 2002, p. 138; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361), makes the species particularly vulnerable to the threat of adverse natural (e.g., genetic, demographic, or environmental) and manmade (e.g., hunting or deforestation) events that destroy individuals and their habitat (Young and Clarke 2000, pp. 361–366; Holsinger 2000, pp. 64–65; Primack 1998, pp. 279–308). Small population sizes render species vulnerable to genetic risks that can have individual or population-level consequences on the genetic level and can increase the species' susceptibility to demographic problems, as explained in more detail above for the blue-billed curassow (Factor E, Small Population Size) (Charlesworth and Charlesworth 1987, p. 238; Shaffer 1981, p. 131). Once a population is reduced below a certain number of individuals, it tends to rapidly decline towards extinction (Holsinger 2000, pp. 64–65; Soulé 1987, p. 181; Gilpin and Soulé 1986, p. 25; Franklin 1980, pp. 147–148).

In the absence of quantitative studies specific to this species, a general approximation of minimum viable population size is the 50/500 rule, as described above as part of the Factor E analysis for the brown-banded antpitta (Shaffer 1981, pp. 132–133; Soulé 1980, pp. 160–162). The total population size of the gorgeted wood-quail is estimated to be between 186 and 486 individuals. While 186 individuals is above the minimum population size required to avoid short-term genetic consequences, 486 falls just below the threshold minimum number of 500 individuals required for long-term fitness of a population and does not take into account that not all members of the population will be contributing to population growth at any one time.

Because the gorgeted wood-quail exists in two isolated, disjunct habitat fragments, between which they are unlikely to disperse, an examination of the fitness of each subpopulation is more appropriate. For the purposes of this analysis, although we have reservations about the precision of these estimates (see Population Estimates discussion above), we will use the following two population estimates: 250 individuals in Northern Santander and 30–66 individuals in southern Santander. Upon examination of these estimates, both populations are clearly below the threshold required for long-term fitness in a population. The lower limit of the population estimate for the southern Santander population is below the threshold required to avoid short-term risks such as inbreeding and demographic shifts, whereas the upper limit is barely above the 50-individual threshold. Therefore, we currently consider these subpopulations (and the species as a whole) to be at risk due to the lack of short- and long-term viability.

Summary of Factor E

The gorgeted wood-quail is unlikely or incapable of dispersing into suitable habitat that is isolated from extant populations, and the species' overall small population size makes it vulnerable to genetic and demographic risks that negatively impact the species' short- and long-term viability. Habitat destruction through deforestation (Factor A) and overutilization through hunting (Factor B) have greatly affected the species' current population size. Believed to be extinct or on the verge of extinction within the past 30 years, the species is now confirmed in three areas of two disjunct locations. The gorgeted wood-quail's small population size, combined with its restricted range and inability to repopulate disjunct suitable habitat following local extirpations, makes the species particularly vulnerable to the threat of adverse natural (e.g., genetic, demographic, or environmental) and manmade (e.g., hunting or deforestation) events that destroy individuals and their habitat.

Gorgeted Wood-Quail Status Determination

The five primary factors that threaten the survival of the gorgeted wood-quail are: (1) Habitat destruction, fragmentation, and degradation (Factor A); (2) overexploitation due to hunting (Factor B); (3) predation (Factor C); (4) inadequacy of regulatory mechanisms to reduce the threats to the species (Factor D); and (5) small population size and isolation of remaining populations (Factor E). The gorgeted wood-quail, a small terrestrial bird, prefers primary montane forests or adjacent secondary forests at altitudes between 1,750 and 2,050 m (5,741 and 6,726 ft). The species' historic range has been reduced by 92 percent, extirpating the species from its type locality in the Department of Cundinamarca and causing the species to shift to the extremes of its range and elevational distribution (Factor A). The estimated suitable habitat available to the species is approximately 10–27 km^2 (4–10 mi^2).

Within the past decade, the gorgeted wood-quail has been confirmed in only three locations: Serranía de los Yarguíes, in northern Santander, and adjacent localities in the Guanentá-Alto Rio Fonce Flora and Fauna Sanctuary and Cachalú Biological Reserve, in southern Santander. Much of the primary forest, mid-elevation habitat preferred by the species has been destroyed by human activities, such as slash-and-burn agriculture, grazing, and extractive industries (Factor A). Illegal crop production, which continues throughout the species' range, has altered soil compositions, hindering regeneration of abandoned fields. In addition, drug eradication programs involving the aerial spraying of nonspecific herbicides have further degraded the environment and destroyed primary forest habitat.

In combination, these threats exacerbate the negative consequences to the species. For example, habitat fragmentation (Factor A) increases the species' vulnerability to hunting (Factor B). Poaching, in combination with habitat destruction, may have led to the local extirpation of the gorgeted wood-quail from Cuchilla del Ramo. This population was only discovered in 1970 and, amidst ongoing habitat destruction and hunting pressures, has not been observed there since 1988. Thus, deforestation and hunting within the past 30 years may have led to the extirpation of the gorgeted wood-quail from this location.

Habitat fragmentation also exposes the species to greater risk of extinction caused by adverse natural (e.g., genetic, demographic, or environmental) and manmade (e.g., hunting or deforestation) events (Factor E). The species' population has decreased by up to 9 percent in the past 10 years and has likely been extirpated from at least one location (Cundinamarca) due to habitat loss and from another locality (Cuchilla del Ramo) due to a combination of habitat loss and hunting. The global population of the gorgeted wood-quail is estimated to be between 187 and 486 individuals. Given that the gorgeted wood-quail is likely to interact as subpopulations and is unlikely to disperse between patches of fragmented habitat, the effective population size is actually much smaller than its estimated global population would imply. This small population size puts the gorgeted wood-quail at risk from both near-term genetic complications (such as

inbreeding and demographic shifts) and lack of long-term fitness (such as the ability to adapt to changing conditions). These potential genetic problems are exacerbated by ongoing human-induced threats, such as habitat destruction (Factor A) and hunting (Factor B), factors which are not being mitigated by existing regulations (Factor D) and are further magnified because the species is unlikely to repopulate isolated patches of suitable habitat where the species has undergone decline or local extirpation, increasing the likelihood of local extirpations (Factor E).

The gorgeted wood-quail is listed as critically endangered, making it illegal to hunt the species, and two of the three known localities are within protected areas. However, habitat destruction and poaching are ongoing throughout the species' range (Factor D). Thus, the regulations in place are ineffective in protecting the gorgeted wood-quail and its habitat.

We have carefully assessed the best available scientific and commercial information regarding the past, present, and potential future threats faced by the gorgeted wood-quail. We consider the ongoing threats to the gorgeted wood-quail, habitat destruction (Factor A), hunting (Factor B), and predation (Factor C), exacerbated by the species' small population size and limited dispersal ability (Factor E), and compounded by inadequate regulatory mechanisms to mitigate these threats (Factor D), to be equally present and of the same magnitude throughout the species' entire current range. Based on this information, we find that the gorgeted wood-quail is in danger of extinction throughout its range.

Esmeraldas woodstar (Chaetocercus berlepschi) Biology and Distribution

Species Description

Esmeraldas woodstar, a member of the hummingbird family (Trochilidae) and endemic to Ecuador, is approximately 6.5 cm (2.5 in.) in length (del Hoyo *et al.* 1999, p. 678; Ridgely and Greenfield 2001b, p. 295; Schuchmann 1999, p. 468; Williams and Tobias 1991, p. 39). The species is locally known as ''Colibrí de Esmeraldas'' or ''Estrellita esmeraldeña'' (UNEP–WCMC 2008b). Both sexes have striking violet, green, and white plumage. The male has a narrow band across its breast, whereas the female has a full white underbody (BLI 2007c, p. 1; Ridgely and Greenfield 2001b, plate 42).

Taxonomy

Esmeraldas woodstar was first taxonomically described by Simon in 1889 (BLI 2007e, p. 1). The type specimen (the actual specimen that was first described) of the Esmeraldas woodstar was obtained from the moist forest habitat near Esmeraldas City, in the Department of Esmeraldas (Collar *et al.* 1992, p. 533). Esmeraldas City is, therefore, referred to as the ''type locality.''

Simon placed the species in the Trochilidae family, under the name *Chaetocercus berlepschi.* The species is also known by the synonym *Acestrura berlepschi.* Both CITES and BirdLife International recognize the species as *Chaetocercus berlepschi* (UNEP–WCMC 2008b, p. 1; BLI 2007e, p. 1). Therefore, we accept the species as *Chaetocercus berlepschi,* which follows the Integrated Taxonomic Information System (ITIS 2008).

Habitat and Life History

Esmeraldas woodstar is a range-restricted, forest-dwelling species with highly localized populations (BLI 2007f, pp. 1–3; Schuchmann 1999, p. 532; Collar *et al.* 1992, p. 533). Esmeraldas woodstar prefers primary forest and is usually found in lowland semi-evergreen forests (cloud or fog forests) and has occasionally been seen in secondary-growth semihumid (moist) habitat during the breeding season (Best and Kessler 1995, p. 141; BLI 2007c, p. 3; Hummingbird Monitoring Network 2006, p. 1; BLI 2004, p. 2; Ridgely and Greenfield 2001b, p. 295; del Hoyo *et al.* 1999, p. 678; Schuchmann 1999, p. 468; Stattersfield *et al.* 1998, p. 211; Collar *et al.* 1992, p. 533; Williams and Tobias 1991, p. 39). Esmeraldas woodstar has not been seen in secondary-growth forests at any other time of year, and researchers are not certain that the species can survive in secondary forests year-round (BLI 2007c, p. 3). The species has mostly been recorded at elevations between 50 and 150 m (164 and 492 ft) (Ridgely and Greenfield 2001a, p. 390; Ridgely and Greenfield 2001b, p. 295), but has occasionally been observed above 500 m (1,640 ft) (i.e., at Loma Alta; Factor A) (Ridgely and Greenfield 2001b, p. 295; Best and Kessler 1995, p. 141; del Hoyo *et al.* 1999, p. 678; Schuchmann 1999, p. 468; Stattersfield *et al.* 1998, p. 211; Williams and Tobias 1991, p. 39).

Esmeraldas woodstar has been seen most often along forest borders, with females especially seen perching on dead twigs (Ridgely and Greenfield 2001b, p. 295). The species forages mainly in the canopy and has been recorded ''hawking'' insects from the air, as well as foraging nectar from flowers of the strawberry tree (*Muntingia calabura*), river koko (*Inga vera*), and mango tree (*Mangifera* spp.) (Ridgely and Greenfield 2001b, p. 295; Becker *et al.* 2000, p. 55; del Hoyo *et al.* 1999, p. 678). As recently as 1999, there were no known breeding sites for the Esmeraldas woodstar (del Hoyo *et al.* 1999, p. 678). Today, one breeding site has been located in the cloud forests of the Colonche Hills (Hummingbird Monitoring Network 2006, p. 1), in the Department of Guayas (Best and Kessler 1995, p. 54). The breeding season is from December to March (BLI 2007c, p. 3). Little else is known of the Esmeraldas woodstar's breeding habits or other activities during most of the year (Ridgely and Greenfield 2001a, pp. 389–390). The species seems to ''disappear'' from known locations during nonbreeding months (BLI 2007c, p. 2; Becker *et al.* 2000, p. 55). In general, male hummingbirds breed with several females in one breeding season and the females take responsibility for all remaining reproductive responsibilities, including nest building, incubation, and rearing. Hummingbirds typically produce two eggs per clutch (Schuchmann 1999, pp. 506, 509).

Historical Range and Distribution

The type locality for the Esmeraldas woodstar (the location of its first discovery) was in Esmeraldas, near Esmeraldas City, and the last specimen was observed there and in the Department of Manabi in 1912 (Collar *et al.* 1992, p. 533). The species' historic range has been reduced by 99 percent (Dodson and Gentry 1991, p. 293). The area around its type locality (Esmeraldas City) has been replaced by pastureland and is nearly devoid of all trees (Collar *et al.* 1992, p. 533). After the species went unobserved following the 1912 sightings, it was thought to be extinct, until it was rediscovered in 1990 (Ridgely and Greenfield 2001a, pp. 389–390; Williams and Tobias 1991, p. 39).

Current Range and Distribution

Today, Esmeraldas woodstar ranges in northwestern Ecuador, in the Departments of Esmeraldas, Manabi, and Guayas, along the slopes of the coastal cordillera up to 500 m (1,640 ft) (Ridgely and Greenfield 2001b, p. 295; Schuchmann 1999, p. 468; del Hoyo *et al.* 1999, p. 678; Williams and Tobias 1991, p. 39). The current extent of the species' range is approximately 1,155 km^2 (446 mi^2), in three disjunct and isolated areas (BLI 2004, p. 2; Dodson and Gentry 1991, p. 293).

The species was rediscovered on ridges above the lower Río Ayampe (in northwest Guayas/Manabi) in March 1990, near the Machalilla National Park (BLI 2007c, p. 2; Becker *et al.* 2000, p.

55; Williams and Tobias 1991, p. 39), and again in January 1991 (Ridgely and Greenfield 2001a, p. 389). Subsequent attempts to relocate the species at Río Ayampe (in August 1991 and July 1993) were unsuccessful (Ridgely and Greenfield 2001a, p. 389; Collar *et al.* 1992, p. 533). Researchers subsequently determined that the species occupies this habitat only seasonally, frequenting the Park from December through the spring (March), but is absent from this location during nonbreeding months (BLI 2007c, p. 2; and Greenfield 2001a, p. 389; Becker *et al.* 2000, p. 55) .

Since then, the species has been observed at the following locations: Esmeraldas: Suá, in January 1993, and Muisne, in 1994 (month unknown); Manabi: Isla de La Plata (part of the Machalilla National Park), December–January 1998 (BLI 2007c, p. 2; Ridgely and Greenfield 2001a, p. 389; Williams and Tobias 1991, p. 39). The species was not observed on Isla de La Plata during a bird survey conducted in June 2000 (Cisneros-Heredia 2005, p. 24), reconfirming their absence from this habitat during nonbreeding months.

Population Estimates

Esmeraldas woodstar is considered a rare, range-restricted species with highly localized populations in three general areas (BLI 2007c, pp. 1–3; Schuchmann 1999, p. 532). There have been no population surveys of this species. BirdLife International estimated that the population currently includes between 186 and 373 individuals, based on estimates using similar species of hummingbirds (BLI 2007c, p. 6).

Conservation Status

The Esmeraldas woodstar is identified as an endangered species under Ecuadorian law (EcoLex 2003b, p. 36). This species is classified as 'Endangered' on the IUCN Red List, due to severe fragmentation within the woodstar's restricted range (IUCN 2006).

Summary of Factors Affecting the Esmeraldas Woodstar

Factor A: The Present or Threatened Destruction, Modification, or Curtailment of the Habitat or Range

The Esmeraldas woodstar is restricted to the semihumid forests and woodlands from sealevel to 500 m (1,600 ft) along the Coastal Cordillera of western Ecuador (Ridgely and Greenfield 2001b, p. 295; del Hoyo *et al.* 1999, p. 678). The current extent of the species' range is approximately 1,155 km^2 (446 mi^2), in three disjunct and isolated areas (BLI 2004, p. 2).

Deforestation

The semihumid, semievergreen forest environment preferred by the Esmeraldas woodstar is one of the most threatened forest habitats in the Neotropics (Schuchmann 1999, p. 532; Collar *et al.* 1992, p. 533). This region is also known as the Tumbesian region (which encompasses the coast and foothills beginning in southwestern Ecuador and into the midcoastal area of northwestern Peru) (World Land Trust U.S. 2008, p. 1). This habitat type has been reduced by over 99 percent (Dodson and Gentry 1991, p. 293), making this region one of the most vulnerable endemic bird areas in South America (Stattersfield *et al.* 1998, p. 214). Deforestation, understory degradation, and limited habitat size are among the biggest impacts to resident birds in the Tumbesian region (Stattersfield *et al.* 1998, p. 214).

Forested habitat within western Ecuador, including that within the Esmeraldas woodstar's range, has diminished rapidly due to logging, clearing for agriculture, and road development (Dodson and Gentry 1991, pp. 283–293). The primary moist forest habitat at the species' type locality (Esmeraldas City) has been replaced with pastures and scattered trees (Collar *et al.* 1992, p. 533). Dodson and Gentry (1991, p. 293) indicated that rapid habitat loss is continuing and that extant forests will be eliminated in the near future if deforestation continues. Recent reports indicate that forest habitat loss continues in Ecuador. Between the years 1990 and 2005, Ecuador lost a total of 2.96 million ha (7.31 million ac) of primary forest, which represents a 16.7 percent deforestation rate and a total loss of 21.5 percent of forested habitat since 1990 (Butler 2006b, pp. 1–3; FAO 2003b, p. 1). Very little suitable habitat remains for the species, and remaining habitat is highly fragmented (BLI 2004a, p. 2).

Other Human Factors

Ongoing deforestation has transformed forested habitat within the region to a patchwork of cropland, with fewer than 5 percent of the forested areas remaining only on steep slopes that cannot be cultivated (Best and Kessler 1995, p. 35; Stattersfield *et al.* 1998, p. 214). Persistent grazing from goats and cattle has decimated the understory vegetation and any secondary forest growth (BLI 2004a, p. 2). Researchers have observed that road building and other infrastructure improvements in previously remote forested areas have increased accessibility and further facilitated habitat destruction, exploitation, and human settlement (Etter *et al.* 2006, p. 1; Álvarez 2005, p. 2,042; Cárdenas and Rodríguez Becerra 2004, pp. 125–130; Viña *et al.* 2004, pp. 118–119; Hunter 1996, pp. 158–159). Fragmented habitat also increases predator access to the forest, exposing the species to increased risk of predation (Factor C).

Refugia

The species is currently known in three localities: (1) Isla de la Plata, (2) Machalilla National Park, and (3) Loma Alta Communal Ecological Reserve.

(1) Isla de la Plata: This 1,420-ha (3,508-ac) island is approximately 27 km (17 mi) from the coast of the Department of Manabí and is actually part of the Machalilla National Park (see below). The species was last observed on the island in 1998 (BLI 2007c, p. 2; Becker *et al.* 2000, p. 55). The island is mostly uninhabited, but tourism for bird-watching occurs there year-round (BLI 2007c, p. 9), which occasionally disturbs the native birds. Nonnative domestic animals, including goats (*Capra hircus*), were introduced to the island many years ago (Curry 1993, p. 24). Nonnative predators, which have also been introduced to the island, are discussed below under Factor C. The grazing activity of the goats has destroyed understory habitat on the island. As of 2007, BirdLife International reports that an eradication program is underway to remove these feral animals from the island (BLI 2007c, p. 10). Despite a report, in 1991, that the goat population on the island had reportedly been reduced from an estimated 300 to 30 animals (Curry 1993, p. 24), the colony of goats apparently remains extant to this day (BLI 2007c, p. 10).

(2) Machalilla National Park: This 34,393-ha (84,985-ac) Park was established in 1979 (BLI 2007c, pp. 11, 13) and is designated as a Ramsar Wetland of International Importance (BLI 2007c, p. 13) (see Factor D). In addition to the male sighting on Isla de La Plata, a female was also observed within the Park in 1998 (Becker *et al.* 2000, p. 55). The Park encompasses a variety of habitats, including high-elevation humid and cloud forests and lower-elevation slopes covered with semideciduous and deciduous forests (BLI 2007c, pp. 11).

This park is populated, and residents subsist on farming and cattle-raising (BLI 2007c, pp. 11, 13; Lasso 1997, p. 3). Portions of land within the Park have been converted to pastures or cropland (Lasso 1997, p. 3). Some previously deforested areas have been left to regenerate (BLI 2007c, p. 13). However,

ongoing grazing is hindering understory development in forest areas left to regenerate (BLI 2007c, pp. 10, 13, 17). Residents continue to selectively harvest trees and nontimber products; this activity is not monitored and the extent of the impact is unknown (BLI 2007c, p. 13). The Park is surrounded by a matrix of altered habitat, dominated by agricultural crops such as bananas, corn, sugarcane, tomatoes (*Lycopersicon esculentum*), yucca (*Yucca* spp.), and pasturelands (BLI 2007c, p. 11; Lasso 1997, p. 3). A highway built around the outskirts of the park provides greater access to more areas within the Park (BLI 2007c, p. 13). Other activities in the area, including a fish meal processing plant, petroleum waste discharges into the sea, and accumulation of solid waste, are potential sources of pollution within the Park (Lasso 1997, p. 3).

(3) Loma Alta Communal Ecological Reserve: This 6,000-ha (14,826-ac) area was declared a Reserve in 1996 (BLI 2007c, p. 17). The Reserve was created to protect the watershed and to help preserve the land of four groups of indigenous inhabitants. The Reserve encompasses a variety of habitats from dry to cloud forests (BLI 2007c, p. 15). About 500 ha (1,235 ac) of the Reserve is dedicated to cultivation of the Panama hat plant (*Carludovica palmata,* locally known as ''Paja Toquilla''), which is processed and sold by the community. Cattle-raising has increased in recent years and the regenerating forests have again been decimated by overgrazing. Logging, agriculture, and slash-and-burn farming continue to impact this Reserve (BLI 2007c, p. 17).

Summary of Factor A

Esmeraldas woodstars are rare, range-restricted species with highly localized populations in three disjunct locations within an area of approximately 1,155 km^2 (446 mi^2) (BLI 2004, p. 2; Dodson and Gentry 1991, p. 293). The evergreen forests preferred by this species have undergone extensive deforestation, and remaining habitat is highly fragmented. Habitat alteration and human activities, such as slash-and-burn agriculture and cattle and goat grazing, are occurring throughout the species' range, including the protected areas in which the species occurs (Machalilla National Park, including Isla de la Plata, and Loma Alta Communal Ecological Reserve). Infrastructure development and economic activities (such as fish meal processing and nontimber forest product extraction) occur throughout the species' known breeding range. Logging, road development, and pollution from industrial activities occur within or near protected areas. Habitat destruction, alteration, and conversion have reduced the available habitat for this species by 99 percent. These activities are ongoing throughout the species' range, including within protected areas (Factor D), and are expected to continue.

Factor B: Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Stattersfield *et al.* (1998, p. 214) reported that birds in the Tumbesian region are, in part, impacted by hunting and trade (Stattersfield *et al.* 1998, p. 214). However, we have no current information to suggest that hunting for domestic or international consumption or trade is impacting the Esmeraldas woodstar including BLI (2007c, p. 3, and Best and Kessler 1995? pp. 124, 141)). Locally, the communities in Loma Alta, where this species occurs, are involved in conservation activities, including protecting native species in Loma Alta Communal Ecological Reserve against hunting, timber harvest and agricultural expansion.

In 1987, the Esmeraldas woodstar was listed in CITES Appendix II (UNEP–WCMC 2008b, p. 1), which includes species that are not necessarily threatened with extinction, but which require regulation of international trade to ensure that trade of the species is compatible with the species' survival. International trade in specimens of Appendix-II species is authorized through permits or certificates under certain circumstances, including verification that trade will not be detrimental to the survival of the species in the wild and that the specimens were legally acquired (UNEP–WCMC 2008a, p. 1). According to the World Conservation Monitoring Centre (WCMC), there has been one international transaction permitted by CITES since listing. In 1993, 100 ''bodies'' were imported to Mexico through the United States. According to the trade data, the specimens were being traded for commercial purposes and were seized by inspectors (UNEP–WCMC 2008d, p. 1). No further CITES-recorded trade in this species has occurred since that time. Although we are no longer able to determine the exact details surrounding this seizure, we consider the seizure and lack of ensuing trade to be supportive that CITES has been effective in controlling commercial trade in this species. Therefore, we do not consider international trade for commercial purposes to be a threat to the species.

Tourism occurs year-round at Isla de la Plata and has been known to occasionally disturb the native birds (BLI 2007c, pp. 2, 9–10). There is no information regarding whether Esmeraldas woodstar is among the native species that is adversely affected by ecotourism or other human disturbance.

We are unaware of any other information currently available that addresses the occurrence of overutilization for commercial, recreational, scientific, or educational purposes that may be affecting the Esmeraldas woodstar population. Consequently, we do not consider this factor to be a threat to the species.

Factor C: Disease or Predation

We are unaware of information regarding disease or the potential for significant disease outbreaks in the Esmeraldas woodstar. As a result, we do not consider disease to be a threat to the species.

Hummingbird eggs and chicks are most vulnerable to predation. Known hummingbird predators that are found in cloud forest habitat in Ecuador include domestic cats (*Felis catus*), feral cats, hawks (family Accipitridae), owls (order Strigiformes), and snakes (suborder Serpentes) (Rosso 2006, p. 35; Borchardt 2004, p. 5; The Hummingbird Society, no date (n.d.), p. 1). Many insect-eating predators have been known to prey on hummingbirds because of their small size, including praying mantis (family Mantidae), spiders (class Arachnida), bees and wasps (order Hymenoptera), frogs (order Anura), and largemouth bass (*Micropterus salmoides*) (Rosso 2006, p. 35, Borchardt 2004, p. 5; The Hummingbird Society n.d., p. 1). According to the FAO–Fisheries and Aquaculture Department (2000, p. 1), largemouth bass is a nonnative invasive species that was introduced to Ecuador sometime prior to 1988. Many of these potential Esmeraldas woodstar predators are found within the Machalilla National Park (Emmons and Albuja 1992, pp. 120–121), both on the mainland and on Isla de La Plata (see Factor A).

On Isla de La Plata, nonnative predators, including cats and spiny rats (*Proechimys decumanus*), were introduced to the island many years ago (BLI 2007c, p. 10; Curry 1993, p. 24). Cats are opportunistic predators and their diet comprises a variety of animals, including birds (Rosero 2006, p. 5). It was conjectured that the wild cats on Isla de La Plata would keep the rat population in check. However, Curry (1993, p. 24) examined the stomach contents of several cats on the Island and found that they contained egg shell fragments, not mammal hair, indicating that the cats were preying upon bird

nests. Esmeraldas woodstar is observed on Isla de La Plata only during breeding season (BLI 2007c, p. 2; Cisneros-Heredia 2005, p. 24; Becker *et al.* 2000, p. 55), which renders the woodstar especially vulnerable to egg predation by cats. Cats are also considered among the most common predators of nonnesting hummingbirds, especially during torpor, a resting state induced in hummingbirds when energy levels are low (BLI 2008b, p. 1; The Hummingbird Society n.d., p. 1; Schuchmann 1999, p. 485). During torpor, hummingbirds are slow to react to external stimuli (Schuchmann 1999, p. 485). Cats are responsible for endangering other island-dwelling hummingbirds, including the critically endangered Fernández firecrown (*Sephanoides fernandensis*) (native to the Juan Fernández Islands, Chile) (BLI 2008b, p. 1; The Hummingbird Society n.d., p. 1).

According to BirdLife International, an eradication program is underway to remove feral animals from the island (BLI 2007c, p. 10). One project to control the introduced cat population on Isla De La Plata, being supported by the World Conservation Foundation, would trap the feral cats, neuter them, and return them to the wild, with the eventual goal of preventing further reproduction of the feral population. This project will also help to better quantify the extent of the invasion on the island (Rosero 2006, p. 5). However, predation on the island continues to be a threat to native bird species, including the Esmeraladas woodstar, both on the Island and in Machalilla National Park (BLI 2007c, p. 10; Rosero 2006, p. 5; Emmons and Albuja 1992, pp. 120–121).

The Esmeraldas woodstar's historic range has been reduced by 99 percent (Dodson and Gentry 1991, p. 293), and remaining suitable habitat is highly fragmented (BLI 2004a, p. 2; Stattersfield *et al.* 1998, p. 214; Best and Kessler 1995, p. 35). Studies have shown that habitat fragmentation increases the potential predation pressure within habitat fragments by facilitating the predators' access throughout the fragment and because smaller fragments support smaller predators, which tend to prey upon the more vulnerable life-history stages of the Esmeraldas woodstar, eggs and juveniles (Keyser *et al.* 2002, p. 186; Renjifo 1999, p. 1,133; Keyser *et al.* 1998, p. 991; Arango-Vélez and Kattan 1997, pp. 137–143; Hoover *et al.* 1995, p. 151; Gibbs 1991, p. 157; Wilcove 1985, p. 1,214). These studies were described in more detail above, as part of the Factor C analysis for the blue-billed curassow.

Summary of Factor C

Domestic and feral cats, rats, hawks, owls, snakes, praying mantis, spiders, bees, wasps, frogs, and largemouth bass are all predators of hummingbirds that are found in Esmeraldas woodstar habitat. Predation results in the direct removal of eggs, juveniles, and adults from the population. Esmeraldas woodstars produce a low clutch size and are particularly vulnerable to egg predation by cats on Isla de la Plata (see Habitat and Life History). Esmeraldas woodstar habitat is much reduced and highly fragmented (Factor A), and studies on similar species in similar Andean habitats indicate that vulnerability to predation by generalist predators increases with increased habitat fragmentation and smaller patch sizes. Predation can remove potentially reproductive adults from the breeding pool and exacerbates the genetic complications associated with the species' small population size (Factor E), increasing the species' vulnerability to local extirpation. Therefore, we find that predation, exacerbated by ongoing habitat destruction (Factor A), is a threat to the Esmeraldas woodstar.

Factor D: The Inadequacy of Existing Regulatory Mechanisms

Regulatory mechanisms may provide species-specific or habitat-specific protections. An evaluation of the adequacy of regulatory mechanisms within Ecuador to mitigate or remove the threats to the Esmeraldas woodstar is provided below, beginning with species-specific and followed by habitat-specific protection mechanisms.

The Esmeraldas woodstar is protected under Ecuadorian law by Decree No. 3,516 of 2003 (Unified Text of the Secondary Legislation of the Ministry of Environment (EcoLex 2003b, pp. 1–2 and 36). Decree No. 3,516 summarizes the laws governing environmental policy in Ecuador and provides that the country's biodiversity be protected and used primarily in a sustainable manner. Appendix 1 of Decree No. 3,516 lists the Ecuadorian fauna and flora that are categorized as critically endangered (En peligro critico), endangered (En peligro), or vulnerable (Vulnerable) (EcoLex 2003b, p.17). Under this law, Esmeraldas woodstar is categorized as endangered, under the synonym *Acestrura berlepschi* (EcoLex 2003b, p. 36). This threat status confers protections upon the species, including protection from hunting or commercial take, under Resolution No. 105 of 2000 (Regulatory control of hunting seasons and wildlife species in the country) and Agreement No. 143 of 2003 (Standards for the control of hunting seasons and licenses for hunting of wildlife). Resolution No. 105 and Agreement No. 143 regulate and prohibit commercial and sport hunting of all wild bird species, except those specifically identified by the Ministry of the Environment or otherwise permitted (EcoLex 2000, p.1; EcoLex 2003a, p. 1). Under this law, the Ministry of the Environment does not permit commercial or sport hunting of the Esmeraldas woodstar because of its status as a critically endangered species (EcoLex 2002b, p. 17). However, we do not consider hunting (Factor B) to be a current threat to the Esmeraldas woodstar and these laws do not mitigate threats to the species from habitat destruction (Factor A), predation (Factor C), or its small population size (Factor E). Therefore, protection under these laws does not reduce any existing threats to the species.

Esmeraldas woodstar is listed in Appendix II of CITES, to which Ecuador became a Party in 1975 (UNEP–WCMC 2008a, p. 1; USFWS 2008, p. 1). CITES was described in more detail above, as part of the Factor E analysis for the blue-billed curassow. As discussed under Factor B for the Esmeraldas woodstar, we consider that this international treaty has minimized the potential threat to the species from international trade and do not consider international trade to be a threat impacting the Esmeraldas woodstar. However, this treaty does not mitigate threats to the species from habitat destruction (Factor A), predation (Factor C), or its small population size (Factor E). Therefore, protection under this Treaty does not reduce any existing threats to the species.

Ecuador has numerous laws and regulations pertaining to forests and forestry management, including: the Forestry Act (comprising Law No. 74 of 1981—Forest Act and conservation of natural areas and wildlife (Faolex 1981, pp. 1–54) and Law No. 17 of 2004—Consolidation of the Forest Act and conservation of natural areas and wildlife (Faolex 2004, pp. 1–29)); a Forestry Action Plan (1991–1995); the Ecuadorian Strategy for Forest Sustainable Development of 2000 (Estrategia para el Desarrollo Forestal Sostenible); and Decree 346, which recognizes that natural forests are highly vulnerable (ITTO 2006, p. 225). However, the International Tropical Timber Organization considers ecosystem management and conservation in Ecuador, including effective implementation of mechanisms that would protect the Esmeraldas woodstar and its habitat, to be lacking

(ITTO 2006, p. 229). Habitat destruction is ongoing (Butler 2006b, pp. 1–3; FAO 2003b, p. 1) and extensive (BLI 2004a, p. 2; Stattersfield *et al.* 1998, p. 214; Best and Kessler 1995, p. 35) throughout the species' range (Factor A). Thus, these laws are ineffective at protecting Esmeraldas woodstar habitat.

Extractive harvest practices may pose a threat to the Esmeraldas woodstar (BLI 2007c, p. 13) (Factor A). In 2004, Law No. 17 (Faolex 2004, pp. 1–29) amended the Forest Act of 1981 (Law No. 74) (Faolex 1981, pp. 1–54) to include five criteria for sustainable forest management: (i) Sustainable timber production; (ii) the maintenance of forest cover; (iii) the conservation of biodiversity; (iv) coresponsibility in management; and (v) the reduction of negative social and environmental impacts (ITTO 2006, p. 225; Aguilar and Vlosky 2005, pp. 9–10). In 2001, the Ecuadorian Government worked with the private sector to develop a system of monitoring and control of forest harvest practices. However, in 2003, the Supreme Court of Ecuador declared that the control system was unconstitutional, and new control systems are now being developed (ITTO 2006, p. 225). Approximately 70 percent of the forest products harvested are harvested illegally, are used as fuel wood, or are discarded as waste (ITTO 2006, p. 226; Aguilar and Vlosky 2005, p. 4). Because the extractive harvesting industry is not monitored, the extent of the impact is unknown (BLI 2007c, p. 13). However, we find this law is currently inadequate in monitoring the impacts of extractive harvesting on the Esmeraldas woodstar or to protect the species from potential impacts of extractive harvesting (Factor A).

The governmental institutions responsible for natural resource oversight in Ecuador appear to be under-resourced, and there is a lack of law enforcement on the ground. Despite the creation of a national forest plan, there appears to be a lack of capacity to implement this plan due to insufficient political support, unclear or unrealistic forestry standards, inconsistencies in application of regulations, discrepancies between actual harvesting practices and forestry regulations, the lack of management plans for protected areas, and high bureaucratic costs. These inadequacies have facilitated logging (Dodson and Gentry 1991, pp. 283–293); cattle-raising and persistent grazing from goats and cattle (BLI 2007c, pp. 11, 13, 17; BLI 2004a, p. 2; Lasso 1997, p. 3; Curry 1993, p. 24); clearing for agriculture, subsistence farming, and small local industries (BLI 2007c, pp. 11, 13, 17; Lasso 1997, p. 3; Dodson and Gentry 1991, pp. 283–293); selective harvest of trees for fuelwood and nontimber products (BLI 2007c, p. 13; Aguilar and Vlosky 2005); road development (BLI 2007c, p. 13; Dodson and Gentry 1991, pp. 283–293); and pollution from industrial activities occur within or near protected areas (Lasso 1997, p. 3). In addition, most of Ecuador's forests are privately owned or owned by communities (ITTO 2006, p. 224; Lasso 1997, pp. 2–3), and the management and administration of Ecuador's forest resources and forest harvest practices is insufficient and unable to protect against unauthorized forest harvesting, degradation, and conversion (ITTO 2006, p. 229). Habitat conversion and alteration are ongoing throughout the range of the Esmeraldas woodstar, including within protected areas (BLI 2007c, pp. 10, 13, 17; Butler 2006b, pp. 1–3; FAO 2003b, p. 1). Thus, Ecuadorian forestry regulations have not mitigated the threat of habitat destruction (Factor A).

The Ecuadorian Government recognizes 31 different legal categories of protected lands (e.g., national parks, biological reserves, geo-botanical reserves, bird reserves, wildlife reserves, etc.). Currently, the amount of protected land (both forested and nonforested) in Ecuador totals approximately 4.67 million ha (11.5 million ac) (ITTO 2006, p. 228). However, only 38 percent of these lands have appropriate conservation measures in place to be considered protected areas according to international standards (i.e., areas that are managed for scientific study or wilderness protection, for ecosystem protection and recreation, for conservation of specific natural features, or for conservation through management intervention) (IUCN 1994, pp. 17–20). Moreover, only 11 percent have management plans, and fewer than 1 percent (13,000 ha (32,125 ac)) have implemented those management plans (ITTO 2006, p. 228).

The Esmeraldas woodstar has been recorded in or near two protected areas: (1) Machalilla National Park (Collar *et al.* 1992, p. 533) and (2) Loma Alta Communal Ecological Reserve. As described under Factor A, both of these protected areas are inhabited and, among other activities, deforestation, livestock grazing, and slash-and-burn agriculture are ongoing within these areas (BLI 2004, p. 2; Wege and Long 1995, p. 174). Thus, this protected area status does not mitigate the threats from habitat destruction (Factor A).

Esmeraldas woodstar occurs within the Machalilla National Park, which was included in the Ramsar List of Wetlands of International Importance in 1990 (BLI 2007c, p. 13). The Ramsar Convention, signed in Ramsar, Iran, in 1971, is an intergovernmental treaty that provides the framework for national action and international cooperation for the conservation and wise use of wetlands and their resources. There are presently 158 Contracting Parties to the Convention (including Ecuador, where the Esmeraldas woodstar occurs), with 1,828 wetland sites, totaling 169 million ha (418 million ac), designated for inclusion in the Ramsar List of Wetlands of International Importance (Ramsar Convention Secretariat 2008, p. 1). Experts consider Ramsar to provide only nominal protection of wetlands, noting that such a designation may increase international awareness of the site's ecological value (Jellison *et al.* 2004, p. 19). However, habitat alteration (Factor A) (BLI 2007c, pp. 10–11, 13; Lasso 1997, p. 3) and predation by feral animals (Factor C) (BLI 2007c, p. 10; Rosero 2006, p. 5; Curry 1993, p. 24), key threats to the Esmeraldas woodstar, are ongoing within the Park, and predation has not been considered as part of the most recent Ramsar site review (Lasso 1997, pp. 1–4). Therefore, this designation as a Ramsar Wetland of International Importance does not mitigate the threats from habitat destruction (Factor A).

Summary of Factor D

Ecuador has adopted numerous laws and regulatory mechanisms to administer and manage wildlife and their habitats. The Esmeraldas woodstar is protected under CITES, which we consider has been effective in mitigating the potential threat to this species from commercial trade (Factor B). Esmeraldas woodstar is listed as endangered and ranges within at least two protected areas (Machalilla National Park and Loma Alta Communal Ecological Reserve). However, on-the-ground enforcement of these laws and oversight of the local jurisdictions implementing and regulating activities is insufficient for these measures to be effective in conserving the Esmeraldas woodstar or its habitat. As discussed for Factor A, habitat destruction, degradation, and fragmentation continue throughout the species' range, including lands within protected areas. Therefore, we find that the existing regulatory mechanisms, as implemented, are inadequate to mitigate the primary threats to the Esmeraldas woodstar from habitat destruction (Factor A), predation (Factor C), or its small population size (Factor E).

Factor E: Other Natural or Manmade Factors Affecting the Continued Existence of the Species

Two additional factors affect the Esmeraldas woodstar: Its minimal likelihood for dispersal and the species' small population size.

Likelihood To Disperse

The Esmeraldas woodstar is confined to locations within the Departments of Esmeraldas, Manabi, and Guayas, in lowland moist forest patches that are disjunct and fragmented (BLI 2007f, pp. 1–3; del Hoyo *et al.* 1999, p. 678; Williams and Tobias 1991, p. 39). The distance between known occupied areas is between 125 and 200 km (78 and 124 mi), with minimal habitat between occupied sights (Best and Kessler 1995, p. 141). In light of the species' small overall population size and the distance between the remaining fragmented primary forested habitats, it is unlikely that the Esmeraldas woodstar would repopulate an isolated patch of suitable habitat following decline or extirpation of that patch (Hanski 1998, pp. 45–46).

Small Population Size

The Esmeraldas woodstar inhabits a very small and severely fragmented range, which is decreasing rapidly in size due to habitat destruction and various other human factors (Ridgely and Greenfield 2001a, pp. 389–390; Collar *et al.* 1992, p. 533). Ongoing declines in the bird's population are linked to persistent habitat destruction (BLI 2007c, p. 2). Before the species was rediscovered in 1991, it was thought to be extinct after not being seen since 1912 (Ridgely and Greenfield 2001a, pp. 389–390). Subsequent surveys of previously known occupied areas have not been successful in locating the species on a consistent basis, and little is known of breeding habits or other activities during most of the year (Ridgely and Greenfield 2001a, pp. 389–390). Experts estimate that the species has undergone a 50–79 percent reduction in population size within the past 10 years and predict that this trend will continue (BLI 2007c, p. 5). The current population estimate for this species is between 186 to 373 birds, with a decreasing population trend (BLI 2007, pp. 2, 6).

Small population sizes render species vulnerable to genetic risks that can have individual or population-level consequences on the genetic level and can increase the species' susceptibility to demographic problems, as explained in more detail above for the blue-billed curassow (Factor E, Small Population Size) (Charlesworth and Charlesworth 1987, p. 238; Shaffer 1981, p. 131). Once a population is reduced below a certain number of individuals, it tends to rapidly decline towards extinction (Holsinger 2000, pp. 64–65; Soulé 1987, p. 181; Gilpin and Soulé 1986, p. 25; Franklin 1980, pp. 147–148).

In the absence of quantitative studies specific to this species, a general approximation of minimum viable population size is the 50/500 rule, as described above, as part of the Factor E analysis for the brown-banded antpitta (Shaffer 1981, pp. 132–133; Soulé 1980, pp. 160–162). The total population size of the Esmeraldas woodstar is estimated to be between 186 and 373 individuals. The lower estimate of 186 individuals meets the theoretical threshold for the minimum effective population size required to avoid risks from inbreeding (N_e = 50 individuals). However, the upper limit of the population, 373 individuals, is below the minimum threshold (N_e = 500 individuals) required for long-term fitness of a population that will not lose its genetic diversity over time and will maintain an enhanced capacity to adapt to changing conditions.

The Esmeraldas woodstar's restricted range combined with its small population size (Cuervo 2002, p. 138; Cuervo and Salaman 1999, p. 7; del Hoyo 1994, p. 361) makes the species particularly vulnerable to the threat of adverse natural (e.g., genetic, demographic, or environmental) and manmade (e.g., deforestation, habitat alteration, wildfire) events that destroy individuals and their habitat (Young and Clarke 2000, pp. 361–366; Holsinger 2000, pp. 64–65; Primack 1998, pp. 279–308). Therefore, we currently consider the single Esmeraldas woodstar population to be at risk due to the lack of long-term viability.

Summary of Factor E

The Esmeraldas woodstar is currently limited to a few small populations within a limited habitat range, with a small estimated population size that leaves the species vulnerable to genetic and demographic risks that negatively impact its long-term viability. The species' population size is estimated to have declined considerably within the past 10 years (50–79 percent), and this rate of decline is expected to continue. Based on this information, we have determined that the species is particularly vulnerable to the threat of adverse natural (e.g., genetic, demographic, or predation) and manmade (e.g., slash-and-burn agriculture or infrastructural development) events that destroy individuals and their habitat, and that these genetic and demographic risks are exacerbated by ongoing habitat destruction (Factor A) and predation (Factor C).

Esmeraldas Woodstar Status Determination

The four primary factors that threaten the survival of the Esmeraldas woodstar are: (1) Habitat destruction, fragmentation, and degradation (Factor A); (2) predation (Factor C); (3) inadequate regulatory mechanisms (Factor D); and (4) limited size and isolation of remaining populations (Factor E). The Esmeraldas woodstar is a tiny hummingbird endemic to Ecuador. Esmeraldas woodstars are a rare, range-restricted species with highly localized populations in three disjunct locations—in the Ecuadorean Departments of Esmeraldas, Guayas, and Manabí. The species occurs in lowland semi-humid or semievergreen forests and woodlands, from sealevel to 500 m (1,600 ft) along the Coastal Cordillera of western Ecuador. Preferring primary evergreen forests, the species is also known to occupy low-altitude secondary-growth areas during the breeding season (December–March). The current extent of the species' range is approximately 1,155 km^2 (446 mi^2).

The primary threat to this species is habitat loss (Factor A), caused by widespread deforestation and conversion of primary forests for numerous human activities. The species' range has been reduced by 99 percent. The semihumid and semievergreen forests preferred by this species have undergone extensive deforestation. Habitat-altering activities that have occurred include: logging; cattle-raising and persistent grazing from goats and cattle; forest clearing for agriculture, subsistence farming, and small local industries; selective harvest of trees for fuelwood and nontimber products; road development; and pollution from industrial activities (Factors A). These activities are ongoing and occurring throughout the species' range—including within protected areas where the species occurs (Machalilla National Park, Isla de La Plata, and Loma Alta Communal Ecological Reserve). Because regulatory mechanisms are ineffective at reducing these activities (Factor D), habitat destruction and alteration are expected to continue.

The species' population is estimated to have declined 50 to 79 percent within the last 10 years, a decline which is attributed to habitat loss. The Esmeraldas woodstar has a small estimated population size (between 186 and 373 individuals), which renders the

species vulnerable to the threat of adverse natural (e.g., genetic, demographic, or predation) and manmade (e.g., slash-and-burn agriculture or infrastructural development) events that destroy individuals and their habitat (Factor E). In addition, the direct loss of habitat through widespread deforestation and conversion for human activities has led to habitat fragmentation and isolation of the remaining populations of the Esmeraldas woodstar. The Esmeraldas woodstar currently occupies three disjunct, isolated patches that are separated by large distances (between 125 and 200 km (78 and 124 mi)), with minimal suitable habitat between occupied sites. Given the species' small population size and the distance between the remaining fragmented primary forested habitats, the species is unlikely to repopulate an isolated patch of suitable habitat following decline or extirpation of the species within that patch (Factor E). This renders the species particularly vulnerable to local extirpation from ongoing habitat destruction (Factor A) and predation (Factor C).

Esmeraldas woodstars are vulnerable to predation by a variety of predators, including domestic and feral cats, rats, hawks, owls, snakes, praying mantis, spiders, bees, wasps, frogs, and largemouth bass (Factor C). Habitat fragmentation (Factor A) contributes to this vulnerability, because research indicates that predation increases with increased habitat fragmentation and smaller patch sizes. Predation leads to the direct removal of eggs, juveniles, and adults from the population, exacerbating risks associated with the species' small population size. Esmeraldas woodstars are particularly vulnerable to predation by wild cats during the breeding season on Isla de La Plata, where cats have been known to prey particularly upon bird eggs. Esmeraldas woodstars produce a low clutch size (see Habitat and Life History), and predation can remove potentially reproductive adults from the breeding pool.

The Esmeraldas woodstar is classified as an endangered species under Ecuadorian law, and part of the species' range is included within two protected areas. Despite numerous laws and regulatory mechanisms to administer and manage wildlife and their habitats, existing laws are inadequate (Factor D) to protect the species and its habitat from ongoing habitat loss (Factor A) and predation by nonnative animals (Factor C), even within the protected areas.

We have carefully assessed the best available scientific and commercial information regarding the past, present, and potential future threats faced by the Esmeraldas woodstar. We consider the ongoing threats to the Esmeraldas woodstar, habitat loss (Factor A) and predation (Factor C), exacerbated by the species' small population size and limited dispersal ability (Factor E), and compounded by inadequate regulatory mechanisms (Factor D), to be equally present and of the same magnitude throughout the species' entire current range. Based on this information, we find that the Esmeraldas woodstar is endangered throughout its range.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and encourages and results in conservation actions by national governments, private agencies and groups, and individuals.

Section 7(a) of the Act, as amended, and as implemented by regulations at 50 CFR part 402, requires Federal agencies to evaluate their actions within the United States or on the high seas with respect to any species that is proposed or listed as endangered or threatened, and with respect to its critical habitat, if any is being designated. However, given that the blue-billed curassow, the brown-banded antpitta, the Cauca guan, the gorgeted wood-quail, and the Esmeraldas woodstar are not native to the United States, no critical habitat is being proposed for designation with this rule.

Section 8(a) of the Act authorizes limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered and threatened species in foreign countries. Sections 8(b) and 8(c) of the Act authorize the Secretary to encourage conservation programs for foreign endangered species and to provide assistance for such programs in the form of personnel and the training of personnel.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered and threatened wildlife. Consequently, these prohibitions would be applicable to the blue-billed curassow, the brown-banded antpitta, the Cauca guan, the gorgeted wood-quail, and the Esmeraldas woodstar. These prohibitions, under 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to ''take'' (take includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or to attempt any of these) within the United States or upon the high seas, import or export, deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of a commercial activity or to sell or offer for sale in interstate or foreign commerce, any endangered wildlife species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken in violation of the Act. Certain exceptions apply to agents of the Service and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 for endangered species, and at 17.32 for threatened species. With regard to endangered wildlife, a permit may be issued for the following purposes: for scientific purposes, to enhance the propagation or survival of the species; and for incidental take in connection with otherwise lawful activities.

Required Determinations

National Environmental Policy Act (NEPA)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), need not be prepared in connection with regulations adopted under section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A list of the references cited in this final rule is available at *http://www.regulations.gov* at Docket No. FWS–R9–IA–2009–12 or upon request (see **FOR FURTHER INFORMATION CONTACT**).

Author(s)

The primary authors of this proposed rule are Arnold Roessler of the Endangered Species Program (Sacramento, California) and Dr. Patricia De Angelis of the Division of Scientific Authority, U.S. Fish and Wildlife Service.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we hereby amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. Amend § 17.11(h), by adding new entries for ''Antpitta, brown-banded'', ''Curassow, blue-billed'', ''Guan, Cauca'', ''Wood-quail, gorgeted'', and ''Woodstar, Esmeraldas'' in alphabetical order under ''Birds'' to the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
Birds							
*	*	*	*	*	*		*
Antpitta, brown-banded	*Grallaria milleri*	Colombia, South America.	Entire	E	813	NA	NA
*	*	*	*	*	*		*
Curassow, blue-billed	*Crax alberti*	Colombia, South America.	Entire	E	813	NA	NA
*	*	*	*	*	*		*
Guan, cauca	*Penelope perspicax.*	Colombia, South America.	Entire	E	813	NA	NA
*	*	*	*	*	*		*
Wood-quail, gorgeted	*Odontophorus strophium.*	Colombia, South America.	Entire	E	813	NA	NA
*	*	*	*	*	*		*
Woodstar, Esmeraldas	*Chaetocercus berlepschi.*	Ecuador, South America.	Entire	E	813	NA	NA
*	*	*	*	*	*		*

Dated: September 20, 2013.

Rowan W. Gould,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–25070 Filed 10–28–13; 8:45 am]

BILLING CODE 4310–55–P

FEDERAL REGISTER

Vol. 78 Tuesday,

No. 209 October 29, 2013

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 225, 500 et al.

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 225, 500, 507, and 579

[Docket No. FDA–2011–N–0922]

RIN 0910–AG10

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish requirements for current good manufacturing practice in manufacturing, processing, packing, and holding of animal food. FDA also is proposing regulations to require that certain facilities establish and implement hazard analysis and risk-based preventive controls for food for animals. FDA is taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to animals or humans and is intended to build an animal food safety system for the future that makes modern, science and risk-based preventive controls the norm across all sectors of the animal food system.

DATES: Submit either electronic or written comments on the proposed rule by February 26, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by November 29, 2013 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0922 and/or Regulatory Information Number (RIN) 0910–AG10 by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

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Instructions: All submissions received must include the Agency name and Docket No 2011–N–0922 and RIN 0910–AG10 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

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FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9207, email: *kim.young@fda.hhs.gov*.

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Executive Summary

Purpose and Coverage of the Proposed Rule

The proposed rule would establish regulations regarding the manufacturing, processing, packing, or holding of animal food in two ways. First, it would create new current good manufacturing practice (CGMP) regulations that specifically address the manufacturing, processing, packing, and holding of animal food. Second, it would include new preventive control provisions intended to implement section 103 of the FDA Food Safety Modernization Act (FSMA) for animal food. In general, with some exceptions the new preventive control provisions would apply to animal food facilities that are required to register with FDA under FDA's current food facility registration regulations. These preventive controls would include requirements for covered facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Facilities would also be required to monitor their controls, verify that they were effective, take any appropriate corrective actions, and maintain records documenting these actions.

To put these changes in context, and to provide legal, regulatory, scientific, and technical information relevant to the new provisions, the Agency provides several sections of background. This background discusses the current approaches to animal food safety; summarizes the Food and Drug Administration Amendments Act of 2007 (FDAAA) as it applies to pet food; provides an overview of the provisions of FSMA applicable to this proposed rule; and describes a variety of hazards that have been associated with animal foods and animal food safety problems (including outbreaks of foodborne illness) that have resulted from these hazards. An Appendix also describes the role of testing as a verification measure in a food safety system and the role of supplier approval and verification programs in a food safety system.

Summary of the Major Provisions of the Proposed Rule

The proposed rule would establish certain CGMP provisions to ensure the safety and suitability of animal food. The implementation of these practices and procedures would protect against the contamination of animal food. The proposed CGMPs would establish procedures in areas such as buildings and facilities, design and layout, cleaning and maintenance, pest control, and personnel hygiene.

The proposed rule also would implement the requirements of section 103 of FSMA for animal food facilities that must register under section 415 of the FD&C Act (21 U.S.C. 350d) to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the proposed rule would establish requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls for hazards that are reasonably likely to occur;
- Monitoring;
- Corrective actions;
- Verification; and
- Associated records.

The application of the preventive controls would be required only in cases where facilities determine that hazards are reasonably likely to occur. The Agency does not expect that all possible preventive measures and verification procedures would be applied to all animal foods at all facilities.

The proposed rule would also establish a series of exemptions (including modified requirements in some cases) from the requirements for hazard analysis and preventive controls. Facilities that manufacture, process, pack, or hold animal food and that are required to register with FDA under section 415 of the FD&C Act would be required to comply with the proposed regulation unless they are covered by an exemption. The table immediately below summarizes these proposed exemptions in general terms. Importantly, the table in this Executive Summary does not include all the details that a facility must consider to determine whether an exemption applies. The Agency provides those details in the proposed rule (proposed § 507.5) and explains them in section VIII.C.

PROPOSED EXEMPTIONS FROM THE NEW REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Who or what would be exempt from the requirements for hazard analysis and risk-based preventive controls	Notes
"Qualified Facility" as defined by FSMA • Business with average annual sales of <$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or • Very small business ○ Option 1: Total annual sales of <$500,000 ○ Option 2: Total annual sales of <$1,000,000 ○ Option 3: Total annual sales of <$2,500,000	FDA is proposing three options for defining "very small business" and requests comment on which to adopt in a final rule. Modified requirements would apply—i.e., a qualified facility would be required to: • Notify FDA about its status; and • Either: ○ Notify FDA that it is addressing hazards through preventive controls and monitoring; or ○ Notify FDA that it complies with applicable local regulations, and notify consumers of the name and complete business address of the facility where the animal food was manufactured or processed.
• Low risk, on farm activities performed by a small business (<500 employees): or • Low-risk, on-farm activities performed by a very small business ○ Option 1: very small = <$500,000 ○ Option 2: very small = <$1,000,000 ○ Option 3: very small = <$2,500,000	Small and very small on-farm businesses conducting these low risk activities would be exempt from most of the rule's requirements. The Agency would define the low-risk activities that qualify for the exemption, including the specific foods to which they relate (such as re-packing intact fruits and vegetables, or grinding/milling/cracking/crushing grains).
Activities that are subject to the "low-acid canned food" requirements of § 500.23 (21 CFR 500.23) and part 113 (21 CFR part 113)	• The exemption applies only with respect to microbiological hazards. • The facility must be in compliance with part 113.
Activities of a facility that are subject to section 419 of the FD&C Act (21 U.S.C. 350h) (Standards for Produce Safety)	Published in the **Federal Register** January 16, 2013 (78 FR 3504).
Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	A facility that stores raw agricultural commodities that are fruits or vegetables would not be exempt.
Facilities solely engaged in the storage of packaged animal food that is not exposed to the environment	Modified requirements would apply for the storage of refrigerated packaged animal food.

The proposed rule also would establish the conditions under which an exemption granted to a "qualified facility" could be withdrawn, and the procedures that would be followed to withdraw such an exemption. The proposed rule would establish requirements that would apply to all records that would be required by the various proposed provisions. The proposed recordkeeping provisions would implement specific requirements of FSMA regarding records associated with the new provisions for hazard analysis and risk-based preventive controls and would allow facilities to show, and FDA to determine, compliance with the regulatory requirements.

The proposed rule would require that a qualified individual prepare the food safety plan, validate preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the required reanalysis of a food safety plan. The proposed rule also would establish minimum requirements for the "qualified individual," who would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system. Only a trained individual or individual qualified by job experience is capable of effectively executing these activities.

FDA is requesting comment on when and how other elements of a preventive controls system are an appropriate means of implementing the statutory directives, including: A product testing program, an environmental monitoring program, and a supplier approval and verification program, as appropriate.

Costs and Benefits

The summary of the costs and potential benefits of the proposed rule are presented in the table that follows.

	Total domestic costs annualized at 7 per cent over 10 years (millions)
Proposed Rule with Very Small Business Defined as Less Than or Equal to $500,000 in Annual Revenue	$95
Proposed Rule with Very Small Business Defined as Less Than or Equal to $1,000,000 in Annual Revenue	89
Proposed Rule with Very Small Business Defined as Less Than or Equal to $2,500,000 in Annual Revenue	65

I. Introduction

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). This law enables FDA to better protect public health by helping to ensure the safety and security of the human and animal food supply. FSMA enables the Agency to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides the Agency with new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law gives the Agency important new tools to better ensure the safety of imported human and animal foods and directs the Agency to build an integrated national food safety system in

partnership with State, local, tribal, and territorial authorities.

This new law continues efforts by the human and animal food industries and government to protect and improve the safety of the nation's food supply. At the Federal level, these efforts go back to the Pure Food and Drug Act of 1906, the United States' first national food safety law. FSMA carries forward the basic principle embodied in the 1906 law that food establishments have the primary responsibility and capacity to make food safe and that government's role is to set standards for food safety and provide oversight to help ensure standards are met.

Since passage of the 1906 Act, and the most recent revision of its basic food safety provisions in the Federal Food, Drug, and Cosmetic Act of 1938, the combined efforts of the food industry and government have produced a set of standards and practices that make the U.S. food supply among the safest in the world. These efforts include the development and adoption by FDA of CGMP standards for human food that have long provided the regulatory foundation for human food safety. They also include, in more recent years, the adoption for some elements of the animal and human food supply of more targeted, risk-based approaches, such as embodied in the Hazard Analysis and Critical Control Points (HACCP) approach to food safety.

HACCP was pioneered by the human food industry and reflects the understanding that food safety is best assured if each producer and processor understands the hazards that are reasonably likely to occur in their particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate the hazard. FDA has by regulation required seafood and juice processors to implement the HACCP approach to preventive controls. The U.S. Department of Agriculture (USDA) has also mandated HACCP for meat and poultry processors, and many human food companies have implemented such modern preventive control systems for other commodities.

While these efforts have contributed to progress on food safety, significant human and animal food safety challenges persist in today's complex, dynamic, and global food system. Today's food supply is highly diverse and increasingly complex, with many new foods in the marketplace that pose new food safety challenges. New pathogens are emerging, and the Agency is seeing commonly known pathogens appear in foods where they have not been traditionally seen. The population of individuals at greater risk for foodborne illness, such as those who are immune-compromised, is increasing. When illness outbreaks occur, they can have devastating impacts on public health and impose substantial economic disruption and cost on the human and animal food industry. The food safety challenge is only compounded by globalization and the increasing amount of imported human and animal food.

Congress responded to today's food safety challenges by enacting FSMA. FSMA builds on past experience and the strong foundation provided by the current food safety system, but it also marks an historic turning point for food safety. FSMA directs FDA to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system; meets the food safety challenges of the global food system; and establishes stronger partnerships for food safety across all levels of government and with the private sector to ensure optimal use of public and private resources. FDA has embarked on a comprehensive effort to build the food safety system mandated by Congress, as described on its FSMA implementation Web page at *http://www.fda.gov/fsma*.

A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and FDA's ability to oversee their implementation for both domestic and imported food. These include, among others, regulations establishing preventive control standards for human food and animal food facilities, produce safety standards, standards that define the accountability of importers to verify the safety of food produced overseas, and a new program for accrediting private bodies to provide credible certifications that regulated entities are meeting U.S. safety standards. A proposed rule on foreign supplier verification is closely interconnected to this rule on preventive controls for animal food (and the preventive controls proposed rule for human food), and published in the **Federal Register** on July 29, 2013 (78 FR 45730).

In this document, the Agency proposes standards to implement the requirement in section 103 of FSMA for the adoption of preventive controls in animal food facilities. This preamble provides information on FDA's previous efforts in working to establish CGMPs and process controls for animal food, because these past efforts are the critical starting point and foundation for FSMA implementation. The preamble explains and provides additional background on the rationale for the Agency's proposed regulations implementing FSMA's preventive controls requirement and new CGMPs for the animal food industry. The Agency is seeking comments on all aspects of this proposal.

The document for the proposed rule for preventive controls for human food, published in the **Federal Register** January 16, 2013 (78 FR 3646), contains discussions that are relevant to animal food safety and the development of preventive controls for food for animals. The Agency has identified relevant discussion found in the human food preamble throughout this preamble and references the published document for proposed preventive controls for human food for additional information.

II. Background

Ensuring the safety of animal food is complex in light of several factors. Animal food is made for a wide variety of species, including animals from which human foods are derived, pet animals, and laboratory animals. Many animals consume one food as their sole source of nutrition. Therefore, the food that they consume must be nutritionally adequate or the food presents a safety hazard to the animals. Nutrient deficiencies or excesses can raise safety concerns. Because different species have different nutritional needs, certain quantities of a nutrient that are needed by one species of animal could pose a health risk to another species of animal. Therefore, safety issues for animal food can be raised not only by biological, chemical, physical, or radiological contaminates of the food that can cause animal or human health concerns, but also by nutrient deficiencies (or excesses) for the animals.

Animal foods are also handled in a wide variety of settings. Some foods are handled on farms or in feed mills. Other foods, like pet foods, are handled in homes and often in the kitchen. If the pet food is contaminated with a pathogen of human health concern, this could result in secondary contamination of human food-contact surfaces or human food. Humans could become ill from the pathogen through handling the pet food or through these secondary contaminations.

The discussion that follows explains current regulatory tools and other approaches the Agency has explored to address the safety of animal food for animals, the safety of food from food-producing animals consumed by humans, and the safety of humans handling animal food.

This proposed rule would implement needed controls for animal food. This

proposed rule would also help respond to requests the Agency receives from international standard-setting organizations (e.g., Codex Alimentarius) and individual countries that ask feed-exporting countries to operate animal food safety systems with clear regulatory oversight.

A. Current Approaches to Animal Food Safety

1. Animal Feed Safety System Working Group

The Agency's efforts to upgrade animal food safety in this country are continually evolving. Historically, FDA's animal food program focused on specific safety issues, such as unsafe tissue residues resulting from feeding of medicated animal food, Bovine Spongiform Encephalopathy (BSE), and *Salmonella,* but had not addressed animal food safety in a comprehensive manner. In 2003, FDA introduced the concept of an Animal Feed Safety System (AFSS). A working group, the AFSS Working Group, was established and charged with reviewing the many separate regulations and supporting programs related to regulation of animal food by FDA and the States, and identifying gaps in the regulation of animal food that need to be addressed. The goal of this working group was, and remains, the development and implementation of a comprehensive, risk-based program that describes how all animal food (individual ingredients and mixtures of ingredients) should be manufactured and distributed to ensure the safety of the food for animal consumption, as well as the safety of human food derived from these animals (e.g., meat, milk, and eggs). The working group's concept for an AFSS covers the entire continuum of Agency activities including:

- Pre-approval of additives for use in animal food;
- Establishing limits for hazards in animal food;
- Providing education and training;
- Conducting research;
- Performing inspections;
- Taking enforcement for ensuring compliance with Agency regulations; and
- Establishing partnerships with State regulators with responsibility for animal food safety.

The AFSS concept also includes oversight of animal food production, including manufacture, labeling, storage, distribution and use of all animal food at all stages of production and use. A key element of the AFSS concept is a systems approach that includes best management practices during the ''manufacturing, labeling, storage, and distribution'' of all animal food, coupled with steps to identify hazards and to minimize or eliminate, as appropriate, the occurrence of those hazards.

The AFSS Working Group held public meetings on the AFSS concept in September 2003 and April 2005. The meetings were designed primarily to give stakeholders an opportunity to present information to FDA about the direction and scope of the AFSS. Three additional meetings, held in September 2006, May 2007, and May 2008, informed stakeholders of the risk assessment initiatives being undertaken by the AFSS Working Group. Information on these meetings can be found at the Agency's Web site (Ref. 1).

The AFSS Working Group used a number of sources in developing its current design of components comprising the AFSS, including comments from the public solicited through public meetings and interactions with State regulatory officials, industry representatives, veterinarians and consumers. In addition, the working group reviewed some of the approaches used by the Agency and by industry to ensure human food safety, such as HACCP systems, Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs), and CGMPs, to determine their applicability and usefulness to animal food control and regulatory oversight in a risk-based preventive system. The working group also reviewed the Codex Code of Practice on Good Animal Feeding as a comparison to help identify gaps in the Agency's current regulatory approach to animal food safety (Ref. 2). The Codex Code was accepted by the European Union along with other foreign entities and the U.S. delegation, which was comprised of U.S. Federal and State Government officials and industry advisors to the Codex's Task Force on Good Animal Feeding Practices.

The AFSS Working Group identified seven operating components to comprise the AFSS. These components cover processes to ensure that:

- Ingredients used in animal food are safe;
- The methods used to make, store, and distribute animal food result in safe products;
- The Agency acquires timely information about unsafe animal food and, when appropriate, makes such information publicly available;
- The levels of regulatory oversight are commensurate with risk to human and animal health;
- Training, education, and outreach activities keep the Agency's partners and stakeholders well informed and ensure that the Agency and State animal food regulatory personnel are adequately trained; and
- An active and aggressive research program is employed to generate data to aid in addressing animal food safety issues.

With the assistance of regulated animal food industry, the public, and State regulatory personnel, the working group identified gaps in the regulation of labeling, processing, and distribution of animal food products. The working group describes these gaps and ways to address them in the fourth AFSS Framework Document dated January 2010, which can be found on FDA's Web site (Ref. 3).

One critical gap is the lack of Federal regulations to fully address all aspects of producing safe animal food associated with the receiving, manufacturing, processing, packing, holding and distribution of animal food (including pet food, animal feed, and raw materials and ingredients) that does not contain animal drugs (i.e., non-medicated animal food). To fill this gap, the working group began developing a process control standards proposed rule, which aimed to prevent, eliminate, or reduce to acceptable levels the potential risks posed to human and animal health through a systems approach in which adequate control steps would be established throughout the animal food manufacturing process. After the passage of FSMA, the Agency incorporated the work begun on the proposed rule for process control standards into this proposed rule for preventive controls for animal food.

In addition, the AFSS Working Group is developing and systematically applying a method that ranks risks associated with all identified hazards. The use of risk concepts is not new for the Agency, as FDA routinely tries to estimate public health impact in deciding where to focus regulatory effort in general. The Agency relies heavily on evaluation of risk posed by hazards that occur in animal food when making decisions about food safety. Information on the AFSS can be found at the Agency's Web site (Ref. 4).

2. Section 402 of the FD&C Act

Section 402 of the FD&C Act (21 U.S.C. 342) deems food, including animal food, adulterated in several circumstances, including:

a. If it bears or contains any poisonous or deleterious substance which may render it injurious to health (section 402(a)(1));

b. If it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a) of the FD&C Act (21 U.S.C. 346a) (section 402(a)(2)(B));

c. If it bears or contains an unapproved food additive or an unapproved new animal drug (section 402(a)(2)(C));

d. If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food (section 402(a)(3)); and

e. If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (section 402(a)(4)).

While the Agency has issued regulations related to the safety of specific types of animal food and the use of certain food substances in animal food, as will be described further in this preamble, section 402 of the FD&C Act applies to all animal food in interstate commerce.

3. Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF)

Animal foods that are thermally processed low-acid foods packaged in hermetically sealed containers are subject to the regulations in 21 CFR 500.23, which in turn states the provisions of part 113 (21 CFR part 113) applies to animal food. Part 113 establishes the criteria by which FDA determines whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

4. Animal Proteins Prohibited From Use in Animal Feeds

The regulation in § 589.2000 (21 CFR 589.2000), prohibiting the use of certain animal proteins in ruminant feed, was published on June 5, 1997 (62 FR 30936). It was designed to prevent the establishment and amplification of BSE, through animal food, by prohibiting the use of certain proteins derived from mammalian tissue in the feeding of ruminant animals. This BSE regulation affects renderers, protein blenders, commercial animal food manufacturers, distributors (including retailers), transporters of animal food and ingredients, on-farm animal food mixers, and ruminant feeders.

On December 7, 2000, the USDA/Animal and Plant Health Inspection Service (USDA/APHIS) enacted regulations prohibiting the importation into the United States of all meat and bone meal (MBM), meat meal, bone meal, blood meal, tankage, offal, tallow, or any product containing such, which originated directly from countries identified as having BSE, or from countries having inadequate systems in place to prevent BSE (9 CFR 94.18 and 95.4). The prohibitions include all rendered products of animal origin including poultry meal and fishmeal that are processed in these countries, regardless of species of origin, unless the material is from a non-ruminant species and meets certain conditions assuring no contamination with ruminant material. These prohibitions were deemed necessary by APHIS because of the possibility of cross contamination with the BSE agent. Subsequently, on January 20, 2001, FDA issued Import Alert #99–25, ''Detention Without Physical Examination of Animal Feed, Animal Feed Ingredients and Other Products for Animal Use Consisting or Containing Ingredients of Animal Origin'' (Ref. 5).

On April 25, 2008, FDA published a final rule in the **Federal Register**, amending the BSE regulations to prohibit the use of certain cattle origin material in the food or feed of all animals (73 FR 22720). This final rule established new regulations entitled ''Cattle Materials Prohibited in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy''. The new regulation, § 589.2001 (21 CFR 589.2001), prohibits the use of certain cattle materials in the feed of all animals and is aimed primarily at rendering operations. This new rule also amended the BSE regulation in 21 CFR 589.2000.

FDA assesses compliance of the BSE regulations through the Agency's BSE/Ruminant Feed Ban Inspection Program (7371.009) (Ref. 6). This program is designed to assess an animal food facility's operational practices and procedures in preventing the spread of BSE through inspectional observations and sampling.

5. Medicated Feeds CGMP

Section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) provides that a drug (including a drug contained in a medicated feed) shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirement of the FD&C Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

In May 1965, the Agency issued Current Good Manufacturing Practice for Medicated Feeds, which implemented section 501(a)(2)(B) of the FD&C Act for medicated animal food (30 FR 6475). The purpose of this medicated feed regulation, part 225 (21 CFR part 225), was to establish specific criteria for CGMPs that would ensure the safety, identity, strength, and the quality and purity characteristics of medicated feed. Medicated feed that is not manufactured, processed, packed, or held in conformity with part 225 is adulterated under section 501(a)(2)(B) of the FD&C Act.

The medicated feed CGMPs ensure a pure, safe drug product through requiring specific preventive measures during manufacturing, processing, packing, and holding. In general, the CGMPs in part 225 do not apply to the manufacturing, processing, packing, and holding of non-medicated animal food, even if manufactured in the same facility. However, non-medicated feed would be deemed adulterated under section 402(a)(2)(C)(ii) of the FD&C Act if contaminated with a new animal drug.

6. Animal Food Labeling

FDA regulations that establish animal food labeling standards in part 501 (21 CFR part 501) include requirements for a statement of identity, net quantity statement, manufacturer's name and address, and proper listing of ingredients. In addition, the FDAAA required FDA to issue regulations to update the standards for pet food labeling. These implementing regulations are currently being developed by FDA. Further discussion of FDAAA is presented in section II.B.

7. Generally Accepted as Safe (GRAS) Lists and GRAS Notifications

GRAS is an acronym for the phrase Generally Recognized as Safe. Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), a substance is not a food additive if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. A listing of substances that are considered by the Agency to be generally recognized as safe for specific intended uses in animal food is found in 21 CFR parts 582 and 584.

Under section 201(s) of the FD&C Act and 21 CFR 570.30, a substance may be deemed to be GRAS if it is generally

recognized as having been adequately shown to be safe under the conditions of its intended use in food through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

A GRAS substance is not subject to premarket review and approval by FDA. A firm may market a GRAS substance intended for use in animal food based on its own determination that the intended use is GRAS. If the intended use of the substance is not GRAS, the substance and firm marketing it for this use may be subject to enforcement action by FDA.

Although not required to do so, firms that have determined that the intended use of a substance in animal food is GRAS may petition FDA to affirm that a substance is GRAS under certain conditions of use under 21 CFR 570.35(c). Alternatively, they may participate in FDA's GRAS notification pilot program. On June 4, 2010, FDA announced that it would begin a voluntary pilot program for GRAS notifications for substances added to animal food (75 FR 31800). This program is based on an April 17, 1997 proposed rule on GRAS notification (62 FR 18938).

8. Approved Food Additives

Under section 201(s) of the FD&C Act, a food additive means ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. . .''. Other substances that are excluded from the definition of a food additive include pesticide chemical residues, pesticide chemicals, color additives, prior sanctioned substances, and new animal drugs.

Many substances added to an animal food are food additives, varying by composition and intended use. A food additive generally provides one or more of the following attributes: nutrition, aroma/flavor, stabilization, emulsification, and preservation. A listing of food additives permitted in animal food, including drinking water for animals, is found in 21 CFR part 573.

To market a food additive, a sponsor must first petition FDA by submitting information that includes all relevant data bearing on the effect the additive is intended to have in or on food and full reports of investigations made with respect to the safety of the food additive. If FDA approves the petition, FDA publishes a regulation prescribing the conditions of use under which the additive may be safely used. The regulations that apply to food additives used in animal foods and that describe the food additive petition process are published in 21 CFR part 571.

9. Approved Color Additives

A color additive, as defined in 201(t)(1) of the FD&C Act, includes a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source that is capable of imparting color when added or applied to food. The listing of approved human and animal food color additives is found in 21 CFR parts 73 and 74.

A color additive must be shown to be safe and be listed in the Code of Federal Regulations before it may be used to color foods. An interested person may petition FDA for the listing of a color additive, which includes the submission of data demonstrating the color additive is safe and suitable for the proposed use, as described in 21 CFR part 71. The FDA will, upon written request, advise on the adequacy of studies planned to yield these data (21 CFR 70.42(c)).

10. Animal Food Sampling Program

The Agency's Feed Contaminants Program (FCP) is an animal food sampling and inspection program that addresses most animal food contaminants, including pesticides, industrial chemicals, dioxins, heavy metals, mycotoxins, and pathogens. It does not address drug residues and agents that cause BSE and other transmissible spongiform encephalopathies (TSEs), as those contaminants are tested for under other programs. Under the FCP, FDA conducts random surveillance sample collections and inspections as well as followup investigations when an animal food sample is found to contain violative levels of contaminants.

The contaminants addressed by the FCP can be hazardous to livestock health and production, pet health, and to human health through residues in animal-derived human food. Many of the more frequently identified contaminants in animal food are toxic, carcinogenic, mutagenic, teratogenic, or otherwise deleterious to animals, humans, or both.

Animal food facilities are inspected by FDA and State Agencies. Many of the inspections are performed for FDA by states that have entered into a contract to conduct inspections in accordance with the Agency's procedures. Under State partnership and cooperative agreements, States agree to conduct inspections under their own authorities and to share the results with FDA. Inspections of animal food facilities play an important role in ensuring the safety of the nation's animal food supply.

11. Animal Food Safety Guidance to Industry

FDA has issued numerous guidance documents (hereinafter, ''guidance'' or ''guidances'') to assist the animal food industry in implementing food safety regulatory requirements under FDA's jurisdiction. The Agency issues guidances, in accordance with its regulations in § 10.115 (21 CFR 10.115) for ''good guidance practices,'' to describe its interpretation of or policy on a regulatory issue. Guidances do not establish legally enforceable rights or responsibilities and do not legally bind the public or FDA (§ 10.115(d)(1)). Accordingly, regulated industry is not required to employ the approaches contained in a guidance and instead may choose to use an alternative approach, provided that the alternative approach complies with the relevant statutes and regulations (§ 10.115(d)(2)). Although guidances do not legally bind FDA, they represent the Agency's current thinking on a particular interpretation of or policy regarding a given regulatory issue (§ 10.115(d)(3)). Under § 10.115(c)(1) and (g), FDA publishes a guidance in draft form for public comment before issuing the guidance in final form, except where prior public participation is not feasible or appropriate, if the guidance: (1) Sets forth initial interpretations of statutory or regulatory requirements, (2) sets forth changes in interpretation or policy that are of more than a minor nature; (3) includes complex scientific issues, or (4) covers highly controversial issues.

FDA generally issues guidance to industry for the purpose of communicating the Agency's policy decisions and interpretations of its regulatory requirements so that regulated industry better understands

how to comply with those requirements. In some cases, the Agency issues guidance specifically targeted to assisting industry in complying with a particular food safety regulation. For example, the Agency has issued several guidances to assist industry in complying with the regulatory requirements for BSE (§§ 589.2000 and 589.2001) (Refs. 7, 8, 9, 10, and 11). In other cases, the Agency issued guidance that is more narrowly focused in scope or is not directly targeted to assisting industry in complying with a particular food safety regulation. For example, the Agency has issued guidance that addresses deoxynivalenol (DON), also known as vomitoxin, in grain and grain by-products used for animal food (Ref. 12) and guidance on measures to address the risk for contamination by *Salmonella* spp. in raw meat foods for companion and captive non-companion carnivores and omnivores (Ref. 13).

12. Animal Food Safety Compliance Policy Guides

FDA issues guidance to its staff in the form of a compliance policy guide (CPG). The primary purpose of a CPG is to explain FDA's policy on regulatory issues related to the statutes and regulations that FDA is responsible for implementing. CPGs advise FDA field inspection and compliance personnel as to FDA's standards and procedures to be applied when determining industry compliance with our regulatory requirements. FDA issues CPGs in accordance with its regulation for good guidance practices in § 10.115 and makes the CPGs available to the public, thereby providing regulated industry with additional insight into how the Agency interprets the statutes and regulations it is responsible for implementing for purposes of assessing compliance with the Agency's regulatory requirements. In general, FDA's animal food safety CPGs are relatively focused in scope. For example, the Agency has issued a CPG regarding *Salmonella* contamination in all food for animals (Ref. 14), and a CPG that sets forth the criteria that are to be used by FDA personnel to determine whether to take action on animal foods containing aflatoxins (Ref. 15).

B. The Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the FDAAA (21 U.S.C. 2102) was signed into law (Pub. L. 110–85). Section 1002(a) of Title X (Food Safety) of the FDAAA requires the Secretary of Health and Human Services (HHS), in consultation with relevant stakeholder groups, including the Association of American Feed Control Officials (AAFCO), veterinary medical associations, animal health organizations, and pet food manufacturers, to issue new regulations establishing, among other things, processing standards for pet foods. A public meeting that included representatives for the previously mentioned stakeholders was held May 13, 2008, after publication of a notice in the **Federal Register** on April 21, 2008 (73 FR 21357).

Neither the FDAAA, nor its legislative history, described what Congress meant by ''processing standards'' for pet food. In many instances the same ingredients and manufacturing processes are used to produce animal food for both non-food-producing animals, including pets, and food-producing animals. FDA determined that it would not be feasible to implement or enforce processing standards that only applied to one segment of the industry (i.e., pet food.)

The proposed rule for process control standards that the Agency was developing (see the discussion in section II.A.1) included all animal food. After FDAAA was signed into law, a discussion of FDAAA and the requirements for processing standards for pet food was added to the preamble of the proposed rule for process controls standards to clarify that the proposed rule would satisfy these requirements for pet food. After FSMA was enacted, the Agency decided to issue one rule that would satisfy the mandate of section 1002(a) of FDAAA and section 103 of FSMA.

C. FDA Food Safety Modernization Act

1. Requirements for Food Facilities

FSMA was signed into law by the President on January 4, 2011 (Pub. L. 111–353). Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418 (21 U.S.C. 350g) with the same name. Many of the provisions in section 103 of FSMA that are relevant to this rulemaking are codified in section 418 of the FD&C Act.

a. General requirements. Section 418 of the FD&C Act contains requirements applicable to food facilities and mandates Agency rulemaking. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food (including animal food) manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to ''prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act]. . . .''

In addition to those areas specified in section 418(a) of the FD&C Act, sections 418(b) through (i) contain more specific requirements applicable to facilities. These include corrective actions (section 418(e)), verification (section 418(f)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). Section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit ''[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].'' Section X discusses proposed requirements (proposed subpart C) that would implement these provisions of section 418 of the FD&C Act.

b. Qualified facilities. Section 418(l) of the FD&C Act (Modified Requirements for Qualified Facilities) establishes criteria for a facility to be a qualified facility, establishes an exemption for qualified facilities, establishes modified requirements for qualified facilities, and provides that the Secretary may withdraw the exemption otherwise granted to qualified facilities in specified circumstances. Under section 418(l)(1) of the FD&C Act, a facility is a qualified facility if: (1) It is a very small business as the term would be defined by this rulemaking or (2) it falls within specified limitations on the average annual monetary value of its sales and types of customers. Section 418(l)(2)(A) of the FD&C Act exempts a qualified facility from the requirements for hazard analysis and risk-based preventive controls as set forth in sections 418(a) through (i) of the FD&C Act, as well as the requirements issued under section 418(n) of the FD&C Act. Section 418(l)(2)(B) of the FD&C Act requires a qualified facility to submit documentation to the Secretary of HHS (the Secretary) related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws. Section 418(l)(3) of the FD&C Act authorizes the Secretary to withdraw the exemption from a qualified facility in specified circumstances. Section VIII.C discusses a proposed exemption for qualified facilities (proposed § 507.5(d)). Section XI discusses a proposed process for withdrawing an exemption for a

qualified facility (proposed subpart D). Section VIII.D discusses proposed requirements that apply to qualified facilities (proposed § 507.7).

c. Exemptions and exceptions. In addition to the exemption for qualified facilities in section 418(l)(2)(A) of the FD&C Act, there are several other exemptions and exceptions to the requirements specified in section 418 of the FD&C Act. Section 418(j) of the FD&C Act provides an exemption for facilities that are required to comply and are in compliance with the regulations for seafood HACCP, juice HACCP, or thermally processed low-acid foods packed in hermetically sealed containers. Section 418(k) of the FD&C Act provides an exception for activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety). Section 103(g) of FSMA provides an exemption for certain activities regarding a dietary supplement that is in compliance with section 402(g)(2) of the FD&C Act and section 761 of the FD&C Act (21 U.S.C. 379aa–1). For animal food facilities, only two of those exemptions are relevant: activities that are subject to the requirements for thermally processed low-acid foods packed in hermetically sealed containers (proposed § 507.5(b)), and section 419 of the FD&C Act (proposed § 507.5(c)) as discussed in section VIII.C.

2. Requirements for Agency Rulemaking

Section 103 of FSMA contains two separate rulemaking provisions. Section 103(a) of FSMA requires rulemaking related to the hazard analysis and risk-based preventive controls required by section 418 of the FD&C Act. In addition, section 103(c) of FSMA requires rulemaking in two areas: (1) Clarification of certain aspects of the definition of the term ''farm'' under section 415 of the FD&C Act (Registration of Food Facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 of the FD&C Act (21 U.S.C. 350j) (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report) for certain facilities as the Secretary deems appropriate and as further specified in section 103(c)(1)(D) of FSMA.

a. General rulemaking requirements. Section 418(n)(1)(A) of the FD&C Act requires that not later than 18 months after the date of FSMA's enactment, the Secretary issue regulations ''to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. . . .''

b. Definition of small and very small business. Section 418(l)(5) of the FD&C Act requires the Secretary, in consultation with the Secretary of Agriculture, to conduct a study of the food processing sector regulated by the Secretary and to make determinations in five areas. These areas include, in part: (1) Distribution of food production by type and size of operation, (2) the proportion of food produced by each type and size of operation, (3) the number and types of food facilities co-located on farms, (4) the incidence of foodborne illness originating from each size and type of operation, and (5) the effect on foodborne illness risk associated with certain activities regarding food.

Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business,'' taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. These terms are significant because section 103 of FSMA contains several provisions specific to such entities.

- Small and very small businesses are subject to modifications or exemptions from requirements under section 418 or 421 of the FD&C Act for facilities engaged only in specific types of on-farm activities and involving foods that the Secretary determines to be low risk (section 103(c)(1)(D) of FSMA).
- Small and very small businesses are not subject to section 418 of the FD&C Act until 6 months (small businesses) or 18 months (very small businesses) after the effective date of FDA's final rule (section 103(i) of FSMA).
- A very small business is deemed a ''qualified facility'' and would, therefore, qualify for the exemptions as discussed in section VIII.C.1. (section 418(l)(1)(B) of the FD&C Act).

Consistent with section 418(l)(5) of the FD&C Act, FDA has consulted with the USDA during its study of the food processing sector. The study is available in the docket established for this proposed rule (Ref. 16). The Agency requests comment on that study. Section VIII.B discusses the proposed definitions for small business and very small business for animal food facilities. FDA will consider comments regarding the study, as well as comments regarding the proposed definitions for small and very small business, in any final rule based on this proposed rule.

c. Clarification of the term ''facility.'' Generally, section 418 of the FD&C Act applies to the owner, operator, or agent in charge of a ''facility.'' Section 418(o)(2) of the FD&C Act defines ''facility'' as ''a domestic facility or a foreign facility that is required to register under section 415.'' Section 415 of the FD&C Act, in turn, requires any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States to register with the Secretary.

The requirement in section 415 of the FD&C Act that a facility must register does not apply to farms. FDA's implementing regulations for section 415 (21 CFR part 1, subpart H; later in this document stated as the section 415 registration regulations) define ''farm,'' in relevant part, as ''a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both'' (§ 1.227(b)(3)) (21 CFR 1.227(b)(3)).

The term ''farm'' includes a facility that packs or holds food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(i)). Under that same definition, the term ''farm'' also includes a facility that manufactures/processes food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership (§ 1.227(b)(3)(ii)).

Section 103(c)(1)(A) of FSMA requires that not later than 9 months after the date of enactment, the Secretary publish a notice of proposed rulemaking in the **Federal Register** to issue regulations for purposes of section 415 of the FD&C Act with respect to ''activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership'' and ''activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership.'' The regulation is intended to ''enhance the implementation'' of section 415 and ''clarify the activities that are included within the definition of the term ''facility'' (section 301(c)(1)(B) of FSMA). In section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646), the Agency discusses the proposal to revise the section 415 registration regulations to enhance the implementation of section 415 and to clarify the definition of the term ''facility.'' That discussion applies to activities related to animal food and animal food facilities as well.

d. Science-based risk analysis and requirements under sections 418 and 421 of the FD&C Act. Section 103(c)(1)(C) of FSMA requires that in

issuing the proposed rule the Secretary conduct a science-based risk analysis of:

- ''Specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and
- Specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.''

As part of the rulemaking, the Secretary is required to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in sections 418 and 421 of the FD&C Act or modify those requirements, as the Secretary determines appropriate, if such facilities are only engaged in specific types of on-farm manufacturing, processing, packing, or holding activities the Secretary determines to be low risk, and involving specific foods that the Secretary determines to be low risk (section 103(c)(1)(D)(i) of FSMA). Any exemption or modification is limited to small and very small businesses (section 103(c)(1)(D)(ii) of FSMA).

Section VII discusses the Agency's approach to the requirement in FSMA section 103(c) for a science-based risk analysis of the types of on-farm manufacturing, processing, packing, or holding operations that can involve animal food that is not consumed on that farm or on another farm under common ownership for purposes of section 415 of the FD&C Act and request comment on that approach. The final approach will consider comments received to this proposed rule.

Section VIII.C discusses proposed exemptions for small and very small businesses that are solely engaged in certain types of ''low risk'' activities involving the on-farm manufacturing, processing, packing, and holding of certain ''low risk'' animal foods from the requirements of section 418 of the FD&C Act (proposed § 507.5(e) and (f)). The Agency also discusses its tentative conclusion that it should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in such low-risk activity/food combinations and is a small or very small business.

e. Exemption or modification of requirements for certain facilities. Under section 418(m) of the FD&C Act, the Secretary may exempt or modify the requirements for compliance of section 418 of the FD&C Act for hazard analysis and preventive controls for facilities that are solely engaged in the storage of raw agricultural commodities (RACs) (other than fruits and vegetables) intended for further distribution or processing. As discussed in section VIII.C, in accordance with the discretionary language of section 418(m), FDA tentatively concludes that facilities solely engaged in the storage of RACs for animal food, other than fruits and vegetables, intended for further distribution or processing should be exempt from the requirements for hazard analysis and preventive controls that the Agency is proposing in subpart C of part 507. However, as discussed in section VIII.C, the Agency is asking for comment on whether facilities solely engaged in the storage of grains that are RACs for animal food should be included in the final rule.

Section 418(m) of the FD&C Act also authorizes the Secretary to exempt or modify the requirements for compliance with section 418 for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment. Section VIII.E describes the proposal for how the requirements of proposed part 507 would apply to such facilities that store animal food (proposed § 507.10). Section X.I discusses the proposed modified requirements for such facilities, directed at the storage of packaged animal foods that are not exposed to the environment and that require time/temperature control to limit the growth of, or toxin formation by, microorganisms of animal and human health significance (proposed § 507.48).

FDA proposes to implement section 103 of FSMA in several regulations, rather than a single regulation that covers all food and hazards subject to preventive controls. This proposal is applicable to certain hazards that may be associated with a food facility that manufactures, processes, packs or holds animal food. Section 103 of FSMA applies to ''food,'' which is not limited to human food. Section 201(f) of the FD&C Act defines ''food'' to include ''articles used for food or drink for man or other animals.'' FDA tentatively concludes that the differences between human and animal food are best addressed through separate rulemakings. Section 418(m) of the FD&C Act authorizes the Secretary, by regulation, to modify the requirements for compliance under the section with respect to facilities that are engaged solely in the production of food for animals other than man. The Agency has tentatively concluded that the requirements of section 418 of the FD&C Act are needed to ensure the safety of animal food and in turn the health of animals, the health of humans who are exposed to animal food, and the safety of animal derived products for human consumption. Therefore, the Agency is proposing requirements to implement section 418 of the FD&C Act for animal food with only few modifications (e.g., no allergen controls.) The Agency requests comment on whether the requirements in section 418 of the FD&C Act should be modified further for facilities that are solely engaged in the production of food for animals other than man, based on scientific and public health principles.

f. Intentional adulteration. This proposed rulemaking is not intended to address ''hazards that may be intentionally introduced, including by acts of terrorism'' (section 418(b)(2) of the FD&C Act). FDA plans to address section 103 of FSMA regarding such hazards in a separate rulemaking in the future. FDA tentatively concludes that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, FDA also recognizes that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in animal foods concerning which there is a widely recognized risk of economically motivated adulteration in certain circumstances. An example of this kind of hazard is the addition of melamine to certain food products apparently to enhance perceived quality and/or protein content. The Agency requests comment on whether to include potential hazards that may be intentionally introduced for economic reasons. The Agency also requests comment on when an economically motivated adulterant can be considered reasonably likely to occur.

D. Preventive Controls and Hazard Analysis and Critical Control Points (HACCP) Systems

HACCP is a preventive strategy for food safety that involves a systematic approach to the identification and assessment of the risk (likelihood of occurrence and severity) of hazards from a particular food or food production process or practice and the control of those hazards. FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA. For a full discussion of HACCP and preventive controls systems comparisons, please see section II.C of the document for the proposed rule for the preventive controls for human food (78 FR 3646).

E. Animal Food Safety Incidents: Examples and Monitoring

1. Examples of Animal Food Safety Incidents

Historically, the Agency has focused on specific animal food safety issues as problems arise, typically after the distribution of the contaminated animal food. Examples include safety issues related to BSE, chronic wasting disease, mycotoxins (especially aflatoxin in animal food intended for lactating dairy cattle), dioxins, melamine, and microbial contamination in pet foods.

The massive pet food recall due to adulteration of pet food with melamine and cyanuric acid (chemicals called triazines) in 2007 is a prime example. The actions taken by two protein suppliers in China to intentionally adulterate wheat gluten and rice protein concentrate for economic reasons affected a large number of pet food facilities in the United States and created a nationwide problem by causing illness and death in many dogs and cats. The addition of melamine to wheat gluten and rice protein concentrate resulted in a high nitrogen reading during Kjeldahl testing, a test method used to estimate protein levels in foods. By adding the melamine, a non-protein source of nitrogen, the suppliers created a falsely high estimate of protein in their products. While melamine by itself is relatively non-toxic to mammals, the melamine used to adulterate the wheat gluten and rice protein concentrate in this incident had been combined with cyanuric acid, creating a mixture that became toxic. The presence of cyanuric acid with melamine resulted in a precipitation of crystals (melamine cyanurate) when mixed in a solution (Ref. 17). When the animals ingested the adulterated food, the mix of these two chemicals was absorbed into the blood stream and ultimately created an accumulation of crystals in the tubules of the animals' kidneys, leading to kidney disease and death in many animals.

By the time the cause of the illness and deaths was identified, melamine and cyanuric acid contaminated ingredients resulted in the adulteration of millions of individual servings of pet food. Checks to ensure the safety of the imported ingredients had not been conducted by the importer or by the pet food manufacturers that incorporated the ingredients into pet food.

During the investigation, FDA determined that leftovers from the production of pet food (commonly called fines) and salvaged, finished pet food products were routinely used in the production of feed for some food-producing animals (e.g., swine and poultry). It was ultimately discovered that some of these fines and salvaged pet food were adulterated with melamine (and other triazine analogs). Urine from swine (that were being raised for human food consumption) that had eaten this contaminated food was tested and found to contain melamine. This discovery resulted in the holding of animals before their marketing for human food in order to provide time for the U.S. government to conduct a risk assessment to ensure the safety of the meat for human consumption. It was ultimately determined there was no risk to human health from eating meat from these animals due to the small amounts of contaminants in the animal feed eaten.

The contaminated wheat gluten was also used in the manufacture of fish food used in fish hatcheries for food-producing fish. As a result, there was a recall of the affected fish food. These situations with food-producing animals emphasized the link between adulterated animal food (and ingredients) and the potential for adverse effects on human health.

The melamine incident underscored the difficulty in tracing an adulterated ingredient that has been used in a large number of food products. The list of recalled animal foods was constantly updated for multiple weeks after the initial identification of the adulterated ingredients as the distribution of those ingredients was traced. Pet food companies who thought their pet foods were safe because their formulations did not included the use of wheat gluten or rice protein concentrate were surprised to find some of their products were indeed adulterated with the melamine and cyanuric acid. An FDA investigation revealed that a contracted pet food manufacturer was substituting rice protein concentrate for other sources of protein called for in these formulations without contacting the parent company.

Additional incidents of animal food contamination not discovered until after the food was distributed include the detection of dioxin in feed. Dioxin has been linked to adverse health effects in humans, such as cancer, immune suppression, and reproductive or developmental effects. Dioxin is a concern in food-producing animals because human dioxin exposure in the United States comes primarily from the consumption of animal products. In 1997, the USDA's Food Safety and Inspection Service, through their dioxin sampling survey, identified dioxins in poultry tissue. Through a multi-agency investigation, the FDA traced this contamination to high levels of dioxins present in an anti-caking agent (ball clay) used in animal food. That same year, FDA issued a statement to users of ball clay products in animal feed requesting those companies to cease the use of ball clay products in animal feeds and feed ingredients (Ref. 18). In 2002, a foreign government identified high dioxin levels in a mineral product intended for animal food imported from the United States (Ref. 19). The source of the dioxin was related to the high temperature used in the mineral manufacturing process. In 2003, another dioxin incident in minerals was identified as a result of an FDA food sampling assignment. In this case, the mineral premix manufacturer purchased a trace mineral that was a by-product of a metal smelting process (Ref. 20). Internationally, in 1999, animal feed contaminated with dioxin and polychlorinated biphenyls in Belgium resulted in animal and human exposure in Europe. The Belgium government estimated the economic impact of the dioxin crisis cost $493 million, of which $106 million was lost in the swine industry alone. The total cost is much greater when factoring in the impact that occurred to the animal and human food industries in European countries that imported contaminated animal food (livestock feed) or human food from Belgium (Ref. 21). In 2009, a dioxin incident occurred in Ireland involving swine feed that resulted in a global recall of Irish pork. This incident resulted in the Irish government providing € 200 million ($266 million) compensation packages for the Irish pork industry due to their economic losses (Ref. 22). These incidents raised public awareness of the problem of dioxin contamination in animal food.

Another animal food contaminant that can cause illness and injury to animals and humans is aflatoxin. Aflatoxins are naturally occurring mycotoxins that are produced by many species of the fungus *Aspergillus* on certain agricultural commodities. Since their discovery in the early 1960's, aflatoxins have been shown to be toxic to animals and humans. Aflatoxins have also been shown to be carcinogenic to laboratory test animals. After consumption, aflatoxins are metabolized by the liver to a reactive intermediate and eliminated as aflatoxin M1 in milk or as aflatoxicol in urine. High level aflatoxin exposure produces acute damage and cirrhosis of the liver as well as cancer of the liver. It appears that no animal species, including humans, is immune to the acute toxic effects of aflatoxins. In 2005, a pet food company in South

Carolina recalled dog food that was contaminated with aflatoxin (Ref. 23). The Agency received reports from 4 states of illness in over 40 dogs, including 23 deaths, associated with the consumption of the contaminated pet food. In addition, the company's contaminated pet food was exported to at least 29 foreign countries. The source of this contamination was traced to local corn, which had been contaminated with aflatoxin before entering the pet food facility.

Microbial contamination of animal food is also a high concern for the Agency, not only for animals consuming the contaminated food, but also for humans that handle that contaminated animal food. In 2007, FDA identified S. Schwarzengrund, a rare serotype of *Salmonella* associated with human illness, in a pet food. The Center for Disease Control and Prevention (CDC) traced this rare strain of *Salmonella* to a pet food manufacturing facility located in Pennsylvania. Analytical tests conducted by FDA confirmed S. Schwarzengrund at the Pennsylvania facility. A recall was issued for two brands of dry dog food and the manufacturing facility ceased operations for 5 months for cleaning and disinfecting. Despite the facility's efforts, additional S. Schwarzengrund illnesses in humans were reported to CDC. After further investigations by FDA, the pet food manufacturing facility issued a nationwide voluntary recall of all dry dog and cat food products produced at the facility over a 5 month period. This recall involved approximately 23,109 tons of dry pet foods, representing 105 brands. While no pets were reported sick, 79 people in 21 states were reported ill due to the handling of pet food contaminated with this *Salmonella* strain (Ref. 24).

In 2010, the CDC notified FDA of an outbreak of salmonellosis (*Salmonella* infection) in people in the United Kingdom and the United States. News reports from the United Kingdom indicated over 200 people had become ill, all from the same strain of *Salmonella* (Ref. 25). UK officials had determined patients in the United Kingdom had been exposed to frozen rodents used as animal food for reptiles and determined these frozen rodents were contaminated with the same strain of *Salmonella* that was causing the human illness outbreak. U.K. officials traced the origin of these contaminated frozen rodents to a supplier in the United States. UK officials then contacted the CDC. The CDC determined from illness reports that 34 patients in 17 states in the United States were diagnosed with salmonellosis associated with the same strain of *Salmonella* as the patients in the United Kingdom and of that found in the frozen rodents (Ref. 26). FDA inspected the facility producing the frozen rodents and isolated the same strain of *Salmonella* from frozen rodent products sampled at the facility. The facility had distributed frozen rodents as animal food worldwide.

In June of 2008, following an inspection, FDA initiated a mass seizure of animal food at a pet food distribution center after finding the animal food products were vulnerable to contamination, such as microbial contamination, as a result of infestation of the facility by rodents, birds and other pests. Rodent pellets, rodent urine stains, and bird droppings were found throughout the facility, including on bags and pouches of pet food. Rodents had chewed holes in some of the bags of dry dog and cat food and bird seed. The facility was not taking measures to control pest infestation.

Another mass seizure of animal food was executed in August of 2009 at a feed mill because of similar violations. In both cases, the seized products violated section 402(a)(4) of the FD&C Act because the animal food was being held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.

In April 2012, epidemiologic and laboratory investigations conducted by officials in local, state, and federal public health, agriculture, and regulatory agencies linked a *Salmonella* Infantis outbreak to contaminated dry dog food produced by a single production facility located in South Carolina. A total of 49 people (47 individuals in 20 states and 2 individuals in Canada) were reported infected with *Salmonella* Infantis. Among the 24 human patients with available information, 10 were hospitalized. The results from product testing by multiple agencies along with production codes provided by ill persons, led to multiple recalls by several companies with animal food products manufactured at the implicated production facility. The recalls included 17 brands representing over 30,000 tons of dry dog and cat food produced at the facility. This was the second documented outbreak of human salmonellosis linked to dry pet food in the United States (Ref. 27) (Ref. 28).

These examples demonstrate that the safe production and distribution of animal food and ingredients, along with safe meat, milk, and eggs derived from animals that consume this food is an important public health concern, both domestically and globally. The Agency needs to assure the consumer, both here and abroad, that it has a regulatory system designed to ensure production of safe animal food in the United States. Requiring facilities to manufacture, process, pack, or hold animal food under these proposed CGMPs and proposed preventive controls program would help provide that assurance. In addition, the U.S. Government, the animal food industry, animal producers, pet owners and consumers need to have assurance that animal food imported into the United States is safe.

2. Monitoring and Recalls

FDA monitors adverse food events through various means, such as FDA's Reportable Food Registry, FDA's Pet Food Early Warning Surveillance System, consumer complaints, tracking industry recalls and FDA and State inspection findings. From fiscal year (October through September) 2006 through 2012, there were 2,277 animal food product recalls. In 2007 alone, 1,054 animal food products were recalled due to contamination with melamine. Reasons for other animal food recalls include contamination with aflatoxins, dioxins, *Salmonella,* or metal fragments; improper labeling, such as no BSE warning; and subpotent or superpotent nutrient levels, such as elevated levels of vitamin D, copper, zinc, or urea and low levels of potassium, vitamin D, or thiamine. In fiscal year 2012, there were 191 consumer complaints of ill pets reported to FDA related to the dog food contaminated with *Salmonella* Infantis, discussed previously in this section.

For calendar years 2008 through 2012, over 2,500 consumer complaints were called into FDA's district offices regarding animal food for pets and livestock. The complaints ranged from animals refusing to eat their food to animal illness and deaths associated with consumption of an animal food. During the melamine contamination incident in 2007, FDA received over 13,000 consumer complaints about pet food, and over 18,000 calls. Many of these consumer complaints were associated with recalled pet food products contaminated with melamine and cyanuric acid (a contamination that was linked by laboratory testing to illness and deaths in animals as discussed in section II.E.1).

In September of 2009, the Agency established the Reportable Food Registry (RFR), where manufacturers, processors, packers, and holders of human or animal food are required to report to the Agency if there is reasonable probability that an article of

human or animal food will cause serious adverse health consequences or death to humans or animals. From September 2009 through September 2012 the Agency received 71 primary animal food RFR reports. A primary report is the initial report concerning a reportable food from either industry or public health officials, such as federal, state or local regulators. The hazards identified in the primary animal food reports consisted of 27 microbial hazards, 5 physical hazards, and 39 chemical hazards. The microbial hazards were almost exclusively *Salmonella* bacteria found in the finished product. The physical hazards included glass, metal or plastic in the finished animal food, some of which reportedly resulted in animal injury or death. The largest number of animal illnesses and deaths reported to FDA through the RFR and attributable to animal food were associated with a subset of chemical hazards, nutrient imbalances. Some examples of nutrient imbalances associated with animal illnesses and deaths include excessive levels of urea in cattle food, excessive levels of copper in sheep food, inadequate levels of thiamine in cat food, inadequate levels of vitamin D in swine food. In addition, toxic levels of medication (new animal drugs) have been found in non-medicated animal food.

In May, 2010, the Agency implemented the Safety Reporting Portal, where consumers can submit complaints regarding adverse events in animals associated with the consumption of pet food products. From May 2010 through September 2012 the Agency received over 2,900 consumer complaints for pet food through the Safety Reporting Portal and all were reviewed and evaluated by FDA.

F. The Role of Testing as a Verification Measure in a Food Safety System

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Refs. 29 and 30). Prevention of hazards in animal food is much more effective than trying to differentiate safe from unsafe food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Refs. 31 and 32). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan. As discussed in the Appendix to this document (see sections I.C, I.E, and I.F of the Appendix), microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;
- Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate animal food; and
- Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the animal food.

Each type of testing provides information applicable to managing hazards in animal foods, depending on the animal food and process. The Agency discusses the role of testing as a verification measure in a food safety system in section I of the Appendix to this document.

G. The Role of Supplier Approval and Verification Programs in a Food Safety System

An animal food can become contaminated through the use of contaminated raw materials or ingredients as evident by the large recall of pet food because of contamination of wheat gluten with melamine (see discussion in section II.E.1). The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet facility specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program is essential to provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients. The Agency discusses supplier approval and verification programs in more detail in section II of the Appendix to this document.

III. Public Meeting and Preliminary Stakeholder Comments

On April 20, 2011, FDA held a public meeting entitled ''FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities'' (notice of the meeting published in the **Federal Register** on April 13, 2011; 76 FR 20588). The purpose of the public meeting was to provide interested persons with an opportunity to discuss implementation of the provisions in section 418 of the FD&C Act. A discussion of this meeting can be found in section IV of the document for the proposed rule for preventive controls for human food (78 FR 3646).

IV. Summary of the Scope of the Proposed Rule

This proposed rule would apply to animal facilities required to register with FDA under section 415 of the FD&C Act, unless subject to an exemption. This would include manufacturing, processing, packing, and holding of finished products that are intended to be fed to animals, including livestock, pets, and other captive animals, as well as the manufacturing, processing, packing, and holding of ingredients that may be used in animal foods. Some industry sectors, such as renderers and grain and oilseed processors, have long been considered animal food manufacturers and would be subject to the proposed rule. In addition, industry sectors that are newer, such as biofuel manufacturing (suppliers of distillers grain for animal food), or other entities that may not have been thought of as animal food manufacturers in the past, such as mineral refining and manufacturing, would be subject to the proposed rule to the extent that they are engaged in manufacturing, processing, packing, or holding of animal food.

This proposed rule would not apply to farms. For example, farms manufacturing, processing, packing, and

holding food for consumption by their own animals would not be required to register under section 415 of the FD&C Act and therefore would not be required to comply with the proposed rule. However, if the farm operates an animal food manufacturing business (in addition to its traditional farm activities) that requires registration under section 415 of the FD&C Act, that food manufacturing business would likely need to comply with this proposed rule.

In complying with the Hazard Analysis and Risk-Based Preventive Controls section of the proposed rule (subpart C), facilities that manufacture, process, pack, or hold animal food for a single species of animal would focus on hazards most likely to be associated with the ingredients they use, as well as hazards most likely to occur during manufacturing, processing, packing, or holding at the facility, relevant to that species of animal. Facilities that manufacture, process, pack, or hold an ingredient would focus on reducing hazards associated with the ingredient and those species of animal that may consume animal food containing that ingredient. Facilities that manufacture, process, pack, or hold animal food for a range of species or variety of uses would need to consider a more diverse number and type of hazards. In addition to focusing on hazards associated with their incoming ingredients or the types of equipment they use, a feed mill that manufactures food for multiple species would need to be aware of nutritional sensitivities of the animals for which it makes food. For example, a manufacturer that makes food for swine, which can tolerate a relatively large amount of copper in their diet, and food for sheep, which are very sensitive to copper, would need to adopt controls that would ensure that the sheep food it does not contains levels of copper that are unsafe for sheep.

Pet foods usually contain ingredients from the same sources used to make food for livestock and pet foods are sometimes manufactured in the same facilities as food for livestock. For these reasons the Agency has not proposed different rules for these different types of facilities. However, the hazards associated with pet food may be significantly different from the risks associated with food for livestock, and the facility manufacturing, processing, packing, or holding would need to identify and address these hazards. Pet foods usually come into the home, so in addition to being safe for pets to eat, they also would need to be safe for the pet owner to handle. For example, pet foods and treats have been known to carry *Salmonella* (see section II.E). A facility manufacturing pet food would need to address the potential for injury or illness (including death) from the *Salmonella* hazard in not only animals, but in humans handling that pet food (especially the young, old, or immunocompromised.)

V. Highlights of the Proposed Rule

A. Overview

The proposed rule would establish part 507 and contains regulations regarding the manufacturing, processing, packing, or holding of animal food. The proposed rule would establish new provisions for CGMPs for animal food and ingredients, and it would establish new provisions for risk-based preventive controls.

Under the proposed rule, part 507 would be divided into the following subparts:

- Subpart A—General Provisions;
- Subpart B—Current Good Manufacturing Practice;
- Subpart C—Hazard Analysis and Risk-Based Preventive Controls;
- Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility;
- Subpart E is Reserved; and
- Subpart F—Requirements Applying to Records That Must Be Established and Maintained.

B. Proposed Subpart A—General Provisions

The proposed rule would establish general provisions under subpart A of part 507. These provisions include the applicability and status, definitions, specified exemptions for certain facilities from the requirements of proposed subpart C (hazard analysis and risk-based preventive controls), and specified exemptions for certain establishments from the requirements from subpart B (current good manufacturing practice). The proposed exemptions from subpart C would be consistent with the requirements established by FSMA or the discretion provided by FSMA. The subjects of the specified exemptions relate to:

- Animal food establishments that do not have to register under section 415 of the FD&C Act;
- Activities subject to existing Agency regulations governing microbiological hazards for low acid canned animal foods;
- Activities subject to the Standards for Produce Safety in section 419 of the FD&C Act;
- A ''qualified'' facility;
- Certain low-risk packing or holding activity/animal food combinations conducted on a farm by a small or very small business;
- Certain low-risk manufacturing/processing activity/animal food combinations conducted on a farm by a small or very small business;
- Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing;
- Facilities that are solely engaged in the holding or transportation of RACs; and
- Facilities solely engaged in the storage of packaged animal food that is not exposed to the environment, although the storage of such food that requires time/temperature control to prevent the growth of, or toxin formation by, pathogenic microorganisms would be subject to modified requirements that would be established in proposed subpart C.

Proposed subpart A would also implement certain provisions in sections 418(l) and (m) of the FD&C Act for modified requirements with respect to implementing the modified requirements specified in section 418(l) of the FD&C Act for facilities that satisfy the statutory criteria for a ''qualified facility.'' The Agency proposes to establish requirements that include:

- Submission to FDA of documentation that the facility is a qualified facility; and
- Submission to FDA of documentation demonstrating that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or
- Submission to FDA of documentation that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

C. Proposed Subpart B—Current Good Manufacturing Practice

Proposed subpart B would establish general baseline good manufacturing practices for facilities manufacturing, processing, packing, and holding animal food. These provisions would include specific requirements for:

- Personnel in animal food facilities such as following good hygiene practices, and protection of food from contamination from personal effects;
- The plant and grounds including proper cleaning, maintenance, and elimination of pests;

- Sanitary operations including maintaining clean and sanitary conditions of food contact surfaces, proper use and storage of toxic cleaning compounds, and exclusion of pests;
- Sanitary facilities and controls such as the plant's water supply, plumbing, and toilet and hand-washing facilities;
- Equipment and utensils including the cleaning and maintenance of such items and protecting animal food from contamination;
- Processes and controls including following adequate sanitation principles, proper labeling of ingredients and finished animal food, ensuring the safety of raw materials, and prevention of contamination of animal food during processing; and
- Warehousing and distribution to protect animal food against contamination and deterioration.

D. Proposed Subpart C—Hazard Analysis and Risk-Based Preventive Controls

1. Written Food Safety Plan

The Agency proposes to require that the owner, operator, or agent in charge of a facility have and implement a written food safety plan that includes as applicable:

- A hazard analysis;
- Preventive controls;
- Monitoring procedures;
- Corrective Action procedures;
- Verification procedures; and
- A recall plan.

2. Written Hazard Analysis

The Agency proposes to require that the written hazard analysis identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur, including biological, chemical, physical, and radiological hazards. The hazard analysis would include an evaluation of the identified hazards to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

3. Written Preventive Controls

The Agency proposes to require that the owner, operator, or agent in charge of a facility identify and implement preventive controls (including at critical control points, if any) to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented and that the animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act. The preventive controls would include, as appropriate:

- Parameters associated with the control of the hazard and the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur;
- Process controls;
- Sanitation controls;
- A recall plan; and
- Any other necessary controls.

4. Written Recall Plan

The Agency proposes to require that the written recall plan be developed for animal food with hazards that are reasonably likely to occur.

5. Monitoring

The Agency proposes to require the monitoring of the preventive controls to provide assurance that they are consistently performed, including requirements to establish and implement written monitoring procedures and establish and maintain records documenting the implementation of the monitoring procedures.

6. Corrective Actions

The Agency proposes to require that facilities establish and implement written corrective action procedures that would be used if preventive controls are not properly implemented and take corrective actions in the event of an unanticipated problem.

7. Verification

The Agency proposes to require that facilities conduct certain verification activities, including:

- Validation of a subset of the preventive controls;
- Verification that monitoring is being conducted;
- Verification that appropriate decisions about corrective actions are being made; and
- Verification that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur.

The Agency also proposes to require reanalysis of the food safety plan at least once every 3 years and more often when circumstances warrant.

8. Modified Requirements for a Facility Solely Engaged in the Storage of Packaged Animal Food That is Not Exposed to the Environment

Acting on the discretion provided to FDA by section 418(m) of the FD&C Act, the Agency proposes to require that the owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment conduct certain activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance, including:

- Establishing and implementing temperature controls;
- Monitoring the temperature controls;
- Taking appropriate corrective actions when there is a problem with temperature controls;
- Verifying that temperature controls are consistently implemented; and
- Establishing and maintaining the following records:
- Records documenting the monitoring of temperature controls;
- Records of corrective actions; and
- Records documenting verification activities.

The Agency requests comments on these proposed requirements.

9. Qualified Individual

The Agency proposes to establish qualification requirements for a ''qualified individual,'' who would be required to do or oversee the preparation of the food safety plan, validation of preventive controls, review records for implementation and effectiveness of preventive controls and the appropriateness of corrective actions, and perform the reanalysis of a food safety plan. A ''qualified individual'' would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

10. List of Required Records

The Agency proposes to establish a list of records that would be required under proposed subpart C, including the written food safety plan and records documenting monitoring of preventive controls, corrective actions, verification,

and applicable training for the qualified individual.

E. Proposed Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

Proposed subpart D would implement the provisions of section 418(l)(3) of the FD&C Act and establish the conditions under which an exemption granted to a ''qualified facility'' could be withdrawn, and the procedures that would be followed to withdraw such an exemption.

F. Proposed Subpart F—Requirements Applying to Records That Must Be Established and Maintained

Proposed subpart F would establish requirements that would apply to all records that would be required by the various proposed provisions of proposed part 507, including:

- General requirements related to the content and form of records;
- Additional requirements specific to the food safety plan;
- Requirements for record retention;
- Requirements for official review of records by FDA; and
- Public disclosure.

VI. Compliance Dates

Section 103(i)(1) of FSMA, General Rule, provides that ''[t]he amendments made by this section shall take effect 18 months after the date of enactment'' (i.e., by July 4, 2012). Section 103(i)(2) of FSMA, Flexibility for Small Businesses, provides that ''[n]otwithstanding paragraph (1),'' the amendments made by this section ''shall apply'' to a small business and very small business beginning on the dates that are 6 months and 18 months, respectively, ''after the effective date'' of FDA's final regulation.

FDA is implementing the amendments made by section 103 to the FD&C Act through this rulemaking for animal food (except as they relate to intentional contamination). FDA tentatively concludes that it is appropriate to provide a sufficient time period following publication of the final regulation for facilities to come into compliance. The final regulation will contain provisions that affect which facilities are subject to section 418 and which provisions apply to particular facilities. Without these provisions of the regulation in effect, facilities would be uncertain as to the applicability of certain requirements to them. Further, FDA tentatively concludes that compliance with section 418 will be facilitated greatly by the detail and explanation that will be provided by the final regulation.

Most animal food facilities have not been subject to CGMPs and no animal food facility has been subject to preventive controls as put forth in this proposed rule. However, individual animal food facilities, either individually or through feed industry associations have implemented SOPs that are likely to be sufficient to satisfy some of the proposed requirements. The Agency tentatively concludes that the concepts in the proposed CGMPs will not be new to the animal food industry. Still, the Agency expects that the majority of facilities will need to make substantial changes if the proposed regulations are adopted. FDA recognizes that it can take time to implement a food safety system for animal food that would require among other things, CGMPs, performance of a hazard analysis, development of preventive controls, and monitoring of preventive controls.

FDA is proposing that the final rule would be effective 60 days after publication in the **Federal Register**, with staggered compliance dates (see section VI.) However, the Agency recognizes that animal food businesses of all sizes may need more time to comply with the new requirements. FDA believes that it is reasonable to allow for 1 year after the date of publication of the final rule for businesses other than small and very small businesses to come into compliance with the new requirements established under FSMA. FDA also believes that it is reasonable to allow for 2 years after the date of publication of the final rule for small businesses to come into compliance with the new requirements established under FSMA, and 3 years after the date of publication of the final rule for very small businesses to come into compliance with the new requirements. FDA intends to work closely with the animal food industry, extension and education organizations, and state partners to develop the tools and training programs needed to facilitate implementation of the final rule.

VII. Rulemaking Required by Section 103(c) of FSMA: On-Farm Activities

A. Section 103(c) of FSMA

1. Clarification of the Activities That Are Included As Part of the Definition of the Term ''Facility'' under Section 415 of the FD&C Act

Section 103(c)(1)(A) of FSMA requires the Secretary to ''publish a notice of proposed rulemaking in the **Federal Register** to promulgate regulations with respect to—(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 350d), as amended by [FSMA]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415.'' Section 103(c)(1)(B) of FSMA stipulates that such rulemaking ''shall enhance the implementation of such section 415 and clarify the activities that are included as part of the definition of the term ''facility'' under such section.'' Section 415 of the FD&C Act, in turn, directs the Secretary to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. The registration requirement in section 415 of the FD&C Act does not apply to farms. FDA regulations that implement section 415 and require food facilities to register with FDA are established in part 1 (21 CFR part 1), subpart H (Registration of Food Facilities) (the section 415 registration regulations).

A discussion of the Agency's clarification of the treatment of activities that are included as part of the definition of the term ''facility'' in section 415 as well as proposed changes to definitions in the section 415 registration regulations can be found in section VIII of the document for the proposed rule for preventive controls for human food (78 FR 3646).

2. Science-Based Risk Analysis Covering Specific Types of On-Farm Packing, Holding, Manufacturing, Processing, Packing and Holding Activities

Section 103(c)(1)(C) of FSMA directs the Secretary to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover ''(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.'' Section VII.B describes a draft Qualitative Risk Assessment (the section 103(c)(1)(C) draft RA) (Ref. 33) the Agency performed to satisfy this requirement.

3. Exemptions and Modified Requirements for Certain Facilities

Section 103(c)(1)(D)(i) of FSMA requires that, as part of the section 103(c) rulemaking, ''the Secretary shall consider the results of the science-based risk analysis . . . and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by [section 103 of FSMA]) including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201 [of FSMA]), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' Section 103(c)(1)(D)(ii) of FSMA provides that the exemptions or modifications described in section 103(c)(1)(D)(i) ''shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by [FSMA], if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act.'' Section VII.C discusses the results of the section 103(c)(1)(C) draft RA. In section VII.D, the Agency sets forth its tentative conclusions regarding combinations of on-farm manufacturing, processing, packing, and holding activities and animal foods determined to be low risk, considering the results of the section 103(c)(1)(C) draft RA. In section VII.E, the Agency discusses a proposed approach to using the results of the section 103(c)(1)(C) draft RA for the purposes of section 421 of the FD&C Act. Section VIII.C. discusses the Agency's proposal to exempt low-risk combinations of activities and animal foods from the requirements of section 418 of the FD&C Act when performed by farm mixed-type facilities that are small or very small businesses as would be defined in proposed § 507.3.

For a complete discussion of FSMA section 103(c) and on-farm activities, please refer to section VIII.B through VIII.D of the document for the proposed rule for preventive controls for human food (78 FR 3646).

B. Qualitative Risk Assessment of On-Farm Activities Outside of the Farm Definition

As discussed in section VII.A, section 103(c)(1)(C) of FSMA directs the Secretary to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover ''(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.''

As used in section 103(c)(1) of FSMA, the term ''risk analysis'' is ambiguous. One interpretation is that the common meaning of the term is intended—a simple evaluation of whether activity/animal food combinations are likely to result in the consumer (animals in relation to food for animals) becoming ill. Another interpretation is that the ''risk analysis'' should be consistent with the formal definition and related terms used by Codex with respect to food safety (Ref. 34):

- Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
- Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication.
- Risk assessment is a scientifically-based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization.
- Risk management is the process, distinct from risk assessment, of weighing policy alternatives, in consultation with interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
- Risk communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Because section 103(c)(1)(C) of FSMA calls for a science-based risk analysis, the Agency is applying the Codex definitions to the extent possible. It is not clear whether the requirement of section 103(c)(1)(C) of FSMA to conduct a science-based risk analysis was intended to encompass all three components of risk analysis. Section 103(c)(1)(D) of FSMA requires the Secretary to consider the results of the science-based risk analysis and exempt certain facilities from the requirements in section 418 of the FD&C Act, including hazard analysis and preventive controls, and the mandatory inspection frequency of section 421, or to modify those requirements for facilities engaged in on-farm manufacturing, processing, packing, or holding activities determined to be low risk involving animal foods determined to be low risk. Thus, section 103(c)(1)(D) of FSMA is focused on ensuring that the Agency's risk management decisions with respect to exempting or modifying requirements applicable to low-risk on-farm activity/animal food combinations under sections 418 and 421 are science-based, as determined by an analysis of the risk of specific types of on-farm activity/animal food combinations required by section 103(c)(1)(C). The Agency therefore tentatively concludes that the analysis required by section 103(c)(1)(C) should be limited to an assessment of the risk of specific types of on-farm activity/animal food combinations for the purposes of making the risk management decisions required by section 103(c)(1)(D). The risk communication component of the risk analysis is accomplished through the discussion of that assessment in this document, the opportunities for public comment (on the risk assessment and on this proposed rule), and the Agency's evaluation of, and response to, comments in a final rule.

Consistent with this approach, the Agency conducted a qualitative risk assessment (Ref. 33) (''section 103(C)(1)(C) draft RA'') related to activity/animal food combinations for the purpose of determining which activity/animal food combinations would be considered low risk. The Agency focused on activity/animal food combinations that were identified as being conducted on farms (and, thus, might be conducted by farm mixed-type facilities), but the Agency did not consider activity/animal food combinations that would be solely within the farm definition (such as the growing and harvesting of crops) and, thus, are not relevant to the requirements of section 103 of FSMA. The Agency focused on considering the risk of activity/animal food

combinations rather than separately considering the risk of specific animal food categories because doing so better enabled the Agency to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on animal food by a farm mixed-type facility warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act.

Elsewhere in this issue of the **Federal Register**, FDA is making the section 103(C)(1)(C) draft RA for animal food available for public comment in the docket established for this proposed rule (Ref. 33). The Agency will consider comments regarding the section 103(C)(1)(C) draft RA in preparing a final version of the RA and will announce the availability of the final version of the RA when it is available. The final preventive controls rule for animal food will take into account the final version of the section 103(C)(1)(C) draft RA.

C. Results of the Qualitative Risk Assessment

In this section, the Agency reports the results of the section 103(C)(1)(C) draft RA, arranged in three lists. References to ''farms'' in these lists should be understood to include farm mixed-type facilities. The lists are shaped by the proposed definitions for harvesting, manufacturing/processing, packing, or holding in the section 415 registration regulations (discussed in section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646), the organizing principles (discussed in section VIII.D of the document for the proposed rule for preventive controls for human food) that form the basis for those proposed definitions, and the examples of activity classifications. As discussed in section VIII.E of the document for the proposed rule for preventive controls for human food, the same activity may be classified differently (among the categories of harvesting, manufacturing/processing, packing, or holding) depending on whether the animal food being operated upon is a RAC and whether the RAC was grown or raised on the farm or farm mixed-type facility performing the activity or a farm under the same ownership and whether the animal food is consumed on the farm that produced it or another farm under the same ownership. The Agency requests comment on the lists in sections VII.C.1, VII.C.2, and VII.C.3.

For purposes of this document, grains are the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, and cereals (including cereal grains, pseudo cereals, pulses, and other plants used in the same fashion) to be used in animal food. Examples of animal food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, and buckwheat. Oilseeds are the small, hard fruits or seeds of arable crops that are grown and processed mainly for the oil that is extracted from them. Examples of animal food oilseeds include soybean, cottonseed, and rapeseed. Grains and oilseeds are field-dried before harvest. Post-harvest drying or dehydrating that further reduces the moisture content of harvested grains and oilseeds for the purpose of storage or transportation is considered an activity separate from field drying done before harvest. In the lists that follow, the terms grain and oilseed are used in a general sense while the terms dried grain and dried oilseed are used to designate specifically those harvested grains and oilseeds that have been further dried or dehydrated for the purpose of storage or transportation.

1. List of Low-Risk On-Farm Packing and Holding Activity/Animal Food Combinations When Conducted on Animal Food Not Grown, Raised, or Consumed on That Farm or Another Farm Under the Same Ownership

The section 103(c)(1)(C) draft RA identified the following low-risk packing and holding activity/animal food combinations when conducted on a farm on animal food not grown, raised, or consumed on that farm or another farm under the same ownership:

- Conveying, weighing, sorting, culling, or grading (incidental to storing):
- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
- Oilseed (e.g., cottonseed, linseed, rapeseed, soybean, sunflower);
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., almond, peanut or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Storing:
- Dried grain;
- Dried oilseed;
- Byproducts of dried grain or dried oilseed;
- Forage; or
- Other plants or plant byproducts.
- Packing:
- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage; or
- Other plants or plant byproducts.
- Mixing (incidental to packing or storing):
- Grain, whole; or
- Forage.

The Agency notes that the same activities performed on a farm's own RACs, or animal food consumed on the farm or another farm under the same ownership, would be within the farm definition and therefore were outside the scope of the section 103(c)(1)(C) draft RA.

2. List of Low-Risk On-Farm Manufacturing/Processing Activity/Animal Food Combinations When Conducted on the Farm's Own Raw Agricultural Commodities for Distribution Into Commerce

The section 103(c)(1)(C) draft RA identified the following low-risk manufacturing/processing activity/animal food combinations when conducted on a farm on the farm's own RACs distribution into commerce:

- Cracking, crimping, or flaking:
- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
- Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower) ; or
- Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage
- Chopping, or shredding hay.
- Extracting (mechanical) or wet rolling:
- Grain; or
- Oilseed.

3. List of Low-Risk On-Farm Manufacturing/Processing Activity/Animal Food Combinations When Conducted on Animal Food Other Than the Farm's Own Raw Agricultural Commodities for Distribution Into Commerce

The section 103(c)(1)(C) draft RA identified the following low-risk manufacturing/processing activity/animal food combinations when conducted on animal food other than the farm's own RACs for distribution into commerce:

- Cracking, crimping, flaking, or shelling:
- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

- Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower) ; or
- Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage.
- Chopping or shredding hay.
- Extracting (mechanical) or wet rolling:
- Grain; or
- Oilseed.
- Labeling:
- Grain, whole;
- Oilseed, whole;
- Sifting, separating, or sizing:
- Grain;
- Oilseed;
- Grain or oilseed byproducts; or
- Other plants or plant byproducts.

D. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Animal Food Combinations Under Section 418 of the FD&C Act

Based on the results of the section 103(c)(1)(C) draft RA regarding on-farm low-risk activity/animal food combinations, the Agency is proposing in § 507.5(e) and (f) to exempt farm mixed-type facilities that are small or very small businesses (as defined in proposed § 507.3) from requirements under section 418 of the FD&C Act if the only activities subject to section 418 that the business conducts are low-risk activity/animal food combinations (see the discussion of these proposed exemptions in section VIII.C). The proposed exemptions would not exempt eligible facilities from the requirement to register under section 415 of the FD&C Act.

E. Tentative Conclusions Regarding On-Farm Low-Risk Activity/Animal Food Combinations Under Section 421 of the FD&C Act

The Agency tentatively concludes that it should consider the low-risk on-farm activity/animal food combinations identified in the section 103(c)(1)(C) draft RA as a factor in identifying high-risk facilities that are small and very small businesses and allocating inspection resources under section 421 of the FD&C Act, Targeting of Inspectional Resources for Domestic Facilities. However, at this time, the Agency tentatively concludes that it should not exempt or modify the frequency requirements under section 421 based solely upon whether a facility only engages in such low-risk activity/animal food combinations and is a small or very small business. Current data limitations impact the Agency's ability to accurately identify such facilities, and it must be able to identify such facilities in order to implement an exempted or modified inspection frequency schedule. The Agency requests comment on whether it should establish data submission requirements that would allow the Agency to identify these types of facilities in order to exempt such facilities from the inspection frequencies, or modify the inspection frequencies that apply to such facilities, under section 421 of the FD&C Act. Examples of data elements that the Agency might need in order to identify these facilities include: Identification of a facility as a farm mixed-type facility, annual monetary value of sales, number of employees, animal food category/activity type. The Agency also requests comment on these possible data elements and any other criteria that may be appropriate for the purposes of allocating inspection resources to these facilities.

VIII. Proposed Subpart A—General Provisions

A. Proposed § 507.1—Applicability and Status

FDA is proposing in § 507.1(a) that the criteria and definitions in part 507 apply in determining whether an animal food is adulterated: (1) Within the meaning of section 402(a)(3) of the FD&C Act in that the animal food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the FD&C Act in that the animal food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Proposed § 507.1(a) also would establish that the criteria and definitions in part 507 apply in determining whether an animal food is in violation of section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). The Agency notes that section 418(a) of the FD&C Act provides that facilities subject to that section must ''identify and implement preventive controls to . . . provide assurances that . . . food is not adulterated under section 402 [of the FD&C Act]'' and that similar references to preventing adulteration under section 402 of the FD&C Act also appear in section 418(c) and (e). The Agency tentatively concludes that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 507 in determining whether, under particular circumstances, an animal food is adulterated under section 402(a)(3) or (a)(4) or in violation of section 361 of the PHS Act.

Section 103(e) of FSMA amends section 301 of the FD&C Act by adding a new section—(uu)—to the list of acts and the causing thereof that are prohibited. Under section 301(uu), the following act, and the causing thereof, is prohibited:''[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act].'' To clearly communicate that failure to comply with regulations established under section 418 is a prohibited act, proposed § 507.1(b) would establish that the operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the FD&C Act or the regulations implementing section 418 [of the FD&C Act] in subparts C, D, or F of proposed part 507, and § 507.7 of proposed part 507, is a prohibited act under section 301(uu) of the FD&C Act.

Proposed § 507.1(c) would establish that animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations. FDA has established CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (proposed rule, 41 FR 30444, July 23, 1976; final rule, 44 FR 16209, March 16, 1979; currently established in part 113; and 61 FR 37681, July 19, 1996; currently established in § 500.23). Therefore, animal foods that are subject to 21 CFR 500.23 and part 113 are subject to the requirements of § 500.23 and part 113 even though they are foods covered by the current good manufacturing practice requirements of proposed part 507.

Proposed § 507.1(d) would apply to facilities that manufacture, process, pack, or hold animal food and human food. The Agency wanted to address the instances where a facility may handle both animal and human food in some form, to make it clear which proposed rule would apply for that facility manufacturing, processing, packing, or holding these foods. In addition, in some facilities, ''waste'' from human

food production, such as by-products that may not be edible for humans, or lack nutritional value for humans, are used or sold for animal food. Many species of animals have different digestive systems and nutritional requirements than humans, thus allowing for this use. For the human food manufactured, processed, packed, or held, the facility would need to comply with proposed part 117 (proposed rule for preventive controls for human food (78 FR 3646)), subparts B and C as applicable (facilities subject to subpart B may not also be subject to subpart C), and as subject to the exemptions for proposed part 117. For the animal food manufactured, processed, packed, or held, the facility may choose to comply with either proposed part 507 subparts B and C as applicable or proposed part 117 subparts B and C as applicable, so long as the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances. ''Food'' used in proposed part 117 would be read to include ''animal food'' when the facility is applying proposed part 117 to the animal food. For example, human food waste that is used for animal food would be treated as ''food'' for the purposes of its animal food use and as waste for the purposes of its role in human food production. The Agency tentatively concludes that this will provide facilities the flexibility to streamline their compliance efforts, while also ensuring human and animal food safety.

FDA requests comment on the applicability of the requirements of this proposed rule to FSIS official establishments that manufacture, process, pack, or hold food for animals. And, if applicable, to what extent should the requirements apply to these establishments?

B. Proposed § 507.3—Definitions

1. Definitions That FDA is Proposing

In developing the following proposed definitions, FDA aimed to be consistent with proposed part 117 of the proposed rule for preventive controls for human food (see the document for the proposed rule for preventive controls for human food (78 FR 3646)). The Agency also considered how these currently existing and proposed definitions should be clarified for use in the animal food context.

The Agency is proposing in § 507.3 that the terms defined in section 201 of the FD&C Act would be applicable to such terms when used in this part, unless otherwise specified. Additional terms are listed, defined, and discussed in alphabetical order in this section. These definitions are based on the Agency's experience in regulating human food, animal food, common usage in the animal food industry, and definitions in section 418 of the FD&C Act.

Proposed § 507.3 defines ''adequate'' as that which is needed to accomplish the intended purpose in keeping with good public health practice.

FDA is proposing to define the term ''affiliate'' as it is defined in section 418(l)(4)(A) of the FD&C Act to mean any facility that controls, is controlled by, or is under common control with another facility. This term relates to the determination of whether a facility meets the definition of a qualified facility.

Proposed § 507.3 defines ''animal food'' as food for animals other than man, and includes pet food, feed, and raw materials and ingredients. When used in this part, the phrase ''animal food'' does not refer to food derived from animals that is intended for human consumption.

Proposed § 507.3 defines ''batter'' to mean a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Proposed § 507.3 defines ''blanching'' to mean, except for tree nuts and peanuts, a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Proposed § 507.3 defines ''calendar day'' to mean every day shown on the calendar.

Proposed § 507.3 defines ''critical control point (CCP)'' as a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

The Agency is proposing to define the term ''environmental pathogen'' to mean a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. *Salmonella* would be an example of an environmental pathogen, particularly in regards to pet food, given that it is a microorganism of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, and holding. An animal food may be injurious to the health of animals if it is contaminated with a *Salmonella* serotype that is pathogenic to the animal species intended to consume the food. With respect to the risk to humans, pet food and pet treats that are intended to be fed to animals in homes and are contaminated with any *Salmonella* serotype may be injurious to human health, especially where the food is likely to be directly handled by the elderly or individuals with compromised immune systems, or be ingested by children. FDA requests comment on this definition and the types of organisms that should be considered environmental pathogens for animal food, including whether spores of pathogens such as *Clostridium* spp. and *Bacillus anthracis* should be considered environmental pathogens.

FDA is proposing to define the term ''facility'' as it is defined in section 418(o)(2) of the FD&C Act to mean a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act, in accordance with part 1, subpart H. FDA tentatively concludes that the definition of facility should include a reference to the regulation that implements section 415 of the FD&C Act and proposed to update the definition in § 1.227 in section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646). The regulation implementing section 415 of the FD&C Act provides important details to help firms determine whether they are required to register.

The Agency is proposing to cross-reference the definition of ''farm'' rather than to define it in proposed part 507 because the definition of ''farm,'' under both current § 1.227(b)(3) and proposed § 1.227 (found in section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646)) includes the word ''facility'' with a meaning that is broader than the meaning of ''facility'' in section 418(o)(2) of the FD&C Act. Under part I, subpart H, the term ''facility'' is not limited to entities that are required to register under section 415 of the FD&C Act. The Agency is proposing to cross-reference the definition of ''farm'' to reduce the potential confusion that could result if the Agency used the term ''facility'' to have two different meanings within proposed part 507.

Proposed § 507.3 defines ''food'' to mean food as defined in section 201(f) of the FD&C Act and includes raw materials and ingredients.

Proposed § 507.3 defines ''food-contact surfaces'' as those surfaces that contact food and those surfaces from

which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' includes food-contact surfaces of utensils and equipment. The Agency is proposing this definition to clarify the meaning of the phrase ''food-contact surfaces'' when used in this proposed part.

The Agency is proposing to define the term ''harvesting'' as follows: Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting. The Agency is proposing the same definition of ''harvesting'' here as in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646)).

The Agency is proposing to define ''hazard'' to mean any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in animals or humans in the absence of its control. The phrase ''in animals or humans'' is included in this definition because a biological, chemical, physical, or radiological agent in animal food could cause injury and illness to not only animals, but to humans that handle the animal food, or eat products (such as milk, meat, or eggs) derived from animals that ingested the food. The Agency is proposing to include radiological agents to implement section 418(b)(1)(A) of the FD&C Act, which includes radiological hazards as an example of known or reasonably foreseeable hazards that may be associated with a facility. For further discussion on the definition of ''hazard'' and its consistency with HACCP, see section X.B of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The Agency is proposing to define the phrase ''hazard reasonably likely to occur'' to mean a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls. For further discussion on the definition of ''hazard reasonably likely to occur'' and its consistency with HACCP, see section X.B of the document for the proposed rule for preventive controls for human food (78 FR 3646). This concept is used in FDA's HACCP regulations for juice (21 CFR 120.7(a)(2)) and seafood (§ 123.6(a) (21 CFR 123.6(a))), and in the meat and poultry HACCP regulation (9 CFR 417.2(a)(1)).

The Agency is proposing to define the term ''holding'' to mean storage of food. Holding facilities would include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding would also include activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. The Agency is proposing the same definition of ''holding'' here as in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human (78 FR 3646)).

The Agency is proposing to define the term ''lot'' to mean the food produced during a period of time indicated by a specific code.

The Agency is proposing to define the term ''manufacturing/processing'' to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. The proposed definition would also state that examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing would not include activities that are part of harvesting, packing, or holding. The Agency is proposing the same definition of ''manufacturing/processing'' here as in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646)).

Proposed § 507.3 defines ''microorganisms'' to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having animal or human health significance. The term ''undesirable microorganisms'' includes those microorganisms that are of animal and human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. FDA considers not only yeasts, molds, bacteria and viruses, but also protozoa and microscopic parasites, to be microorganisms of importance in the safe and sanitary production of animal food.

The Agency is proposing to define the term ''mixed-type facility'' to mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility would be a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. The Agency is proposing to use the same definition as would be established in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human (78 FR 3646)).

The Agency is proposing to define the term ''monitor'' to mean to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification. For further discussion on the definition of ''monitor'' and its consistency with HACCP, see section X.B of the document for the proposed rule for preventive controls for human (78 FR 3646)).

The Agency is proposing to define the term ''packaging'', when used as a verb, to mean placing food into a container that directly contacts the food and that the consumer receives. This definition would match the definition of ''packaging'' in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human (78 FR 3646)). For purposes of animal food, the use of the term ''consumer'' refers to the person purchasing the animal food to feed to an

animal(s) and the animal(s) consuming the food.

The Agency is proposing to define the term ''packing'' as it is defined in proposed § 1.227 (see section VIII.E of the document for the proposed rule for preventive controls for human food (78 FR 3646) to mean placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act.

Proposed § 507.3 defines ''pest'' to mean any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae. For example, mice would be objectionable animals in the animal food manufacturing, processing, packing or holding environment because they can cause contamination of food and food contact surfaces with pathogens of animal or human health significance.

Proposed § 507.3 defines ''plant'' to mean the building or establishment or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of food.

The Agency is proposing to define ''preventive controls'' to mean those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. The proposed definition would incorporate the definition in section 418(o)(3) of the FD&C Act.

Proposed § 507.3 defines ''qualified end-user'' to mean, with respect to an animal food, the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

a. Is located:

○ In the same State as the qualified facility that sold the food to such restaurant establishment; or

○ Not more than 275 miles from such facility; and

b. Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

The proposed definition matches the definition in section 418(l)(4)(B) of the FD&C Act. As discussed previously in this section of the document, for purposes of this proposed rule, the term ''consumer'' refers to the purchaser of the animal food to feed to an animal(s), and the animal(s) consuming the food. With respect to animal food, restaurants include pet shelters, kennels and veterinary facilities in which animal food is provided to animals, as provided in § 1.227 of this chapter.

Proposed § 507.3 defines ''qualified facility'' to mean (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility as to which both of the following apply:

- During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and
- The average annual monetary value of the animal food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

This definition is based on the criteria in section 418(l)(1) of the FD&C Act. The Agency is specifying ''animal food'' in this definition as it intends to only include the sale of food for animals and not the sale of human food in determining whether a facility meets the requirements in those cases where a facility sells both. The Agency requests comment on whether food for animals and humans should be aggregated in determining whether a facility that sells both meets the statutory criteria of a qualified facility.

Proposed § 507.3 defines ''qualified individual'' to mean a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. The Agency is proposing to define the term ''qualified individual'' to have a concise term to use in proposed provisions that would require that an activity be performed by such an individual. The Agency is proposing to establish requirements for a qualified individual in proposed section § 507.50 (see section X.J).

Proposed § 507.3 defines ''quality control operation'' to mean a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Proposed § 507.3 defines ''reasonably foreseeable hazard'' ''to mean a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food. This term is used in FSMA and the concept is grounded in the hazard evaluation process in HACCP systems.

Proposed § 507.3 defines ''rework'' to mean clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as animal food.

Proposed § 507.3 defines ''safe moisture level'' as a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Proposed § 507.3 defines ''sanitize'' to mean to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal and human health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans. For example, an appropriate sanitizing process for a facility that manufactures, processes, packs or holds animal food can be one that does not cause illness to the person implementing it and does not make the food unsafe for the intended animal species, person handling the food or humans consuming human food derived from animals that consume the animal food. It is well established that sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces (Ref. 35). The Agency recognizes that in certain situations effective cleaning and sanitizing of food-contact surfaces for animal food helps protect the health of animals by controlling the transmission of animal diseases. Effective cleaning and sanitizing of food-contact surfaces for animal food can also protect human

health by preventing transmission of human diseases that occur through handling of the contaminated food.

Proposed § 507.3 defines ''should,'' explaining that ''should'' is used to state recommended or advisory procedures or identify recommended equipment. ''Should'' denotes non-binding guidance. Consistent with the Agency's good guidance practices regulation (21 CFR 10.115), proposed provisions containing the word ''should'' are draft guidance at this stage. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The Agency is proposing to define ''significantly minimize'' to mean to reduce to an acceptable level, including to eliminate. ''Significantly minimize'' and ''preventive control'' are terms used in FSMA and are consistent with the definition of ''control measure'' in the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP guidelines, the Codex HACCP Annex, and FDA's HACCP regulation for juice. The NACMCF HACCP guidelines define ''control measure'' as any action or activity that can be used to prevent, eliminate or reduce a significant hazard (Ref. 29). The Codex HACCP Annex defines ''control measure'' as any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (Ref. 36). For further discussion on the definition of ''significantly minimize'' and its consistency with the term ''control measure'' as used in HACCP, see section X.B.4 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The Agency is proposing to define the term ''small business'' to mean a business employing fewer than 500 persons. See section VIII.B.2 for additional discussion of small business.

The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. FDA conducted a study as required by section 418(l)(5) of the FD&C Act that was used to help determine this definition. That study is available in the docket established for this proposed rule (Ref. 16). The Agency requests comment on that study, particularly in regards to business size for animal food facilities. The Agency will consider comments regarding the study, as well as comments regarding its proposed definition for small business, in any final rule based on this proposed rule.

The Agency is proposing to define the term ''subsidiary,'' as it is defined in section 418(l)(4)(D) of the FD&C Act, to mean any company that is owned or controlled directly or indirectly by another company.

The Agency is proposing to define the term ''validation'' to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

The Agency is proposing to define the term ''verification'' to mean those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan. For further discussion on the use of the terms ''validation'' and ''verification'' in HACCP, see section X.B.4 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The Agency is proposing to define the term ''very small business'' to mean, for purposes of this proposed part 507, a business that has less than $500,000 in total annual sales of animal foods, adjusted for inflation (Option 1 of co-proposal). As one co-proposal, the Agency is proposing to define the term ''very small business'' to mean a business that has less than $1,000,000 in total annual sales of animal foods, adjusted for inflation (Option 2). As another co-proposal, the Agency is proposing to define the term ''very small business'' to mean a business that has less than $2,500,000 in total annual sales of animal foods, adjusted for inflation (Option 3). See section VIII.B.2 for additional discussion of the definition of very small business.

The Agency is proposing to define the term ''water activity (a_w)'' to mean a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

2. Food Processing Sector Study and the Definitions of ''Small Business'' and ''Very Small Business''

FDA conducted a Food Processing Sector Study as required by section 418(l)(5) of the FD&C Act (Ref. 16). The purpose of that study was to make determinations in five areas as required by section 418(l)(5)(A) of the FD&C Act and to use the results of the study in defining the terms ''small business'' and ''very small business.'' These areas include, in part: (1) Distribution of food production by type and size of operation, (2) the proportion of food produced by each type and size of operation, (3) the number and types of food facilities co-located on farms, (4) the incidence of foodborne illness originating from each size and type of operation, and (5) the effect on foodborne illness risk associated with certain activities regarding food. The Food Processing Sector Study provides information on the number of establishments and average sales per establishment by industry and size of operation. FDA's proposed definitions are informed by that study. The food processing sector study is available in the docket established for this proposed rule (Ref. 16). The Agency requests comment on that study. The Agency will consider comments regarding the study, as well as comments regarding its proposed definitions ''small business'' and ''very small business,'' in any final rule based on this proposed rule.

Section 418(l)(5)(B) of the FD&C Act required consideration of harvestable acres, income, the number of employees, and the volume of product in defining the terms ''small business'' and ''very small business.'' The Food Processing Sector Study (Ref. 16) concluded that there was no consistent pattern across food categories, including the pet food and animal feed categories, in terms of which sizes of establishments contribute most to foodborne illness risk. ''Harvestable acres,'' ''income,'' ''the number of employees,'' and ''the volume of food harvested'' are all ways to measure the size of an operation. Income does not appear to be the most relevant measure, since facility income may be derived from multiple sources, many of which are not food-related. ''Harvestable acres'' and ''volume of food harvested'' are similar measures that appear primarily relevant to the growing and harvesting of crops, which are activities not subject to this regulation. Harvestable acres and volume of food harvested do not provide a meaningful measure with respect to the risk from pet food or animal feed produced by a farm mixed-type facility (a pet food or animal feed facility co-located on a farm subject to this regulation); the Agency's qualitative risk assessment of manufacturing, processing, packing, and holding activities conducted in a facility co-located on a farm showed that risk was related to activity/animal food combinations; these animal foods could be harvested from large or small farms (see section VII.B for a discussion of that qualitative risk assessment). A high risk activity/animal food combination (i.e., a not low-risk activity/food combination) could be conducted on a farm with

many harvestable acres or very few harvestable acres. For example, an on-farm facility mixing and/or blending for the purpose of making a complete animal food (which would not be considered a low-risk activity/food combination) could be one that has very few acres, or the mixing and/or blending for the purpose of making a complete animal food could be a small component of a large farm operation. FDA has previously used both number of employees and annual sales as criteria for defining small and very small businesses, e.g., in § 120.1(b)(1) and (b)(2) (21 CFR 120.1(b)(1) and (b)(2)) for human food. However, FDA has not previously defined small or very small businesses with regard to pet food or animal feed businesses. The Agency has limited data on number of employees, income, and annual sales upon which to base its definitions of small and very small business for animal food, but no data for ''harvestable acres'' or ''the volume of food harvested.''

a. Definition of ''Small Business.'' FDA is proposing to define the term ''small business'' to mean, for the purposes of part 507, a business employing fewer than 500 persons. The proposed limit of 500 employees would include all employees of the business rather than be limited to the employees at a particular facility. The Agency is proposing to establish the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR part 121 for most food manufacturers. This is also the same definition for small business the Agency used to define a small business in its juice HACCP regulation (§ 120.1(b)(1)). The definition of small business is relevant to two provisions in the proposed rule. It would affect which facilities qualify for the exemption in proposed § 507.5(e) for on-farm packing or holding, and the exemption in proposed § 507.5(f) for on-farm manufacturing/processing, of animal food by a small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/animal food combinations listed in those sections. It would also affect what the compliance date is for facilities that meet the definition.

Effect on Proposed § 507.5(e) and (f)

Under proposed § 507.5(e) a farm mixed-type facility that meets the definition of a small business and only conducts specific packing or holding activity/animal food combinations would be eligible for an exemption from subpart C. Similarly, under proposed § 507.5(f) a farm mixed-type facility that meets the definition of a small business and only conducts specific manufacturing/processing activity/animal food combinations would be eligible for an exemption from subpart C. Based on the Food Processing Sector Study, the Agency estimates that approximately 4,439 facilities would be part of a small business under the proposed definition and thus satisfy the size requirement of the exemption in proposed § 507.5(e) and proposed § 507.5(f). Of those facilities, the Agency estimates that approximately 188 would be co-located on farms. A subset of those facilities would qualify for the exemption from subpart C based on their manufacturing/processing and packing and holding activities.

Other Effects

Based on the Food Processing Sector Study the Agency estimates that businesses employing fewer than 500 employees produce approximately 18 percent (based on sales) of all manufactured food produced in the United States and 86.9 percent of all manufactured pet food and animal feed. As discussed in section VI, the compliance date for a small business would be 2 years after the date of publication of the final rule. Under this proposed definition, 4,439 facilities would be subject to this compliance date.

b. Definition of ''Very Small Business.'' In addition to defining ''small business,'' FDA is required to define ''very small business.'' FDA has not reached a tentative conclusion on how best to define ''very small business'' for the purposes of this rule. Consequently, the Agency is proposing three possible definitions based on annual sales of animal food of $500,000, $1,000,000, or $2,500,000 and requesting comment on which of these three options to include in a final rule. The Food Processing Sector Study provided information for the development of the three proposed definitions (Ref. 16). The Agency requests comment on whether a dollar amount of sales that is more than, or less than, the $500,000, $1,000,000, or $2,500,000 dollar amounts it is proposing would be appropriate. The Agency also requests comment on how a particular dollar amount of sales would be in keeping with Congressional intent, i.e., in light of the provisions in section 418(l) of the FD&C Act regarding qualified facilities, including the statutory limitations on sales to qualified end-users.

The definition of very small business is relevant to 3 provisions of the proposed rule. It would affect which facilities qualify for the exemption in § 507.5(e) for on-farm packing or holding, and the exemption in § 507.5(f) for on-farm manufacturing/processing, of animal food by a very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/animal food combinations listed in those sections. It would also affect which facilities are automatically ''qualified'' facilities subject to the modified requirements in § 507.7 and what the compliance date is for such facilities.

Effect on Proposed § 507.5(e) and (f)

The definition of very small business affects which facilities qualify for the exemption in § 507.5(e) for on-farm packing or holding, and the exemption in § 507.5(f) for on-farm manufacturing/processing, of animal food by a very small business if the only activities subject to section 418 of the FD&C Act are the specific low-risk activity/animal food combinations listed in those sections,

Other Effects

The definition of very small business affects which facilities are automatically ''qualified'' facilities subject to the modified requirements in proposed § 507.7, and the applicable compliance dates for such facilities. There are two ways a facility may be ''qualified'' and thus subject to the modified requirements in proposed § 507.7. The first, limited annual monetary value of sales, is based on fixed criteria set out in FSMA section 418(l)(1)(C). The second, as provided by section 418(l)(1)(B), is to be a very small business as defined by FDA. Therefore, the Agency discusses the effect of the proposed definitions for very small business in relation to the existing requirements for qualified facilities in section 418(l)(1)(C).

Less Than $500,000 in Total Annual Sales—Effect on Proposed § 507.5(e) and (f)

One possible definition of the term ''very small business,'' for the purposes of proposed part 507, would be a business that has less than $500,000 in total annual sales of animal food, adjusted for inflation (Option 1 of the co-proposal). From the Food Processing Sector Study it is apparent that the number of co-located facilities is concentrated at the smaller end of the size spectrum. Using data from Dun & Bradstreet, FDA estimates that 3 co-located facilities would meet the size requirement for the exemptions in proposed § 507.5(e) and (f). A subset of those facilities might then qualify for

the exemption from subpart C based on their manufacturing/processing, packing, or holding activities.

Less Than $500,000 in Total Annual Sales—Effect on Number of Qualified Facilities

The proposed definition of $500,000 uses a dollar amount for sales that is, essentially, the same as the maximum dollar amount of sales by a qualified facility to end-users other than those that would satisfy the definition of ''qualified end-users,'' except unlike with section 418(l)(1)(C) of the FD&C Act, there would be no requirement that more than half of sales must be to qualified end-users. The $500,000 definition of very small business would add approximately 3 domestic facilities to the number of qualified facilities. FDA estimates that no additional domestic animal food facilities beyond these 3 domestic facilities would be qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 3 domestic qualified facilities. These 3 domestic qualified facilities would have a 3 year compliance date. As a group, businesses with less than $500,000 in total annual sales of animal food produce less than 0.003 percent of all animal food produced in the United States when measured by dollar value.

Less Than $1,000,000 in Total Annual Sales—Effect on Proposed § 507.5(e) and (f)

One possible definition of the term ''very small business,'' for the purposes of proposed part 507, would be a business that has less than $1,000,000 in total annual sales of animal food, adjusted for inflation (Option 2 of the co-proposal). Using data from Dun & Bradstreet (in the Food Processing Sector Study), FDA estimates that the same 3 facilities that met the $500,000 exemption would meet this exemption level but no additional facilities would meet the size requirement for the exemptions in proposed § 507.5(e) and proposed § 507.5(f). A subset of those facilities might then qualify for the exemption from subpart C based on their manufacturing/processing, packing, or holding activities.

Less Than $1,000,000 in Total Annual Sales—Effect on Number of Qualified Facilities

Defining very small business to mean a business that has less than $1,000,000 in total annual sales of animal food would add approximately 619 domestic facilities to the number of qualified facilities. FDA estimates that no additional domestic pet food or animal feed facilities beyond these 619 domestic facilities would be qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 619 domestic qualified facilities. These 619 domestic qualified facilities would have a 3-year compliance date. As a group, businesses with less than $1,000,000 in total annual sales of animal food produce less than 1.71 percent of all pet food and animal feed produced in the United States when measured by dollar value.

Less Than $2,500,000 in Total Annual Sales—Effect on Proposed § 507.5(e) and (f)

One possible definition of the term ''very small business,'' for the purposes of proposed part 507, would be a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation (Option 3 of the co-proposal). Using data from Dun & Bradstreet, FDA estimates that the same 3 facilities that met the $500,000 and $1,000,000 exemption would met this exemption level but no additional facilities would meet the size requirement for the exemption in proposed § 507.5(e) and proposed § 507.5(f). A subset of those facilities might then qualify for the exemption from subpart C based on their manufacturing/processing, packing, or holding activities.

Less Than $2,500,000 in Total Annual Sales—Effect on Number of Qualified Facilities

As compared to Option 2, defining very small business to mean a business that has less than $2,500,000 in total annual sales of animal food would add another approximately 2,880 domestic facilities to the number of qualified facilities. FDA estimates that no additional domestic pet food or animal feed facilities beyond these 3,499 (the 619 facilities that qualify at the $1,000,000 exemption level plus the 2,880 facilities that qualify at the $2,500,000 exemption level) domestic facilities would be qualified facilities under section 418(l)(1)(C) of the FD&C Act, leading to a total of 3,499 domestic qualified facilities. These 3,499 domestic qualified facilities would have 3 year compliance date. As a group, businesses with less than $2,500,000 in total annual sales of animal food produce less than 20.8 percent of all pet food and animal feed produced in the United States when measured by dollar value.

Differences From the Proposed Preventive Control Rule for Human Food

FDA is proposing different annual gross sales levels for the three definition options of very small business for animal food facilities than proposed for human food facilities. In the proposed rule for preventive controls for human food (78 FR 3646), FDA proposed three options for annual gross sales levels for very small business. Option 1 would be $250,000, Option 2 would be $500,000, and Option 3 would be $1 million. For the proposed rule for preventive controls for animal food, FDA is proposing three different options for annual gross sales levels for very small business. Option 1 would be $500,000, Option 2 would be $1 million, and Option 3 would be $2.5 million. In general, the animal food industry sector is more heavily weighted toward the medium and larger facilities, when based on gross annual sales, than is the human food industry sector. For example, facilities producing livestock or poultry feed often buy and sell product measured in tons, resulting in high annual gross sales. Though the annual gross sales levels would be higher for each option in the proposed animal food rule, the percent of facilities and percent of sales exempted would be comparable to the annual gross sales levels for the three options for the proposed rule for human food.

C. Proposed § 507.5—Exemptions

1. Proposed § 507.5(a)—Exemption Applicable to Establishments Not Required To Register Under Section 415 of the FD&C Act

Proposed § 507.5(a) would exempt establishments not required to register under section 415 of the FD&C Act. According to section 415(c)(1) of the FD&C Act, establishments that are not required to register include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in 21 CFR 123.3(k)). The Agency has interpreted these terms in § 1.227. For example, in the animal food context, a ''restaurant'' includes pet shelters, kennels, and veterinary facilities in which food is provided to animals. A ''retail food establishment'' is an establishment that sells food directly to consumers as their primary business function, where the term ''consumer'' does not include a business. A grocery store, including the pet food aisle, would be an example. In

addition, the Agency has interpreted ''nonprofit food establishment'' to include a charitable entity that provides food or meals for consumption by animals in the United States. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code. Certain nonprofit wildlife rehabilitation centers would likely fall into this category.

In section VIII.B of the document for the proposed rule for preventive controls for human food (78 FR 3646), FDA proposed to further clarify the scope of the definition of ''farm'' for the purposes of section 415 of the FD&C Act to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' would include: (1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership and (2) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. Because this definition of ''farm'' reflects the Agency's interpretation of the term in section 415 of the FD&C Act, establishments that meet this definition would not be required to register under section 415 of the FD&C Act and would therefore be excluded from the scope of this rulemaking under proposed § 507.5(a). For example, a farm that manufactures/processes food, e.g., by using mobile equipment to mix grain and forage with a commercially produced protein/mineral supplement into a total-mixed ration to feed to dairy cattle on its farm, or another farm under the same ownership, would be exempt from this proposed rule. As another example, a crop farm that grows, harvests, and stores agronomic crops such as alfalfa hay, corn, and other feed grains for distribution into commerce as animal food would be exempt from the proposed rule.

Similarly, the exemption in § 507.5(a) would exempt activities of farm mixed-type facilities that fall within the farm definition previously mentioned. As discussed in section VIII.B of this document and section VIII.E.1 of the document for the proposed rule for preventive controls for human food (78 FR 3646), a ''mixed-type facility'' would be an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. An example of such a facility would be a ''farm mixed-type facility,'' an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. FDA tentatively concludes that the portion of a farm mixed-type facility that is within the farm definition—and therefore the portion that is exempt from registration under section 415 of the FD&C Act—should be treated the same way for the purposes of proposed § 507.5(a) as the same activities on farms that only conduct activities within the farm definition.

Section 418 of the FD&C Act sets forth requirements for the owner, operator, or agent is in charge of a ''facility,'' defined in 418(o)(2) as a domestic facility or foreign facility that is required to register under section 415. Therefore section 418 of the FD&C Act only applies to establishments that are required to register under section 415.

The Agency tentatively concludes that these facilities should not be subject to the CGMPs in proposed part 507 for several reasons. Establishments that are not required to register under section 415 of the FD&C Act are not commonly known to be sources of animal food adulteration, they do not commonly stockpile large inventories of animal food, and the rapid turnover of inventory further reduces the risk that these establishments will adulterate animal food products they use. In addition, most of the animals that are housed and cared for by this sector are not food-producing animals, narrowing the scope of the human health risk.

Most of these establishments are already regulated by other agencies, often multiple agencies, who already address animal food safety to some degree. For example, many establishments that are not required to register under section 415 of the FD&C Act fall under the purview of the Animal Welfare Act (AWA), implemented by USDA. The AWA and its implementing regulations provide for safe food and housing for animals in indoor, outdoor and sheltered housing establishments, and those under the control of dealers and exhibitors, among others. Implementing regulations enforced by USDA specify that the food provided to animals in these establishments must be uncontaminated and wholesome (e.g., 9 CFR 3.9). In addition, veterinary clinics, among others of these types of establishments, are regulated by State governments.

FDA also has other established regulations that incorporate feeding practices and animal food storage. For example, § 589.2000, Animal Proteins Prohibited in Animal Feed, addresses, among other things, the feeding of ruminant animals. The Agency does inspect ruminant feeders, including farms and other establishments that may feed ruminant animals to ensure compliance with this regulation. Although the focus of the Agency's inspection work under this regulation is farms raising ruminant animals such as cattle, sheep, goats, elk, and bison intended to produce meat and milk for human consumption, the Agency also visits a small number of other establishments to make sure those industry sectors are aware of, and following, these regulations as they care for their ruminant animals.

Certain establishments that are not required to register under section 415 of the FD&C Act conduct nonclinical laboratory studies in animals to support applications for research or marketing permits for products regulated by FDA, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. These establishments must comply with Good Laboratory Practice regulations already in place in part 58 (21 CFR part 58), which include certain food safety measures. For example, § 58.45 states ''there shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means.'' In addition, § 58.90(g) states ''feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol . . .''

Finally, while establishments that are not required to register under section 415 of the FD&C Act would not need to comply with the proposed rule, they would still be subject to the adulteration provisions of section 402 of the FD&C Act.

2. Proposed § 507.5(b)—Exemption Applicable to Animal Food Subject to § 500.23 and Part 113-Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

Section 418(j)(1)(C) of the FD&C Act provides that section 418 of the FD&C Act shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with,

and is in compliance with, ''[t]he Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the [FDA] (or any successor standards).'' (The Agency interprets ''Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards'' to mean the requirements of § 500.23 and part 113. Section 500.23 establishes that part 113 also applies to food for animals.) Importantly, section 418(j)(2) of the FD&C Act limits the express exemption associated with § 500.23 and part 113 to microbiological hazards that are regulated under § 500.23 and part 113 (or any successor regulations). FDA considers the language of section 418(j)(1)(C) of the FD&C Act to be ambiguous with regard to application of the exemption. The language of section 418(j)(1)(C) exempts a facility from section 418 of the FD&C Act if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, § 500.23 and part 113 ''with respect to such facility[.]'' However, § 500.23 and part 113 do not apply to ''facilities,'' establishments, or plants. Rather, they apply to the specified foods (low-acid canned foods) and to persons defined as ''commercial processors'' who conduct certain activities involving those foods. See, e.g., § 113.3(d) (definition of ''Commercial processor''), and section 404 of the FD&C Act (21 U.S.C. 344), which provides FDA with legal authority to issue § 500.23 and part 113 (''[The Secretary] shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food [presenting specific risks defined in the section] in such locality of permits to which shall be attached such conditions governing the manufacture, processing, or packaging of such class of food . . .''). Thus, it is unclear for purposes of section 418(j)(1)(C) under what circumstances a low-acid canned food processor is required to comply with § 500.23 and part 113 ''with respect to [a] facility,'' especially when such a person also conducts activities involving other foods not subject to § 500.23 and part 113 at the same facility.

The Agency tentatively concludes that it should interpret section 418(j)(1)(C) to exempt those activities of a facility that are subject to § 500.23 and part 113, and only those activities. Such an interpretation would fulfill the apparent goal of the exemption without being too narrow or too broad. The Agency also tentatively concludes that it should include the exemption provided in section 418(j)(1)(C) of the FD&C Act in the proposed rule to establish by regulation the reach of the exemption as the Agency has interpreted it. Proposed § 507.5(b) would provide that subpart C would not apply with respect to activities that are subject to § 500.23 and part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, § 500.23 and part 113 with respect to such activities. Consistent with section 418(j)(2) of the FD&C Act, proposed § 507.5(b) would establish that the exemption would be applicable only with respect to the microbiological hazards that are regulated under § 500.23 and part 113. A facility that is required to comply with, and is in compliance with, § 500.23 and part 113 would be subject to the requirements in proposed subpart C for hazards such as chemical hazards (e.g., pesticide residues), physical hazards (e.g., metal fragments that could be introduced from equipment) and radiological hazards (e.g., high concentrations of radium-226, radium-228 or uranium in well water used in product). A facility that is required to comply with, and is in compliance with, § 500.23 and part 113 also would be subject to the requirements in proposed subpart C for biological hazards not regulated under § 500.23 and part 113. For example, the heat-stable toxin produced by the *Staphylococcus aureus* is a biological hazard that would not be inactivated or destroyed by the processing required under § 500.23 and part 113 (Ref. 37) (Ref. 38).

The Agency requests comment on the criteria that should be used to determine whether a facility is in compliance with § 500.23 and part 113.

3. Proposed § 507.5(c)—Exemptions Applicable to Activities Subject to Standards for Produce Safety in Section 419 of the FD&C Act

Section 418(k) of the FD&C Act provides that section 418 of the FD&C Act ''shall not apply to activities of a facility that are subject to section 419 [of the FD&C Act].'' Section 419, ''Standards for Produce Safety,'' requires FDA to establish by regulation ''science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which [FDA] has determined that such standards minimize the risk of serious adverse health consequences or death.'' Section 419(h) of the FD&C Act provides that section 419 of the FD&C Act ''shall not apply to activities of a facility that are subject to section 418 [of the FD&C Act.]'' FDA issued a proposed rule to implement section 419 on January 16, 2013 (78 FR 3504.) That proposed rule would apply section 419 to ''farms'' (as would be defined in proposed §§ 1.227 and 1.328 of the proposed rule for preventive controls for human food (78 FR 3646) that are not required to register under section 415 of the FD&C Act and to farms that conduct an activity (or activities) that triggers the section 415 registration requirement (''farm mixed-type facilities''), but only with respect to their activities that are within the farm definition and therefore do not trigger the registration requirement. The Agency tentatively concludes that it should include a provision implementing section 418(k) of the FD&C Act in the proposed rule for clarity and consistency, though section 419 of the FD&C Act applies only to human food. Proposed § 507.5(c) would provide that subpart C would not apply to activities of a facility that are subject to section 419 of the FD&C Act (Standards for Produce Safety).

4. Proposed § 507.5(d)—Exemption Applicable to a Qualified Facility

Section 418(l) of the FD&C Act establishes modified requirements for ''qualified facilities.'' The Agency describes what a qualified facility is in section VIII.D, where the Agency proposes the requirements for such a facility (proposed § 507.7). The Agency also defines the term ''qualified facility'' in proposed § 507.3 (see the discussion of definitions in section VIII.B). Section 418(l)(2)(A) of the FD&C Act provides that a qualified facility ''shall not be subject to the requirements under [sections 418(a) through (i) and (n) of the FD&C Act];'' as a practical matter with respect to the provisions of this proposed rule, section 418(l)(2)(A) of the FD&C Act provides that a qualified facility would be exempt from the requirements of proposed subpart C. Importantly, section 418(l)(3) of the FD&C Act provides that the Secretary of HHS may withdraw the exemption provided in section 418(l)(2)(A) under certain circumstances. The Agency discusses the withdrawal provisions of section 418(l)(3), and its proposed provisions to implement section 418(l)(3) (proposed subpart D), in section XI.

The Agency tentatively concludes that it should include the exemption provided in section 418(l)(2)(A) of the FD&C Act in the proposed rule to establish by regulation the reach of the provision. Proposed § 507.5(d) would provide that subpart C would not apply

to a qualified facility, except as provided by subpart E (i.e., except as provided by the proposed provisions for withdrawal), and that qualified facilities are subject to the requirements in § 507.7.

5. Proposed § 507.2(e) and (f)—Exemption Applicable to Certain On-farm Manufacturing, Processing, Packing or Holding Food by a Small or Very Small Business

a. Requirements of section 103 of FSMA. As discussed in section VII.A.1, section 103(c)(1)(A) of FSMA requires that the Secretary publish a proposed rule to issue regulations with respect to ''(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the [FD&C Act]; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of section 415.'' Section 103(c)(1)(B) of FSMA directs that the rulemaking ''shall enhance the implementation of such section 415 [of the FD&C Act] and clarify the activities that are included as part of the definition of the term ''facility'' under such section 415.'' In section VII, the Agency discusses clarifications of certain on-farm activities and whether they trigger the section 415 registration requirement in order to enhance the implementation of section 415 by clarifying the treatment of various activities for purposes of section 415, including activities conducted on farms.

In the proposed rule for preventive controls for human food (78 FR 3646), FDA proposed adding a new definition of the term ''Mixed-type facility'' to § 1.227. The proposed definition would also state that an example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals, and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered. Mixed-type facility would mean an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. Because the specific classes of activities mentioned in FSMA section 103(c) are, by definition, on-farm activities that do not fall within the farm definition, Congress has explicitly directed FDA to engage in rulemaking addressing establishments that conduct activities that are outside the farm definition on farms. Accordingly, FDA proposed to define the term ''farm mixed-type facility'' to refer to these establishments (78 FR 3646).

As discussed in section VII.A.2, section 103(c)(1)(C) of FSMA requires that the Secretary conduct a science-based risk analysis of ''(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific animal foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.'' As discussed in section VII.B, consistent with the requirements of section 103(c)(1)(C) of FSMA the Agency has conducted a qualitative risk assessment related to activity/animal food combinations for the purpose of determining which activity/animal food combinations would be considered low risk.

Section 103(c)(1)(D)(i) of FSMA requires that, in issuing the regulations under section 103(c)(1)(A), ''the Secretary shall consider the results of the science-based risk analysis conducted under [section 103(c)(1)(C) of FSMA], and shall exempt certain facilities from the requirements in section 418 of the [FD&C Act] . . ., including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of [the FD&C Act] . . . or modify the requirements in [sections 418 or 421 of the FD&C Act], as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' Section 103(c)(1)(D)(ii) of FSMA provides that ''[t]he exemptions or modifications under section 103(c)(1)(D)(i) of FSMA shall not include an exemption from the requirement to register under section 415 of the [FD&C Act] . . . if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the [FD&C Act].''

b. FDA's interpretation of section 103(c)(1)(D)(i) of FSMA. FDA considers the language of section 103(c)(1)(D)(i) of FSMA to be unambiguous with regard to the reach of the exemption. The language of section 103(c)(1)(D)(i) includes the requirement ''if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.'' FDA tentatively concludes that this language is unambiguous and means that Congress intended us to exempt a facility from, or modify the requirements of, section 418 of the FD&C Act under this authority if the facility only conducts a limited set of low-risk activity/animal food combinations that would otherwise be subject to section 418, that is, to the extent the facility is subject to section 418, it ''is engaged only in'' the identified activities involving the identified foods. This interpretation seems both protective of public health and consistent with the preventive purpose of section 418 of the FD&C Act. This interpretation would mean that a facility would be required to conduct a hazard analysis and establish and implement risk-based preventive controls for all activities conducted on all animal foods (including low-risk activity/animal food combinations) if a facility conducts a single activity subject to section 418 of the FD&C Act that is not a low-risk activity/animal food combination, unless the facility qualifies for another exemption from subpart C.

c. Proposed § 507.5(e)—Exemptions for on-farm low-risk packing or holding activity/food combinations. Proposed § 507.5(e) would provide that subpart C would not apply to on-farm packing or holding of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the FD&C Act that the business conducts are the following low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership:

1. Conveying, weighing, sorting, culling, or grading (incidental to storing):
- Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
- Oilseed (e.g., cottonseed, linseed, rapeseed, soybean, sunflower);
- Grain or oilseed byproducts;
- Forage (e.g., hay or ensiled material); or
- Other plants or plant byproducts (e.g., almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

2. Storing:
- Dried grain;
- Dried oilseed;
- Byproducts of dried grain or dried oilseed;

- Forage; or
- Other plants or plant byproducts.

3. Packing:
- Grain;
- Oilseed;
- Grain or oilseed byproducts;
- Forage; or
- Other plants or plant byproducts.

4. Mixing (incidental to packing or storing):
- Grain, whole; or
- Forage.

The low-risk on farm packing and holding activity/animal food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership reflect the findings of the analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VII.B and VII.C.

For purposes of proposed § 507.5(e) and (f), ''other plant byproducts'' includes such things as barley hulls, cottonseed hulls, corn cobs, oat hulls, rice hulls, and straw. Grain and oilseed byproducts can be considered part of ''grain and oilseed'' as a general matter, but FDA has addressed those foods separately for the purpose of the risk evaluation and the proposed § 507.5(e) and (f) exemptions in order to accurately reflect differences in activity/animal food combinations likely to be performed on farm mixed-type facilities on grain and oilseed byproducts as compared to other grains and oilseeds, as well as differences in risk across those activity/animal food combinations.

d. Proposed § 507.5(f)—Exemptions for on-farm low-risk manufacturing/processing activity/animal food combinations. Proposed § 507.5(f) would provide that subpart C would not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FD&C Act that the business conducts consists of the following:

1. When conducted on a farm/farm mixed-typed facility's own (those grown or raised on that farm/farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) raw agricultural commodities for distribution into commerce:
- Cracking, crimping, flaking:
  - Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
  - Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or
  - Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
  - Grain;
  - Oilseed;
  - Grain or oilseed byproducts;
  - Forage (e.g., hay or ensiled material); or
  - Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage.
- Chopping, or shredding hay.
- Extracting (mechanical) or wet rolling:
  - Grain; or
  - Oilseed.

2. When conducted on animal food other than the farm mixed-typed facility's own raw agriculture commodities for distribution into commerce:
- Cracking, crimping, flaking, or shelling:
  - Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);
  - Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or
  - Grain or oilseed byproducts.
- Crushing, grinding, milling, pulverizing, or dry rolling:
  - Grain;
  - Oilseed;
  - Grain or oilseed byproducts;
  - Forage (e.g., hay or ensiled material); or
  - Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).
- Making silage.
- Chopping or shredding hay.
- Extracting (mechanical) or wet rolling:
  - Grain; or
  - Oilseed.
- Labeling:
  - Grain whole; or
  - Oilseed whole.
- Sifting, separating, or sizing:
  - Grain;
  - Oilseed;
  - Grain or oilseed byproducts; or
  - Other plants or plant byproducts.

The low-risk on-farm manufacturing/processing activity/animal food combinations reflect the findings of the analysis required by section 103(c)(1)(C) of FSMA, discussed in sections VII.B and VII.C.

6. Proposed § 507.5(g) and (h)—Exemptions Applicable to Raw Agricultural Commodities (RACs)

In § 507.5(g), the Agency is proposing that subpart C would not apply to facilities solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. And in § 507.5(h), the Agency is proposing that subpart B would not apply to the holding or transportation of one or more ''raw agricultural commodities,'' as defined in section 201(r) of the FD&C Act.

The current 21 CFR 110.19(a) for human food, provides that establishments engaged solely in the harvesting, storage, or distribution of one or more RACs, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public, are exempt from the requirements of part 110 (21 CFR part 110). In section VIII.D of the document for the proposed rule for preventive controls for human food (78 FR 3646), the Agency discusses the meaning of the term raw agricultural commodity. The Agency tentatively concludes that the exemption for RACs from proposed part 507 subpart B for animal food is consistent with the treatment of RACs for human food.

Section 418(m) of the FD&C Act provides in relevant part that FDA may by regulation ''exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in . . . the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing''.

This provision would exempt, for example, facilities that only store whole grains (such as corn, wheat, barley, oats, and soybeans) for animal food from subpart C. This would include facilities such as grain elevators provided that such facilities do not conduct other activities subject to section 418 of the FD&C Act. Outbreaks of illness associated with feeding RACs to animals have not been traced back to storage facilities solely engaged in the storage of RACs. In addition, facilities that are solely engaged in the storage of RACs are exempt from the current part 110 CGMP regulations for human food, and FDA proposes to also exempt these facilities from the proposed CGMPs for animal food. Such facilities would remain subject to the requirements of the FD&C Act. For example, if animal food is stored under insanitary conditions whereby the animal food may become contaminated with filth or rendered injurious to health, the animal food would be adulterated under section 402(a)(4) of the FD&C Act.

While outbreaks of illness associated with feeding RACs to animals have not been traced back to storage facilities solely engaged in the storage of RACs, FDA is aware of changes in feeding practices which might increase the risk associated with feeding RACs obtained

directly from storage facilities. FDA is aware that some farms function as animal feeding operations, growing no crops for animal food use, but simply purchasing animal food, raw agricultural commodities, or animal food ingredients for further manufacturing into animal food for animals held on that farm. In the animal food industry, raw agriculture commodities such as corn, wheat, oats, barley, rye, milo, rice, soybeans, peanuts, and canola are shipped directly from grain elevators to farms that raise animals for human food production such as poultry farms (broilers, layers), dairy farms, beef-feed lots, and swine farms. At these farms, the raw agricultural commodity received from the grain elevators is mixed (processed) into animal food rations.

While the Agency tentatively concludes that animal food facilities such as grain elevators that are solely engaged in the storage of grains that are raw agricultural commodities should be exempt from proposed subpart B and proposed subpart C, the Agency does have some concerns. One of those concerns is the potential for mycotoxins, such as aflatoxins, fumonisins, and DON, to be present in RACs obtained by farms and fed to animals. This concern is largely mitigated for RACs intended for human food because RACs for human food routinely undergo further processing and are rarely consumed in the ''raw'' state.

Mycotoxins are toxic by-products of mold that can develop in certain agricultural commodities pre-harvest or post-harvest while in storage. Mycotoxins can reduce animal productivity, cause sudden death if fed in large quantities, and can become a component of milk and eggs intended for human consumption.

Mycotoxin contamination varies greatly from year to year and by geographic region of the country, depending on weather conditions that stress crops and predispose to mold growth. In regions of the country where conditions tend to favor mold growth, grain elevators and other buyers routinely monitor for this hazard and turn away producers whose crops exceed FDA's action levels for the various mycotoxins. For example, grain elevators will reject corn that tests higher than 20 parts per billion for aflatoxin, the action level established by FDA for use in feed for animal species other than beef cattle, swine, poultry, or when the intended species is not known. Grain elevators in other regions of the country are familiar with the weather phenomena that predispose to mycotoxin production and monitor incoming shipments of grain accordingly. The grain industry is also familiar with proper drying and storing procedures to prevent mold growth and mycotoxin production. Therefore, due to controls already in place by the grain industry, and due to regulatory oversight by USDA under the United States Grain Standards Act, FDA has tentatively concluded to exempt facilities solely holding grains from preventive controls.

However, the Agency is seeking comment on whether animal food facilities, such as grain elevators, that are solely engaged in the storage of grains that are raw agricultural commodities should be exempt from subpart B and subpart C of proposed part 507; how many of these types of facilities and operations are in the United States; and what is the best approach to ensure that the raw agricultural commodities distributed by these facilities to animal feeding operations are free of hazards that would be likely to cause illness or injury to animals or humans.

7. Applicability of Part 507 to Alcoholic Beverages

In the proposed rule for preventive controls for human food (78 FR 3646), the Agency is proposing that proposed subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' would not apply to certain alcoholic beverages and a very narrow set of prepackaged other food at alcoholic beverage facilities, based on the Agency's interpretation of section 116 of FSMA. Under proposed § 117.5(i), subpart C of the human food rule would not apply with respect to food that is not an alcoholic beverage at certain alcoholic beverage facilities, provided that such food (1) is in prepackaged form that prevents any direct human contact with such food, and (2) constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury (see section X.C.7 of the document for the proposed rule for preventive controls for human food (78 FR 3646)). Section 116 of FSMA applies to animal food. However, the Agency is not aware of any animal food at alcoholic beverage facilities that would be exempt from section 418 of the FD&C Act under the proposed interpretation, and therefore is not aware of any animal food at alcoholic beverage facilities that would be exempt from proposed subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' for animal food. For example, FDA understands that many breweries and distilleries sell spent grains, such as brewers dried grains and distillers dried grains, as animal food. Because those spent grains are not alcoholic beverages themselves, and they are not in a prepackaged form that prevents any direct human contact with the food, the Agency tentatively concludes that subpart C of this proposed rule would apply to them.

D. Proposed § 507.7—Requirements That Apply to a Qualified Facility

1. Requirements of Section 418(l) of the FD&C Act

Section 418(l) of the FD&C Act establishes modified requirements for ''qualified facilities.'' As discussed in section II.C, section 418(l)(1) of the FD&C Act establishes the conditions for a facility to be a ''qualified facility'' based on either business size (section 418(l)(1)(B) of the FD&C Act) or a combination of the average monetary value of the food sold and the value of food sold to qualified end users as compared to all other purchasers (section 418(l)(1)(C) of the FD&C Act), and proposed § 507.3 would establish a definition for ''qualified facility'' based on section 418(l)(1).

Sections 418(l)(2)(A) and (B) of the FD&C Act provide that a qualified facility is exempt from the requirements of sections 418(a) through (i) and (n) of the FD&C Act (i.e., the requirements for hazard analysis and risk-based preventive controls), but must instead submit two types of documentation to the Secretary of HHS. The first type of required documentation relates to food safety practices at the facility, and section 418(l)(2)(B)(i) of the FD&C Act provides two options for satisfying this documentation requirement. Under section 418(l)(2)(B)(i)(I) of the FD&C Act, the qualified facility may choose to submit documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective. Alternatively, under section 418(l)(2)(B)(i)(II) of the FD&C Act, the qualified facility may choose to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law.

The second type of required documentation relates to whether the facility satisfies the definition of a qualified facility. Under section 418(l)(2)(B)(ii) of the FD&C Act, the facility must submit documentation, as specified by the Secretary in a guidance document, that the facility is a qualified facility under section 418(l)(1)(B) of the FD&C Act or section 418(l)(1)(C) of the FD&C Act.

Section 418(l)(7)(A) of the FD&C Act requires that a qualified facility that is exempt from the requirements under sections 418 (a) through (i) and subsection (n), and that does not prepare documentation under section 418(l)(2)(B)(i)(I)of the FD&C Act, provide notification to consumers by one of two procedures, depending on whether a food packaging label is required on the food. With respect to an animal food for which an animal food packaging label is required by the Secretary of HHS under any other provision of the FD&C Act, section 418(l)(7)(A)(i) of the FD&C Act requires that a qualified facility include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed. With respect to an animal food for which an animal food packaging label is not required by the Secretary of HHS under any other provisions of the FD&C Act, section 418(l)(7)(A)(ii) of the FD&C Act requires that a qualified facility prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

2. Proposed § 507.7(a)—Documentation To Be Submitted

a. Proposed § 507.7(a)(1)—Documentation That the Facility Is a Qualified Facility

Proposed § 507.7(a)(1) would require that a qualified facility submit to FDA documentation that the facility is a qualified facility. Consistent with the conditions in section 418(l)(1) of the FD&C Act for a facility to be a qualified facility, and the Agency's proposed definition (proposed § 507.3) of ''qualified facility,'' the documentation would be directed to either the status of the facility as a very small business (as would be defined in proposed § 507.3) or the applicability of conditions for average annual monetary value and the value of food sold to qualified end users as compared to other purchasers (as would be included in the definition of qualified facility in proposed § 507.3). As discussed further in section VIII.D.5, FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility is a very small business, otherwise meets the definition of a qualified facility under proposed § 507.3, or both, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 507.7(a)(1). The Agency would not, for example, require that a facility submit financial information to FDA demonstrating its total sales or to the proportion of sales to qualified end users.

Proposed § 507.7(a)(1) also would establish that, for the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011. The conditions related to average annual monetary value established in section 418(l)(1)(C) of the FD&C Act, and the definition of very small business in proposed § 507.3, allow adjustment for inflation. To establish a level playing field for all facilities that may satisfy definition of a qualified facility, the Agency is proposing to establish the baseline year for the calculation in proposed § 507.7(a)(1). The Agency is proposing to establish 2011 as the baseline year for inflation because 2011 is the year that FSMA was enacted into law. The Agency tentatively concludes that because Congress provided a specific dollar amount in section 418(l)(1)(C)(ii)(II) of the FD&C Act, i.e., $500,000, and it provided that the dollar amount should be adjusted for inflation, it is reasonable to establish the baseline year as the year that the law was enacted.

b. Proposed § 507.7(a)(2)—Documentation Related to Food Safety Practices at a Facility

Proposed § 507.7(a)(2) would provide two options for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility. Proposed § 507.7(a)(2)(i) would allow qualified facilities to submit documentation to demonstrate that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective to satisfy this requirement.

Proposed § 507.7(a)(2)(i) would implement the provisions of section 418(l)(2)(B)(i)(I) of the FD&C Act, except that proposed § 507.7(a)(2)(i) would specify monitoring the performance of the preventive controls to ensure that such controls are effective (emphasis added). As discussed in section II.C, under the overall framework of the proposed requirements that would be established in subpart C, monitoring is directed to performance of preventive controls. Thus, proposed § 507.7(a)(2)(i) is consistent with the statute and the overall framework of this proposed rule.

Proposed § 507.7(a)(2)(ii) would provide another option for satisfying the documentation requirement in section 418(l)(2)(B)(i) of the FD&C Act related to food safety practices at the facility by allowing qualified facilities to submit documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Proposed § 507.7(a)(2)(ii) would implement the provisions of section 418(l)(2)(B)(i)(II) of the FD&C Act.

FDA tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility: (1) Has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective or (2) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 507.7(a)(2). The Agency would not, for example, require that a facility submit documentation to FDA demonstrating the content of their hazard identification, preventive controls, or monitoring of the implementation of preventive controls; or copies of their non-Federal licenses, inspection reports, certificates, permits, credentials, or certifications.

3. Proposed § 507.7(b)—Procedure for Submission

Proposed § 507.7(b) would require that qualified facilities submit the

documentation that would be required by proposed § 507.7(a) by one of two procedures. Proposed § 507.7(b)(1) would provide an option to submit documentation electronically at *http://www.access.fda.gov* by following the instructions to be provided on that Web page. Proposed § 507.7(b)(1) would inform facilities that this Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. Although electronic submission is not required, proposed § 507.7(b)(1) would encourage electronic submission, which is efficient for FDA and should also be efficient for facilities. Electronic submission generally would be available 24 hours a day, 7 days a week, unless the Web site is experiencing technical difficulties or is undergoing maintenance.

Proposed § 507.7(b)(2) would provide an option to submit documentation by mail. A qualified facility would have the option to submit documents in a paper format or in an electronic format on a CD–ROM, by mail to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. ''Mail'' would include the U.S. mail and businesses that can deliver documents to the address provided. The Agency would recommend that an owner, operator or agent in charge of a qualified facility submit by mail only if the qualified facility does not have reasonable access to the Internet. It is not efficient for FDA to receive such documents by mail.

The Agency is not proposing to provide for submission by fax. The Agency expects that there may be technical difficulties or loss or mix-up of some submitted information if the Agency were to allow for submission by fax.

4. Proposed § 507.7(c)—Frequency of Submission

Proposed § 507.7(c)(1) would require that the documentation that would be required by section § 507.7(a) be submitted to FDA initially within 90 days of the applicable compliance date of the rule. As discussed in section VI, the compliance date for a small business would be 2 years after the date of publication of the final rule and the compliance date for a very small business would be 3 years after the date of publication of the final rule.

Proposed § 507.7(c)(2) would require that the documentation that would be required by proposed § 507.7(a) also must be resubmitted to FDA at least every 2 years, or whenever there is a material change to the information that would be described in proposed § 507.7(a). For the purposes of proposed § 507.7, a material change would be one that changes whether or not a facility is a ''qualified facility.'' The status of a facility as a qualified facility has the potential to change materially on an annual basis. For example, if a facility reports that it is a very small business (i.e., under one option identified in proposed § 507.3, has less than $500,000 in total annual sales of animal food, adjusted for inflation), its total annual sales of animal food likely would change on an annual basis, and could change so as to exceed $ 500,000. Likewise, if a facility reports that it otherwise satisfies the definition of a qualified facility, its total annual sales of animal food and value of animal food sold to qualified end users as compared to other purchasers likely would change on an annual basis, and could change so as to no longer satisfy the definition of a qualified facility.

5. Information That Would Be Submitted

Consistent with section 418(l)(2)(B)(ii) of the FD&C Act, the Agency intends to issue guidance regarding documentation that would be submitted under proposed § 507.7(a)(1) to demonstrate that a facility is a qualified facility. As discussed in sections VIII.D.2.a and VIII.D.2.b, the Agency tentatively concludes that certified statements from the owner, operator, or agent in charge of a qualified facility would be acceptable for the purposes of satisfying the requirements that would be established in proposed § 507.7(a)(1) and (a)(2).

To inform the guidance required under section 418(l)(2)(B)(ii) of the FD&C Act and any other guidance that may be useful in addressing questions regarding submission of documentation under this subpart, in this document the Agency requests comment on an option it is considering regarding the submission of documentation. Specifically, the Agency requests comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility. A facility that does not identify itself as a qualified facility would not be prompted to provide additional information under proposed § 507.7(a).

A facility that identifies itself as a qualified facility would be prompted to provide the following information by checking items that apply. Such items could include:

- Whether the facility satisfies the conditions for a qualified facility:
  - ○ As a very small business as that term would be defined in proposed § 507.3;
  - ○ As a facility that otherwise satisfies the definition of qualified facility in proposed § 507.3 based on average monetary value of sales and value of animal food sold to qualified end users as compared to other purchasers; or
  - ○ Both of the conditions.
- Whether the facility:
  - ○ Has identified the potential hazards associated with the animal food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective;
  - ○ Is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries; or
  - ○ Both of the conditions.

In essence, such a system would provide for self-certification that the facility has appropriate information demonstrating that the facility is a qualified facility and either has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the implementation of the preventive controls to ensure that such controls are effective; or is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries. Such a system may include a statement reminding submitters that anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties under 18 U.S.C. 1001. Using such a system, a qualified facility could update the documentation required by proposed § 507.7(a) during the biennial registration required by section 415(a)(3) of the FD&C Act.

6. Proposed § 507.7(d)—Notification to Consumers

Proposed § 507.7(d) would require that a qualified facility that does submit the type of documentation directed to food safety practices described in § 507.7(a)(2)(i) provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. box, city, State, and zip code for domestic facilities, and comparable full address information for foreign facilities) consistent with section 418(l)(7) of the FD&C Act. If an animal

food packaging label is required, proposed § 507.7(d)(1) would require that the required notification appear prominently and conspicuously on the label of the animal food. If an animal food packaging label is not required, proposed § 507.7(d)(2) would require that the required notification appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

Proposed § 507.7(d) would enable consumers to contact the facility where an animal food was manufactured or processed (e.g., if the consumer identifies or suspects a food safety problem with a product) irrespective of whether the animal food product bears a label. The use of the term ''business address'' in section 418(l)(7) of the FD&C Act contrasts with Congress' use of a different term, ''place of business,'' in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods in package form are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. The Agency's regulations interpret ''place of business'' as requiring only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 CFR 501.5(d)). The Agency tentatively concludes that the use of the term ''business address'' in section 418(l)(7) demonstrates Congress' intent to require the facility's full address, including the street address or P.O. box, to appear on labels or other required notifications when the facility has opted to not submit documentation directed to food safety practices under section 418(l)(2)(B)(i)(I) of the FD&C Act. If Congress had considered the less complete address already required under section 403(e)(1) of the FD&C Act and the ''place of business'' labeling regulation (§ 501.5(d)) to be adequate for notification to consumers for animal foods required to bear labels, there would have been no need to impose a new, more specific requirement in section 418(l)(7) for the facility's ''business address'' to appear on the food label. When proposed § 507.7(d) would apply to an animal food for which a food packaging label is required under any other provision of the FD&C Act, the complete business address would substitute for the ''place of business'' required under section 403(e)(1) of the FD&C Act and § 501.5(d) and would not impose any requirement for a label that would be in addition to any label required under any other provision of the FD&C Act. The Agency asks for comment on this interpretation.

7. Records

Proposed § 507.7(e) would require that a qualified facility maintain records relied upon to support the documentation that would be required by § 507.7(a). Proposed § 507.7(a) would not require that a qualified facility establish any new records, but merely retain those that the facility relied upon to support the documentation that would be required by proposed § 507.7(a). Proposed § 507.7(e) would establish that the records that a qualified facility must maintain are subject to the requirements of subpart F of part 507. As discussed in section XII, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by proposed part 507, including provisions for retention of records and for making records available for official review. Together, proposed § 507.7(a) and (b) would make the underlying records qualified facilities would rely on to support their self-certifications available to FDA upon request. The Agency tentatively concludes that it is appropriate to require that the records relied upon to support a self-certified statement be retained and made available to FDA upon request.

E. Proposed § 507.10—Applicability of Subpart C to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Section 418(m) of the FD&C Act provides, in relevant part, that ''[t]he Secretary may, by regulation, exempt or modify the requirements for compliance under [section 418 of the FD&C Act] with respect to facilities that are solely engaged in . . . the storage of packaged foods that are not exposed to the environment.''

2. Petition Relevant to Section 418(m) of the FD&C Act

In a letter dated July 22, 2011, an industry coalition of the American Bakers Association, the American Frozen Food Institute, the Grocery Manufacturers Association, the International Bottled Water Association, the International Dairy Foods Association, the International Warehouse Logistics Association, the Peanut and Tree Nut Processors Association, and the Snack Food Association (the section 418(m) petitioners) submitted a citizen petition (Docket No. FDA–2011–P–0561). The petition requests that FDA issue regulations under section 418(m) of the FD&C Act ''to exempt from compliance or modify the requirements for compliance under section 418 [of the FD&C Act] for facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment, by allowing such facilities to satisfy the requirements of that section through compliance with the [CGMPs] mandated for such facilities by [current] § 110.93.'' For full discussion of this petition, please see the discussion in section X.D of the document for the proposed rule for preventive controls for human food (78 FR 3646).

3. FDA's Tentative Response to the Petition

The Agency tentatively agrees in part, and disagrees in part, with the section 418(m) petitioners. As discussed more fully in the paragraphs that follow, FDA agrees that it is appropriate for facilities solely engaged in the storage of unexposed packaged animal food to be exempt from the requirements that would be established in proposed subpart C, provided that the animal food does not require time/temperature control for safety. For unexposed packaged animal food that requires time/temperature control for safety, FDA disagrees that such an exemption is warranted, but tentatively concludes that unexposed packaged animal food that requires time/temperature control for safety could be subject to modified requirements rather than to the full requirements that would be established in proposed subpart C.

The Agency disagrees that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls. The principal hazard that would be identified in any hazard analysis for unexposed packaged animal food is the potential for the growth of, or toxin formation by, microorganisms of animal or human health significance when an unexposed refrigerated packaged animal food requires time/temperature control for safety. Information about this hazard and appropriate preventive controls for this hazard is widely available (Refs. 39, 40, and 41). For example, the 2009 Edition of FDA's Food Code defines ''Potentially Hazardous Food (Time/Temperature Control for Safety Food)'' as a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin

formation (Ref. 39). Earlier editions (e.g., the 2001 Food Code) included a similar definition for ''potentially hazardous food''; since 2005, the definition jointly refers to ''potentially hazardous food'' and ''time/temperature control for safety food'' (commonly referred to as TCS food) to emphasize the importance of temperature control in keeping food safe. Although FDA disagrees that warehouse operators do not have access to information relevant to conducting a hazard analysis and establishing risk-based preventive controls, the Agency agrees that it is not necessary for each facility solely engaged in the storage of unexposed packaged animal food to conduct its own hazard analysis to identify this hazard for unexposed refrigerated packaged animal food as reasonably likely to occur and for each such facility to determine that time/temperature control is the appropriate preventive control.

FDA also disagrees that proposed § 507.28 alone would be adequate for addressing environmental problems such as a flood in the facility and pest control problems, even though the animal food in question is not exposed to the environment and pest control problems with the container would likely be visible to the warehouse operator. However, FDA tentatively concludes that proposed § 507.28, along with other applicable provisions of proposed part 507, subpart B, such as pest control in proposed § 507.19, do adequately address most safety-related issues that may arise in facilities solely engaged in the storage of unexposed packaged animal food. FDA disagrees that proposed § 507.28, or other provisions in proposed part 507, subpart B, justifies the exemption from all preventive control requirements sought by the petitioners in the specific case of unexposed refrigerated packaged animal food that requires time/temperature control for safety (later in this document stated as unexposed refrigerated packaged TCS animal food). As discussed more fully in section X.I, such animal food requires the implementation of an appropriate preventive control (temperature), monitoring that control, taking corrective actions when there is a problem with that control, verifying that the control is consistently implemented, and establishing and maintaining records documenting the monitoring, corrective actions, and verification. FDA tentatively concludes that it is appropriate to distinguish between packaged animal food that requires such time/temperature control and packaged animal food that does not.

FDA also disagrees that an exemption provided under section 418(m) of the FD&C Act should be established in a manner that has the potential to be interpreted more broadly than section 418(m) provides. The section 418(m) petitioners request that FDA establish a provision that ''A facility that is engaged solely in the storage, holding, warehousing, or distribution of packaged foods that are not exposed to the environment shall be exempt from the requirements of section 418 [of the FD&C Act]'', whereas section 418(m) provides discretion for an exemption ''with respect to facilities that are solely engaged in . . . the storage of packaged foods that are not exposed to the environment.'' Under proposed § 507.3, ''holding'' would mean storage of animal food, and holding facilities would include, relevant to unexposed packaged animal food, warehouses and cold storage facilities. To the extent that a facility that is engaged solely in ''warehousing'' or ''distribution'' of unexposed packaged animal food is merely ''storing'' or ''holding'' the animal food, an exemption established using the language provided by section 418(m) would apply to that facility. However, to the extent that a facility that is engaged solely in ''warehousing'' or ''distribution'' of unexposed packaged animal food is not merely ''storing'' or ''holding'' the animal food, an exemption established using the language provided by section 418(m) would not apply to that facility.

In response to the petition, FDA is proposing to establish an exemption from subpart C for facilities solely engaged in the storage of unexposed packaged animal food (proposed § 507.10). FDA also is proposing to establish modified requirements at such facilities to require that the owner, operator, or agent in charge of such a facility comply with modified requirements for any unexposed refrigerated packaged TCS animal food (proposed § 507.48). See the discussion of proposed § 507.10 in the next section and the discussion of proposed § 507.48 in section X.I.

4. Proposed § 507.10—Applicability of Part 507 to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

Proposed § 507.10(a) would provide that subpart C does not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment. Proposed § 507.10(b) would establish that unexposed packaged animal food at such facilities is subject to modified requirements that would be established in proposed § 507.48. As discussed more fully in section X.I, the modified requirements would mandate that such a facility establish and implement appropriate temperature controls, monitor the temperature controls, take corrective actions, verify that the temperature controls are consistently implemented, and establish and maintain records documenting the monitoring, corrective actions, and verification activities for unexposed refrigerated packaged TCS animal food. These modified requirements would be a subset of the proposed requirements that would be established in subpart C.

There are limited routes of contamination for unexposed packaged animal food in a facility that solely stores unexposed packaged animal food (e.g., packaged animal food in containers in a warehouse). Contamination can occur, for example, if rodents gnaw through packages or if human waste from an improperly maintained toilet facility spills and seeps into paper-based packaging. However, with one exception, the CGMP requirements in proposed subpart B (e.g., proposed §§ 507.17, 507.19, 507.20, and 507.28) would apply to the storage of unexposed packaged animal food and be adequate to prevent such contamination so that it would not be necessary for the owner, operator, or agent in charge of a facility to address these routes of contamination by applying the hazard analysis and risk-based preventive controls that would be established in proposed subpart C. The exception would be for the rare circumstances in which RACs are packaged in a manner in which the RACs are not exposed to the environment. An establishment solely engaged in storing RACs would be exempt from CGMPs in proposed subpart B. Such an establishment would continue to be subject to section 402(a)(4) of the FD&C Act. An establishment that is solely engaged in the storage of packaged RACs that are not exposed to the environment may find the provisions of proposed subpart B helpful in ensuring compliance with section 402(a)(4) of the FD&C Act.

Many of the requirements that would be established in proposed subpart C would be directed to manufacturing, processing, and packing animal food and would not apply to the storage of unexposed packaged animal food that does not require time/temperature control for safety. This is the case for:

- Process controls (proposed § 507.36(d)(1));
- Sanitation controls (proposed § 507.36(d)(2));

- Monitoring of process controls and sanitation controls (proposed § 507.39);
- Corrective actions (proposed § 507.42);
- Verification (including initial validation) of process controls (proposed § 507.45); and
- A recall plan (proposed § 507.38) (recalls generally are initiated by the manufacturer, processor, or packer of the animal food).

FDA tentatively concludes that the outcome of a hazard analysis for storage of unexposed packaged animal food that does not require time/temperature control for safety is that there are no hazards reasonably likely to occur. FDA also tentatively concludes that there would be little animal and human health benefit to requiring the owner, operator, or agent in charge of each facility solely engaged in the storage of such animal food to conduct its own hazard analysis and document that outcome in its own animal food safety plan. Likewise, FDA tentatively concludes that there would be no need for the facility to establish and implement preventive controls, with corresponding monitoring, corrective actions, or verification (including validation), because there would be no hazards reasonably likely to occur to trigger such activities. FDA also tentatively concludes that there would be no need for a qualified individual to conduct activities such as preparing the animal food safety plan (proposed § 507.30(c)); validating the preventive controls (proposed § 507.45(a)); reviewing records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (proposed § 507.45(c)); or performing reanalysis of the animal food safety plan (proposed § 507.45(e)(4)), because the facility would not need to conduct these activities. Thus, with the exception of the unexposed refrigerated packaged TCS animal food, FDA tentatively concludes that the animal food safety system that would be established in proposed subpart C is not needed to significantly minimize or prevent the occurrence of hazards that could affect unexposed packaged animal food at a facility solely engaged in the storage of such animal food.

The purpose of proposed § 507.10(b) is to make clear that although a facility solely engaged in the storage of unexposed packaged animal food is exempt from subpart C, such a facility is subject to modified requirements that would be established in proposed § 507.48. These requirements would apply to the storage of unexposed refrigerated packaged TCS animal food. The Agency explains the basis for those proposed requirements in section X.I.

IX. Proposed Subpart B—Current Good Manufacturing Practice

A. Animal Food and Current Good Manufacturing Practices (CGMPs)

The preventive controls system will result in controls that are specific to each facility based on the hazards it identifies and the controls it determines are necessary to control such hazards. Although FDA has had general baseline controls that apply to most establishment manufacturing, processing, packing, and holding human food in its current good manufacturing regulations under part 110, FDA has not had such baseline controls for facilities manufacturing, processing, packing, and holding animal food. The animal food industry, as well as governmental entities and international bodies, have recognized the need for basic safety and sanitation measures that apply across the board to facilities handling animal food. The AAFCO passed its ''Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients'' in August 2009 and published them in 2010 in the AAFCO *Official Publication* (Ref. 42). AAFCO is a voluntary membership association of State and Federal Agencies charged with the regulation, sale, and distribution of animal feeds. The goal of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions, and enforcement policies for regulating the manufacture, labeling, distribution, and sale of animal feeds. AAFCO's Model CGMPs stipulate basic requirements for the production of safe animal food, and cover the following areas: Personnel; establishments, including construction, design, and grounds; maintenance and housekeeping, including pest control; equipment, including construction and design; receiving and storage for further manufacture; manufacturing; labeling; storage of finished feed and/or feed ingredients; inspection, sampling, and testing of incoming and finished feed and/or feed ingredients for adulterants; transportation of feed and/or feed ingredients; and voluntary recall/withdrawal. AAFCO is not an enforcement agency, however in States that adopt the model CGMPs into their State animal feed regulations, failure of an animal food facility to adhere to these CGMPs would be grounds for enforcement action by the state.

The Codex Animal Production and Health Manual of Good Practices for the Feed Industry is a collaborative effort between the Food and Agriculture Organization (FAO) of the United Nations, and the International Feed Industry Federation, with significant contributions from members of a number of national feed industry trade associations, members of individual companies within the feed industry, and animal feed experts from universities. The good manufacturing practices (GMPs) described in Section 3 (Ref. 43) of the manual are practices and procedures intended to ensure the safety and suitability of animal food throughout the feed chain, and provide for such practices and procedures to be implemented in the following areas: Buildings and facilities; location of feed establishment; design and layout; internal structure and fittings; water supply; cleaning facilities; air quality, temperature and ventilation; lighting; equipment; personal hygiene; cleaning; maintenance; pest control; waste; drains; storage; transport; and training.

The Prerequisite Programmes for Food Safety in the Manufacture of Food and Feed for Animals (Publicly Available Specification (PAS) 222) (Ref. 44) were prepared by the British Standard Institution and the PAS 222 Steering Group, with sponsorship by Safe Supply of Affordable Food Everywhere. The British Standard Institution is an independent, private, non-governmental, non-industry organization that develops standards for a variety of industries. It is the standards setting body of the United Kingdom (Ref. 44). The steering group was made up of members from Agriculture Industries Confederation, Cargill, FAO, Foundation for Food Safety Certification, Land O'Lakes, Nestle, and Nutreco. PAS 222 specifies requirements addressing the following areas: Site and associated utilities; processes, including workspaces and employee facilities; supplies of air, water, and other utilities; supporting services, including waste disposal; suitability of equipment and accessibility for cleaning, maintenance, and preventive maintenance; management of ingredients; management of medications; measures for the prevention of contamination; sanitation; pest control; personnel hygiene; rework; product withdrawal procedures; warehousing and transportation; formulation of products; specifications for services; training and supervision of personnel; product information; and food defense, biovigilance, and bioterrorism.

The GMPs described previously are the product of efforts by government, industry, and international animal health organizations. They are very

similar to each other and similar to the CGMPs that FDA is proposing in part 507 because they all have in common the goal of ensuring that all food, including animal food, is manufactured under conditions and practices that protect against contamination with undesirable biological, chemical, physical, and radiological agents. At least one organization, Codex, in the context of animal food, articulated the need for a facility to have a prerequisite program, such as CGMPs, before establishing a HACCP program (Ref. 43). FDA's adoption of animal food CGMPs would establish such a prerequisite program for the preventive controls program for animal food under section 418 of the FD&C Act. Such a prerequisite program already exists for human food.

In addition to the risk to animals, the proposed animal food CGMPs address risks to human health from individuals handling animal foods or individuals consuming products from food-producing animals. The human food CGMPs in part 110 are designed to address risks to humans, and the Agency has experience and expertise in the human food CGMPs. Therefore, after considering the animal food CGMP documents from the previously mentioned organizations, and the Agency's CGMP regulations for human food, the Agency tentatively concludes that the human food CGMPs provide an appropriate starting point for the animal food CGMPs. The Agency requests comments on this tentative conclusion. The CGMPs proposed here in subpart B for animal food address the same areas as the current human food CGMPs in part 110 and the proposed revisions that would be incorporated into proposed part 117 (under the proposed rule for preventive controls for human food published (78 FR 3646)) and cover the following areas: Personnel; plant and grounds; sanitary operations; sanitary facilities and controls; equipment and utensils; processes and controls; and warehousing and distribution.

The proposed animal food CGMPs are not identical to the current and proposed human food CGMPs. The proposed animal food CGMPs do not address ''cross-contact'', which for human foods is related to the inadvertent incorporation of allergens into foods. The Agency is not aware of evidence indicating that foodborne allergens pose a significant health risk to animals, or to humans through handling animal food. In addition, the proposed animal food CGMPs do not include a provision related to raw materials and ingredients, including rework susceptible to contamination with pests, undesirable microorganism, or extraneous materials complying with FDA regulations for natural or unavoidable defects if a manufacturer wishes to use such materials in manufacturing such food. Unlike for human food, there is no agency regulation for natural or unavoidable defects for animal foods at this time. The proposed animal food CGMPs do not include the limitation in the current human food CGMPs (part 110) that food manufacturing areas and equipment used for manufacturing human food must not be used to manufacture nonhuman food grade animal food or inedible products, unless there is no reasonable possibility for contamination of the human food. The Agency does not consider such a limitation necessary for ensuring the safety of animal food, if the animal food is subject to the proposed CGMPs.

While FDA has tentatively concluded that CGMPs similar to those for human food would be appropriate for animal food, the Agency understands that animal food is produced in a wide diversity of facility types, from small portable animal food mixing units that travel from farm to farm, to large facilities that manufacture food for multiple species of livestock and pets. The Agency is also aware that once the animal food is produced, it may be fed to animals in environments and on surfaces that are not clean. However, basic sanitation measures for animal food are important. For example, the 2010 *Salmonella* Enteritidis outbreak in eggs coming from an egg producer and its associated facilities, demonstrated that *Salmonella* Enteritidis, once in the animal food, could contribute to maintaining the infection of the birds and the eggs they produce (Ref. 45). CDC reported over 1,900 human illnesses related to the outbreak, and FDA reported eggs were shipped to 22 states and Mexico by the initial producer identified in Iowa, and to 14 states by a second producer identified in Iowa (Ref. 46). This *Salmonella* contamination resulted in more than 500 million eggs being recalled. This incident alone demonstrates that the lack of control over the areas this rule is proposing to cover under CGMPs (personnel; plant and grounds; sanitary operations; sanitary facilities and controls; equipment and utensils; processes and controls; and warehousing and distribution), can and does lead to the spread of contamination of animal food within a facility. The loss of control in these areas resulted in the spread or recycling of the contamination, and at a very minimum, limited the ability of the producer to eliminate the contamination within the feed mill.

To emphasize the need for required CGMPs in the animal food industry, the following are actual observations from the FDA 483, List of Observations for a feed mill associated with the *Salmonella* in eggs outbreak (Ref. 47). This feed mill supplied animal food to both facilities involved in the outbreak:

''8. On xx/xx/10, the following observations were noted at the ****** Feed Mill located at *****, IA:

Specifically,

- Birds were observed roosting and flying, chicks heard chirping in the storage and milling facility. In addition, nesting material was observed in the feed mill closed mixing system, ingredient storage and truck filling areas.
- Raw ingredient bins and feed sensors accessible from the roof of the facility had rusted holes and feed grain level sensors ajar in the outdoor environment. These include:
- Ingredient storage bin 12 containing slat, had a rusted gap about a ½ inch wide the length of the lid of the roof level covered ingredient bin chute.
- Ingredient storage bin 21 containing ground corn had a hole approximately 3 inches by ½ inch wide at the base of the roof level cover ingredient bin chute.
- At the base of the feed grain level sensor leading into ingredient storage bin 21, containing ground corn, there was an open hole.
- Feed grain level sensor leading into ingredient storage bin 7, containing meat and bone meal, was off to the side with approximately a 2 inch gap. Avian like feces was observed on top to this feed sensor.
- Finished feed tanks 4 and 18 did not have covers on top of the finished feed tank chutes.
- Outdoor whole kernel corn grain bins 4 and 6 observed to have the top side doors/lids open to the environment and pigeons were observed entering and leaving these opening. Birds were also observed sitting/flying around and over openings.''

In addition to the previous observations, environmental samples collected from a top floor outlet location and two second floor covers all tested positive for *Salmonella* Enteritidis that the FDA laboratory confirmed as indistinguishable from the outbreak strain. The environmental positives at various levels within the feed mill are noteworthy because they illustrate the importance of overall sanitation within the facility. Without addressing worker hygiene practices, and other sanitary

practices detailed in the proposed CGMPs, a situation could arise whereby contamination could be spread throughout the facility by workers, equipment, and pests.

Whether animal food was the source of this *Salmonella* Enteritidis outbreak was never determined, but it is clear that the lack of overall sanitation contributed to contaminated feed and infection in the laying flock. Adherence by this firm to CGMPs for animal food could have been critical in controlling Salmonella contamination of the poultry facility.

As discussed in section II.E, the CDC reported that in a 2006–2007 multi-state outbreak, 79 human cases of salmonellosis were subsequently linked to *Salmonella* Schwarzengrund in dry dog foods that were manufactured by a company in the United States (Ref. 24). The company stopped production at the facility on July 29, 2007, when it was alerted to a possible link between dry pet food produced at the plant and people infected with *Salmonella* Schwarzengrund. The facility immediately recalled the suspected product. The source or cause of the contamination at the facility was not determined, but the company stopped production at the facility, did extensive cleaning, and resumed production at the facility after the cleaning and sampling showed negative *Salmonella* results from environmental and equipment sampling. The company ultimately closed the facility in 2008 when subsequent finish product testing by the facility again revealed *Salmonella* Schwarzengrund (Ref. 24).

The previous examples demonstrate that failure of an animal food facility to control the overall plant production environment, whether the plant manufactures, processes, packs, or holds food for pets or for food-producing animals, can and does result in human disease. In addition, regulations addressing the production of human food obtained from animals do not address the safety or production of animal food being fed to those food-producing animals. The Agency concludes that the previously described situations point to the need for this proposed rule for animal food, including the need for CGMPs.

The Agency realizes that there is a spectrum of animal food producers and production facilities and that the hazards and risks can vary greatly. Therefore the Agency is requesting comment on its thinking that CGMPs similar to those for human food are appropriate for animal food. The Agency is also requesting comment on whether CGMP requirements that would be more appropriate for some types of animal food may not be appropriate for other types, and, if so, how the Agency can or should distinguish between those types during the various stages of animal food processing.

The need for enforceable baseline standards for producing safe animal food was a major consideration in FDA's decision to propose CGMPs as part of its preventive controls regulations. Animal food facilities that are not subject to section 418 of the FD&C Act would be required to meet these baseline practices proposed in these CGMPs to prevent contamination of animal food. Facilities that are already adhering to trade association best practices, international standards described above, AAFCO model GMPs, or State animal feed regulations, may have their own strong quality control programs in place and may already be satisfying the CGMP requirements proposed here. Those firms that do not have such practices in place would have to implement them under this proposed rule, or be subject to enforcement action by FDA.

B. Proposed Current Good Manufacturing Practices (CGMPs) for Animal Food

1. Proposed § 507.14—Personnel

FDA is proposing in § 507.14 to require that personnel in animal food facilities conform to hygienic practices and receive appropriate training to protect against contamination of animal food. Section 507.14(a) would require that employees with an illness or open lesion that could reasonably be a source of contamination of animal food report the condition to their supervisor and refrain from performing activities that could result in contamination of animal food.

This proposed requirement is similar to PAS 222 at 13.5, which requires persons known or suspected to be infected with, or carrying, a disease or illness transmissible through animal feed intended for feeding within the home to be prevented from handling such food and food contract surfaces. Codex animal food CGMPs include a similar provision for all food employees who may be carriers for any disease or illness likely to be transmitted through animal food (Refs. 2 and 44).

Proposed § 507.14(a) would also require that while on duty employees maintain adequate personal cleanliness as appropriate for the activities they are performing. For example, employees would be required to wash their hands before starting work and at any other time when the hands become soiled or contaminated. The Agency is not proposing to require that employees wash their hands after each absence from the work station, as in the human food CGMPs, because in the animal food industry employee responsibilities are not typically limited to work stations. Employees would also need to secure jewelry and other objects such as personal belongings, tools, and writing implements to prevent them from falling into animal food, and store clothing and personal belongings in areas where they will not contaminate animal food. The Agency has received RFR reports of foreign objects such as pieces of a metal tape measure, plastic pieces from a hard hat, stainless steel shavings, and fragments of a soda can that were mixed into the animal food. In most of these reports, animal deaths occurred due to the consumption of the foreign objects in the food (Ref. 48).

For animal food, the Agency is not proposing some of the requirements in the human food CGMPs as proposed part 117. FDA tentatively concludes that certain requirements are necessary for ensuring the safety of animal food across the board, while other precautions may be important for some animal food facilities and not others, depending on the type of animal food handled at the facility, the species for which the animal food is intended, and whether human consumers could come into direct contact with the animal food, among other considerations. For example, the Agency is not proposing specific requirements for: Employees to wear certain types of outer garments; maintenance of gloves; wearing, hair nets, beard covers, etc.; confining certain activities to areas other than where animal food may be exposed or where equipment or utensils are washed; or specifying the foreign substances for which necessary precautions must be taken to protect against contamination of animal food, animal food-contact surfaces, or animal food packaging materials. The animal food proposed rule includes a general provision that would require the establishment to take any other necessary precautions to protect against contamination of animal food, animal food-contacts, or animal food packing materials. This broad provision would allow the individual facility to determine if it needed to use outer garments, hairnets, etc. for the particular animal food being manufactured, processed, packed, or held at that facility. FDA tentatively concludes that this approach is appropriate when considering the diversity of the animal food industry.

Both the PAS 222 and the Codex animal food CGMPs address these areas,

requiring personal hygiene for employees and requiring that items such as jewelry be secured. Unlike this proposed rule, the PAS 222 and the Codex animal food CGMPs provide for protective clothing and hair coverings where appropriate (Codex) and fit for the purpose (Refs. 2 and 44).

Proposed § 507.14(b) would recommend that personnel responsible for identifying plant sanitation failures or animal food contamination should have a background of education or experience to provide a level of competency necessary for production of clean and safe animal food. It would also recommend that animal food handlers and supervisors receive appropriate training in proper food handling techniques, food-protection principals, and be informed about the risks of poor personal hygiene and insanitary practices. The PAS 222, the AAFCO Model animal food CGMPs, and the Codex animal food CGMPs all provide for training of personnel in their areas of responsibility. As discussed in section IX.C, FDA is requesting comment on whether to change the recommendations to requirements for education or training in proper food handling techniques and food-protection principles.

FDA is proposing in § 507.14(c) that responsibility for ensuring compliance with all requirements in subpart B be clearly assigned to competent supervisory personnel.

2. Proposed § 507.17—Plant and Grounds

Plant, as defined in proposed § 507.3, means the building or establishment or parts thereof used in connection with the manufacturing, processing, packing, or holding of animal food. FDA is proposing in § 507.17(a) that the area around a plant be maintained so that it does not serve as a source of contamination of animal food.

Methods for adequately maintaining the grounds around a plant include properly storing equipment, removing litter and waste, and cutting weeds and grass within the immediate vicinity of plant buildings and structures. Litter, waste, tall grass, weed, and old equipment around plants can harbor pests which will try to enter the facility and could contaminate animal food and ingredients. Roads, yards, parking lots, and other areas in the vicinity of the plant would be required to be maintained and adequately drained so as not to contribute to contamination of animal food by seepage, foot-borne filth, or providing a breeding place for pests. Water seepage into animal food ingredients and finished products can promote growth of mold which could produce mycotoxins in the animal food. The PAS 222 (p. 4) contains a provision similar to proposed section 507.17(a). It provides the [s]ites to be maintained in good order. Vegetation shall be tended, removed or otherwise managed to address animal food safety hazards. Roads, yards and parking areas shall be drained to prevent standing water and shall be maintained (Ref. 44).

Proposed § 507.17(b) would require that the plant's size, construction and design allow for cleaning, maintenance, and exclusion of pests. Specifically, this proposed section would require that the size of the plant provide sufficient space to place equipment, store materials, and allow precautions to be taken to prevent contamination of animal food inside the plant and in outdoor bulk vessels. It would also require that construction of the plant be such that floors, walls, and ceilings can be kept clean and in good repair; that condensate from fixtures, ducts, and pipes not contaminate animal food; that there be enough space between equipment and walls to permit employees to perform their duties and protect against contaminating animal food; that lighting be adequate, and lighting fixtures, skylights, and other glass suspended over exposed food be of such construction that in case of breakage, glass does not contaminate animal food; that sufficient ventilation be provided to minimize odors and vapors without contaminating animal food; and that where necessary, adequate screening be provided to protect against pests. Proposed § 507.17(b) would also require that the design and construction of buildings and structures allow for separation of operations, for example by location or time, to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging material with microorganisms, chemicals, filth, or other extraneous material.

The Codex animal food CGMPs contain similar provisions that state that locations, design and construction of premises should deter pests and restrict access to pests to a minimum. Building and facilities should be designed to allow easy access for cleaning, including access to the inside of relevant equipment. There should be enough space to satisfactorily conduct all process operations and products inspections. Lighting sources should be sufficient to ensure that hygienic conditions are maintained throughout the product and storage areas. There should be protected lighting fixtures. There should be adequate means of ventilation to minimize airborne contamination of animal food from aerosols and condensation droplets (Ref. 2).

3. Proposed § 507.19—Sanitary Operations

Proposed § 507.19(a) would require that buildings, fixtures, and other physical structures be maintained in sufficient sanitary condition and repair to prevent animal food from becoming adulterated. Equipment and utensils would need to be cleaned and sanitized to protect against contamination of animal food, animal food contact surfaces, and animal food packaging materials. Reports of animal food contamination continue to be reported to the Agency due to improper flushing (cleaning) of equipment. In one incident, a vitamin D supplement for a poultry food was carried over to a dog food. The excessive vitamin D levels in the pet food caused toxicity in the animals consuming the food (Ref. 48). In addition, during facility inspections, FDA has identified forklifts, carts and other material handling equipment as sources of cross contamination between raw ingredients and finished products.

The PAS 222 provides for cleaning programs to be established and documented to maintain hygienic conditions. The Codex animal food CGMPs provide that cleaning should remove residues and dirt that may be a source of contamination. Sufficient standard of cleanliness should be employed to ensure that exposure to pests and pathogens is minimized at all stages of processing, storage, and handling of animal food (Ref. 43).

FDA is proposing in § 507.19(b) that cleaning compounds and sanitizing agents must be free from undesirable microorganisms, and that they must be safe and adequate for the conditions of use. Compliance with this requirement could be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination.

In § 507.19(c), the Agency proposes that only certain types of toxic materials, such as cleaning compounds, laboratory testing reagents, and lubrications for equipment, be used or stored in the plant. In addition these compounds must be identified, held, and stored in a manner that protects against contaminating animal food.

Both the PAS 222 and the Codex animal food CGMPs provide for cleaning and sanitizing agents to be stored separately to minimize the risk of contaminating animal food.

Proposed § 507.19(d) would require that effective measures be taken to

exclude pests from the manufacturing, processing, packing, and holding areas. The use of insecticides or rodenticides would be permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. As in the human food context, pests can be vectors for disease through microbial contamination of animal food. The AAFCO, PAS 22, and the Codex CGMP documents all address the need to exclude pests from the facility.

FDA is proposing in § 507.19(e)(1) and (e)(2) that animal food contact surfaces be cleaned as frequently as necessary to protect against contamination of animal food. Cleaning requirements would vary depending, for example, on whether equipment and utensils are used for manufacturing or holding low-moisture animal food, used for wet processing operations, or used in continuous production operations.

Proposed § 507.19(e)(3) would recommend that single-service articles (such as paper cups or paper towels) be stored in appropriate containers. Section 507.19(e)(3) is also proposing that these single-service articles be handled, dispensed, used, and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. As discussed in section IX.C, FDA is requesting comment on whether to change the recommendations to requirements for the storage of the single-service articles in appropriate containers.

Proposed § 507.19(f) recommends that non-animal food-contact surfaces of equipment used in the operation of the plant be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.19(f) to require rather than recommend that non-animal food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

Proposed § 507.19(g) would recommend that cleaned and sanitized portable equipment with animal food-contact surfaces be stored in a place and in a way that would protect any animal-food contact surfaces from contamination. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.19(g) to require rather than recommend that cleaned and sanitized portable equipment with animal food-contact surfaces and utensils be stored in a location and manner that protects animal food-contact surfaces from contamination.

4. Proposed § 507.20—Sanitary Facilities and Controls

In § 507.20(a), the Agency is proposing that the plant's water supply be sufficient for the operations intended and derived from an adequate source. Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials would need to be safe and of adequate sanitary quality. For example, steam added to animal food during the pelleting process would be required to be from a water source that is not contaminated with chemicals, such as petroleum, or pesticides. Running water at a suitable temperature and pressure would need to be provided in all areas where required for the processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee sanitary facilities.

Proposed § 507.20(b) would require that plumbing in the plant be of adequate size and design and adequately installed and maintained to: (1) Carry sufficient quantities of water to required locations throughout the plant; (2) properly convey sewage and liquid disposable waste from the plant; (3) avoid constituting a source of contamination to animal food, water supplies, equipment, or utensils or creating an unsanitary condition; (4) provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and (5) ensure that there is not backflow from, or cross-connection between piping systems that discharge waste water or sewage, and piping systems that carry water for animal food or animal food manufacturing.

Proposed § 507.20(c) would require that sewage be disposed of through an adequate sewerage system or through other adequate means.

FDA is proposing in § 507.20(d) that each plant provide its employees with adequate, readily accessible toilet facilities, and that the toilet facilities be kept clean and not serve as a potential source of contamination of animal food, animal food contact surfaces, or animal food-packaging materials. Proposed § 507.20(e) would require that each plant provide hand-washing facilities that are adequate, convenient, and furnish running water at a suitable temperature to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. Proposed § 507.20(f) would require that rubbish be conveyed, stored, and disposed of in such a way that minimizes the development of odors and the potential to attract, harbor, or create a breeding place for pests.

Sanitary facilities and controls are similarly addressed in PAS 222 in sections 5.2 (water supply), 6.2 (containers for waste), 6.3 (waste management and removal), 6.4 (drains and drainage), and 13.2 (personnel hygiene facilities) (Ref. 44). Water supply, cleaning facilities, waste, and drains are also covered in the Codex animal food CGMPs (Ref. 43). Many of the requirements in the proposed CGMPs follow closely to the PAS and CODEX provisions.

5. Proposed § 507.22—Equipment and Utensils

The Agency is proposing specific requirements for equipment and utensils used in animal food facilities. Proposed § 507.22(a)(1), (a)(2), and (a)(4) through (a)(6) would require that plant equipment and utensils be designed and constructed to allow for the cleaning and maintenance necessary to ensure that animal food would not be contaminated with non-food-grade lubricants, fuel, metal fragments, contaminated water such as condensate, or other contaminants. These requirements would reduce the likelihood of hazards in the animal food that could come from equipment components, such as coolant from an electrical motor leaking onto food contact surfaces. Animal food contact surfaces of equipment and utensils used in the plant would need to be made of nontoxic materials and resist corrosion from contact with animal food or cleaning and sanitizing agents. Proposed § 507.22(a)(3) would recommend that equipment be installed and maintained in such a way to facilitate the cleaning of that equipment and the adjacent spaces. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.22(a)(3) to require rather than recommend that equipment be installed and maintained in such a way to facilitate the cleaning of that equipment and adjacent spaces.

Proposed § 507.22(b) would require that seams on food-contact surfaces be maintained to minimize accumulation of food particles, dirt, and organic matter and thus minimize the

opportunity for growth of microorganisms. Proposed § 207.22(c) would require that equipment in the animal food manufacturing or handling area that does not come into contact with animal food be constructed in a way that enables it to be kept in a clean condition. Similarly, proposed § 507.22(d) would require that systems such as holding, conveying, and manufacturing, be of a design that would enable them to be maintained in an appropriate sanitary condition.

In § 507.22(e), the Agency proposes that freezer and cold storage compartments must be fitted with an indicating thermometer or temperature recording device if the freezer or compartment will be used to store animal food cable of supporting growth of microorganisms.

Proposed § 507.22(f) would require the instruments and controls used for measuring, regulating, or recording various attributes such as temperature, pH, and water activity (a_w), be accurate, precise, and adequately maintained. There also would need to be an adequate number of devices for their designated use.

Proposed § 507.22(g) would require that if compressed air or other gases are mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment, the gas would need to be treated in a way that would not lead to contamination of animal food.

The proposed requirements in § 507.22 are similar to recommendations in the equipment sections of the AAFCO and Codex CGMPs that address the design, construction, and maintenance of equipment to prevent contamination of animal food (Refs. 42 and 43).

6. Proposed § 507.25—Processes and Controls

Proposed § 507.25(a) addresses operations in the manufacturing, processing, packing and holding of animal food. It would require plant management to ensure that all such operations are conducted in accordance with adequate sanitation principles. In addition, it would require plant management to ensure that appropriate quality control operations are employed so that animal food-packaging materials are safe and suitable, that overall sanitation of the plant is under the supervision of one or more competent individuals assigned responsibility for this function, and that all reasonable precautions are taken so that production procedures do not contribute to contamination from any source. In multiple animal food recalls, the cause of the problem was determined to be *Salmonella* contamination of the finished product by raw ingredients when plant employees failed to properly separate finished product from raw ingredients. Under the proposed rule, chemical, microbial, or extraneous-material testing procedures would be required where necessary to identify sanitation failures or possible animal food contamination. Further, all animal food that has become contaminated to the extent that it is adulterated would be rejected, or if permissible, treated or processed to eliminate the contamination.

Proposed § 507.25(a) also addresses labeling controls. It would require that containers holding animal food, raw materials, or ingredients be labeled to accurately identify the contents. The Agency considers the correct identification of animal food, raw materials, and ingredients to be an important step in preventing or minimizing inappropriate handling or utilization of the animal food products during their manufacture, processing, packing, or holding. Labeling for finished animal food products would be required to contain the specific information and instructions needed so the food can be safely used for the intended animal species. Properly labeled finished product could prevent, for example, animal food containing micronutrients such as copper or selenium from being fed to animals for which these ingredients could be injurious to health.

FDA's human food CGMPs, on which the Agency is modeling these animal food CGMPs, do not include labeling controls. However, the Agency tentatively concludes that such controls are necessary for animal food, because unlike human food, a finished animal food is often the animal's sole source of nutrition. Animals of different species can be adversely affected by too low or too high levels of certain nutrients in the food. Because of this, it is important that the labeling correctly reflects the contents of the product and provides the necessary information on how to use the product safely for the type of animals being fed.

The AAFCO Model animal food CGMPs include labeling controls. It provides that a label or other unique identifier shall be affixed to, or accompany, feed and/or feed ingredients to maintain identity and facilitate safe and effective use. Labels shall be stored, handled and used in a manner that minimizes errors. Obsolete labels shall be discarded promptly (Ref. 42). The PAS 222 provides that information on content and intended use of animal food products shall be communicated to customers, for example, on a product label. It also requires that procedures be in place detailing the correct labeling of products in accordance with applicable regulations (Ref. 44).

FDA is proposing in § 507.25(b) that raw materials and ingredients be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into animal food and stored under conditions that will protect against contamination and deterioration and that water used for washing, rising, or conveying animal food must be safe and of adequate sanitary quality. If water is reused, it must not increase the level of contamination of animal food. This section would also require that raw materials and ingredients including rework, be held in bulk, or in containers designed and constructed to protect against contamination, and be held at a temperature, relative humidity, and manner that would prevent the animal food from becoming adulterated. Material scheduled for rework would need to be identified as such. In addition, proposed paragraph (b) would require that raw materials and ingredients must either not contain levels of microorganisms that are reasonably likely to cause illness or injury to animals, or be processed or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated. Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins would need to be in compliance with current FDA regulations for any poisonous or deleterious substances before these materials or ingredients are incorporated into finished animal food. Raw materials received frozen, such as raw meat for raw pet food, would need to be kept frozen until use. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated. Raw materials received and stored in bulk form would need to be held in a manner that protects against contamination.

Proposed § 507.25(b)(1)(iv) would recommend that containers and carriers of raw materials be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of animal food. Visual inspection alone could identify certain physical hazards in incoming raw materials and ingredients and prevent certain contaminated ingredients from being added to animal food. As discussed in section IX.C, FDA also is

requesting comment on whether to change proposed § 507.22(b)(1)(iv) to require rather than recommend that containers and carriers of raw materials and ingredients be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of animal food.

Proposed § 507.25(c) would require that equipment, utensils, and finished animal food containers used in manufacturing operations be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. All animal food manufacturing, processing, packing, and holding would need to be conducted under conditions that minimize the potential for the growth of microorganisms and contamination of animal food. Animal food that can support the rapid growth of undesirable microorganisms would be required to be held at temperatures that will prevent the animal food from becoming adulterated during manufacturing, processing, packing and holding. Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity that are taken to destroy or prevent the growth of undesirable microorganisms would need to be adequate under the conditions of manufacturing, handling, and distribution to prevent animal food from being adulterated. Effective measures would also need to be taken to protect against the inclusion of metal or other extraneous material in animal food. Animal food, raw materials, and ingredients that are adulterated would need to be disposed of in a manner that protects against the contamination of other animal food or, if the adulterated animal food is capable of being reconditioned, be reconditioned using an effective method that has been proven to be safe.

Proposed § 507.25(c)(10) would recommend that animal food be protected from contaminants that my drip, drain, or be drawn into the food. Section 507.25(c)(11) is proposing to recommend that when heat blanching is required in the preparation of animal food, be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Proposed paragraph (c)(11) of this section also would recommend that thermophilic growth and contamination in blanchers be minimized by the use of adequate operating temperatures and by periodic cleaning. As discussed in section IX.C, FDA also is requesting comment on whether to change proposed § 507.25(c)(10) and (c)(11) from recommendation to requirements.

7. Proposed § 507.28—Warehousing and Distribution

Proposed § 507.28(a) would require storage and transportation of animal food to be conducted under conditions that will protect against biological, chemical, physical, and radiological contamination of animal food, as well as against deterioration of the animal food and the container. Establishing a process to control warehouse and distribution practices ensures that the inventory is depleted before the products have deteriorated or decomposed to the point where a hazard develops that would require a preventive control measure. Conveyances used to distribute animal food, including trucks or rail cars, would need to be in a condition that would not contaminate animal food. The Agency is concerned about animal food being adulterated due to improper clean out of conveyances. In one reported incident, recycled broken glass was not completely cleaned out of a tractor trailer used to ship a cattle feed resulting in the glass being dispersed throughout the animal food when it was delivered to the farm (Ref. 48). Additional incidents of incomplete truck clean out include urea contamination of cattle feed that resulted in illness and death to the animals that ingested it (Ref. 48). Animal food that is loaded into a conveyance concurrently with materials that could contaminate the food would need to be properly protected, or loaded onto a separate conveyance. Deterioration of the animal food leading to spoilage or loss of nutrient value would need to be prevented, for example by using properly enclosed conveyances with functioning refrigeration units for animal food requiring temperature control, and by using a stock rotation system during storage.

The Codex animal food CGMPs provide that all means of transport should be appropriately cleaned to control and minimize the risk of contamination. Such vehicles should be subject to regular cleaning and sanitizing programs to ensure clean transport conditions and no accumulation of residual material (Ref. 2). The AAFCO Model animal food CGMPs provide that vehicles used to transport animal food be inspected for cleanliness and structural integrity prior to loading and that feed ingredients or other materials or substances that may pose a risk of adulterating feed or ingredients must not be loaded onto the same vehicle unless measures are taken to minimize such risk (Ref. 42).

C. Alternative To Establish Requirements in Place of Guidance in the Proposed Current Good Manufacturing Practices (CGMPs)

1. Overview

In this section, the Agency requests comment on whether non-binding (should) provisions in proposed subpart B of proposed part 507, should be changed to required (must) provision in the final rule.

The Agency believes that all of the proposed CGMP provisions, including the ''should'' provisions, are science-based and an important part of a modern food safety system. Because these non-binding provisions have been in place for decades for human food in current part 110, they are widely used and commonly accepted in many sectors of the human food industry. Similarly, the animal food industry is familiar with the principles behind these non-binding provisions. In addition, under section 418(o)(3) of the FD&C Act, the procedures, practices, and processes described in the definition of preventive controls may include sanitation procedures for food contact surfaces of utensils and equipment; supervisor, manager, and employee hygiene training; and CGMPs under part 110 (or any successor regulations).

The costs related to a fully mandatory sanitary operations, process, and controls program would be for the additional time that workers spend in compliance with those parts of proposed §§ 507.19 and 507.20 that are changed from ''should'' to ''must.'' That alternative, when implemented as part of a preventive approach, would impose incremental annual costs to qualified facilities. Those incremental costs have not been estimated due to a lack of data on current compliance with this alternative at those facilities and the incremental work efforts that would be required with these changes. Most non-qualified facilities would have met the requirements by following the requirements for sanitation controls in subpart C. Those that do not have hazards that are reasonably likely to occur or those with sanitation controls that do not fully address the requirements of the sanitary operations, however, would need to review their operations and implement additional procedures.

2. Summary of Alternative To Establish Requirements in Place of Guidance in the Proposed CGMPs

Table 1 identifies each of the potential differences in the CGMPs in proposed part 507 subpart B that would establish requirements (musts) instead of recommendations (shoulds) and either explains the reason for establishing the requirement or, for such differences with longer explanations, refers to the section where the potential requirement is explained.

TABLE 1—ALTERNATIVE TO ESTABLISH REQUIREMENTS IN PLACE OF GUIDANCE IN THE PROPOSED CGMPS

Proposed designation	Alternative to establish a requirement (must) in place of a recommendation (should) (emphasis added)	Basis for requirement
§ 507.14(b) (Education and training).	Personnel responsible for identifying sanitation failures or animal food contamination must have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors must receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.	See explanation and questions about whether more detail would be appropriate in section IX.C.3.
§ 507.19(e)(3) (Sanitation of animal food-contact substances).	Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.	Failure to properly store such articles could lead to contamination of the articles and then to contamination of animal food if the articles come in contact with the animal food.
§ 507.19(f) (Sanitation of non-food-contact substances).	Non-animal food-contact surfaces of equipment used in the operation of an animal food plant must be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.	Failure to clean non-animal food-contact surfaces could lead to contamination of animal food-contact surfaces of the equipment and utensils and then to contamination of animal food if the contaminated equipment and utensils come in contact with animal food. For example, cleaning non-animal food-contact surfaces is essential to prevent contamination of animal food from environmental pathogens such as *Salmonella* spp.
§ 507.19(g) (Storage and handling of cleaned portable equipment and utensils).	Cleaned and sanitized portable equipment with animal food-contact surfaces and utensils must be stored in a location and manner that protects animal food-contact surfaces from contamination.	Failure to properly store and handle such equipment and utensils could lead to contamination of the equipment and utensils and then to contamination of animal food if the equipment and utensils come in contact with animal food.
§ 507.22(a)(3) (Equipment and utensils).	All equipment must be installed and maintained in such a way to facilitate the cleaning of the equipment and of all adjacent spaces.	Failure to properly clean equipment and adjacent spaces due to improper installation and maintenance could lead to contamination of the equipment and then contamination of animal food if the equipment comes in contact with the animal food.
§ 507.25(b)(1)(iv) (Processes and controls—raw materials and ingredients).	Containers and carriers of raw materials must be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of animal food.	Containers and carriers of raw materials not properly maintained can lead to contamination or deterioration of animal food.
§ 507.25(c)(10) (Manufacturing operations).	Animal food must be protected from contaminants that may drip, drain, or be drawn into the animal food during manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, defatting, and forming.	There are no circumstances where it would not be necessary to provide adequate physical protection of animal food from contaminants that may drip, drain, or be drawn into animal food.
§ 507.25(c)(11) (Manufacturing operations).	Heat blanching, when required in the preparation of animal food, must be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay.	Properly heating and cooling animal food during blanching is necessary to protect animal food from contamination and would apply in all cases for animal food when heat blanching is required in the preparation.
§ 507.25(c)(11) (Manufacturing operations).	Thermophilic growth and contamination in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning.	Adequate operating temperatures and proper cleaning are necessary for controlling growth of thermophilic bacteria and contamination and would apply in all cases for animal food when heat blanching is required in the preparation.

3. Alternative to the Proposed CGMPs To Establish Requirements (Must) in Place of Guidance (Should) for Education and Training

Proposed § 507.14(b), provides guidance that personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Proposed § 507.14(b) further recommends that animal food handlers and supervisors receive appropriate training in proper animal food handling techniques and animal food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

As discussed in section II.A.1 of the document for the proposed rule for preventive controls for human food (78 FR 3646), a CGMP Working Group Report identified specific areas that presented an opportunity to modernize the CGMP regulation for human food. One recommendation was to ''require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products. This training must be delivered in a manner that can be easily understood by the worker. Food processors must maintain a record of this training for each worker'' (Ref. 49). The Agency's analysis of human food recalls also indicates that ineffective employee training was a root cause of 32 percent of CGMP-related recalls in the 1999–2003 analysis (Ref. 50); deficiencies in training were identified as a contributing factor in 24 percent of CGMP-related primary recalls in the 2008–2009 analysis (Ref. 51). While the Agency does not currently have animal food CGMP regulations to enable it to analyze animal food recalls based on CGMP violations, it believes that these trends of recalls in the human food facilities due to ineffective employee training would be found in the animal food industry as well. In addition, as discussed with respect to the proposed definition of preventive controls (see section VIII.B), section 418(o)(3) of the FD&C Act recognizes the importance of both training and CGMPs in preventing hazards from occurring in foods in its definition of preventive controls, which identifies supervisor, manager, and employee hygiene training (section 418(o)(3)(B)) and CGMPs under part 110 (section 418(o)(3)(F)) as some of the procedures, practices, and processes that may be included as preventive controls.

The vast majority of costs related to a mandatory education and training program would be for the time that workers would be training rather than in production. Lacking data on the education and training programs offered by animal food production facilities, FDA used responses to a 2010 survey of human food production facilities to gauge training needs. The Agency estimates that this alternative, when implemented as part of a preventive approach, could impose an annual cost of $1,136 for those facilities with 10 production employees to $18,300 for those with 200 production employees and that do not already comply with this alternative. This would result in an estimated total annual cost of $11.0 million for domestic and foreign animal food facilities (Ref. 52).

The Agency requests comment on how best to revise proposed § 507.14(b) in light of section 418(o)(3) of the FD&C Act and the recommendations of the human food CGMP Working Group with respect to training. Should the Agency replace the proposed recommendations for personnel education and experience with requirements? Doing so would be consistent with the emphasis in section 418(o)(3) of the FD&C Act on the importance of both training and CGMPs in preventing hazards from occurring in animal foods in its definition of preventive controls and with the recommendation in the human food CGMP Working Group Report. If so, what is the appropriate level of specificity? For example, should the Agency simply replace the ''shoulds'' in the proposed § 507.14(b) with ''musts''? This would provide flexibility for each establishment to determine the type and frequency of education and training appropriate for its personnel.

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying that each person engaged in animal food manufacturing, processing, packing, or holding (including temporary and seasonal personnel and supervisors) receive training as appropriate to the person's duties;
- Specifying the frequency of training (e.g., upon hiring and periodically thereafter);
- Specifying that training include the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as applied at the facility; and
- Specifying that records document required training of personnel and, if so, specifying minimum requirements for the documentation (e.g., the date of the training, the type of training, and the person(s) trained).

The Agency also requests comment on whether to establish some or all of the potential requirements for education and training in subpart B, subpart C, or both. If the Agency establishes a requirement for education and training in subpart B, that requirement would apply to all persons who manufacture, process, pack, or hold animal food, with the exceptions of persons who would be exempt from subpart B (e.g., under proposed § 507.5(a) and (h), a requirement in subpart B would not apply to farms, or the holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the FD&C Act). On the other hand, if the Agency establishes a requirement for education and training in subpart C, that requirement would not apply to persons who would be exempt from the requirements of proposed subpart C (e.g., qualified facilities).

X. Proposed Subpart C—Hazard Analysis and Risk-Based Preventive Controls

A. Proposed § 507. 30—Requirement for a Food Safety Plan

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act requires that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act] to address those hazards. Section 418(h) of the FD&C Act also requires such written plan, together with the documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 507.30—Requirement for a Food Safety Plan

Proposed § 507.30(a) would specify that the owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan. The Agency uses the term ''written food safety plan'' in proposed § 507.30(a) to mean the ''written plan'' referred to in section 418(h) of the FD&C Act. To make clear that the written plan is related to animal

food safety rather than to other plans a facility may have (such as quality control plans or food defense plans), the Agency has designated the ''written plan'' to be a ''written food safety plan.''

In drafting the proposed requirements for subpart C described in the paragraphs that follow, the Agency uses wording and formatting that is in some cases slightly different from analogous provisions in the proposed rule for preventive controls for human food published (78 FR 3646). Two types of differences are meant to be substantive: Those relating to ready-to-eat food and those relating to food allergens. Both of those concepts are not applicable in the animal food context. In addition, proposed subpart C of proposed part 507 addresses nutrient imbalances, which are relevant to animal food but not, for the most part, to human food. Otherwise, provisions in proposed subpart C of proposed 507 are meant to have the same meaning as the analogous provisions in proposed subpart C of proposed rule for human food.

Proposed § 507.30(a) would require that the plan be written as is expressly required by section 418(h). A written food safety plan is essential for the facility to implement the plan consistently, train its employees, and periodically reanalyze and update the plan. It is also essential to a facility's food safety team, to auditors, and to inspectors. Proposed § 507.30(a) would implement section 418(h) of the FD&C Act. Proposed § 507.30(a) would provide flexibility for the owner, operator, or agent in charge of the facility to either prepare the written food safety plan or have that plan prepared, in whole or in part, on its behalf. In addition, proposed § 507.30 would provide flexibility for facilities in the development of their food safety plans by allowing facilities to group animal food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical.

Proposed § 507.30(a) would require that the owner, operator, or agent in charge of a facility implement the written food safety plan. Although section 418(h) of the FD&C Act is silent with respect to implementation of the required written plan, other provisions of section 418 address implementation. For example, section 418(c) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility both establish and implement preventive controls (emphasis added). In addition, other provisions of section 418 (e.g., section 418(d) regarding monitoring, section 418(e) regarding corrective actions, and section 418(f) regarding verification) all establish requirements related to the preventive controls required under section 418(c). As discussed later in this section of the document, the written food safety plan would include the hazard analysis required under section 418(b) of the FD&C Act, the preventive controls required under section 418(c) of the FD&C Act, the monitoring procedures required under section 418(d) of the FD&C Act, the corrective action procedures required under section 418(e) of the FD&C Act, the verification procedures required under section 418(f) of the FD&C Act, and the recall plan as authorized by section 418(o)(3)(E) of the FD&C Act. Specific provisions for implementing these sections of the statute would be established throughout proposed subpart C.

3. Proposed § 507.30(b)—Preparation of the Food Safety Plan by a Qualified Individual

Proposed § 507.30(b) would specify the food safety plan must be prepared by (or its preparation overseen by) a qualified individual. (See the discussion in section X.J regarding the qualifications of a qualified individual as would be established in proposed § 507.50(b)). Section 418 of the FD&C Act requires that firms identify and implement preventive controls and that facilities monitor and verify the effectiveness of the preventive controls. A qualified individual must develop the food safety plan in order to ensure the preventive controls are effective. The plan must be designed to identify and to significantly minimize or prevent hazards in order to prevent illness or injury to animals or humans. Designing a plan requires an individual who is knowledgeable in the concepts of preventive controls, the hazards associated with a product and process, the appropriate preventive controls, with associated monitoring and corrective actions for those hazards, and appropriate verification activities for the applicable preventive controls. Such knowledge requires scientific and technical expertise developed through training, experience, or both.

Section 418 of the FD&C Act does not address the qualifications of the individual who would prepare the food safety plan. However, proposed § 507.30(b) is consistent with the Federal regulations for seafood, juice, and meat and poultry (parts 123 and 120 (21 CFR parts 123 and 120) and 9 CFR part 417 respectively). One way to comply with proposed § 507.30(b) could be for a team of individuals (for example, a ''HACCP team'' or a ''food safety team'') to develop the food safety plan under the oversight of a qualified individual. Each member of a HACCP or food safety team generally brings specific expertise important in developing the plan. For example, a microbiologist could provide knowledge of microbial hazards, an engineer could establish the critical parameters for delivery of heat treatments, and a maintenance supervisor could identify sources of metal contamination. Proposed § 507.30 would not require that all such members of a food safety team satisfy the requirements in proposed § 507.30(b) for a qualified individual. However, under proposed § 507.30(b), a qualified individual must be responsible for ensuring that all components the food safety plan have been developed, including reviewing all information contained in the food safety plan, thereby verifying the hazard analysis and food safety plan developed by the food safety team.

4. Proposed § 507.30(c)—Contents of a Food Safety Plan

Proposed § 507.30(c)(1) through (c)(6) would require that the contents of a written food safety plan include:

- The hazard analysis as required by § 507.33;
- The preventive controls as required by § 507.36;
- The recall plan as required by § 507.38;
- The procedures, and the frequency with which these procedures will be performed, for monitoring the implementation of the preventive controls as required by § 507.39;
- The corrective action procedures as required by § 507.42; and
- The verification procedures and the frequency with which they will be performed as required by § 507.45.

Section 418(h) requires that the written plan document and describe the procedures used by the facility to comply with the requirements of section 418, ''*including* analyzing the hazards under [section 418(b) of the FD&C Act] and identifying the preventive controls adopted under [section 418(c) of the FD&C Act] to address those hazards'' (emphasis added.) Although section 418(h) of the FD&C Act explicitly references sections 418(b) and (c), the term ''including,'' indicates that the contents of a food safety plan need not be limited to the provisions of sections 418(b) and (c) of the FD&C Act.

FDA interprets the requirement in section 418(h) of the FD&C Act that the written plan document and describe the procedures used by the facility to comply with the requirements of section

418 of the FD&C Act to mean that the written food safety plan would include all procedures required under section 418 of the FD&C Act. As discussed in sections X.E.4.a, X.F.2, X.G.6, and X.D.2, the proposed rule would require written procedures for monitoring the implementation of the preventive controls (proposed § 507.39); written corrective action procedures (proposed § 507.42); written procedures for some verification activities (proposed § 507.45); and a written recall plan (proposed § 507.38).

FDA interprets the requirement in section 418(h) that the written plan describe the procedures used by the facility to comply with the requirements of section 418, including analyzing the hazards and identifying the preventive controls adopted to address those hazards, to mean that the contents of the food safety plan must include the hazard analysis conducted by the facility and the preventive controls that a facility must establish for hazards that its hazard analysis identifies as reasonably likely to occur, rather than procedures for analyzing the hazards and procedures for identifying the preventive controls. The general requirement in section 418(a) of the act is directed, in relevant part, to evaluating the hazards that could affect animal food manufactured, processed, packed, or held by a facility, and identifying and implementing preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such animal food is not adulterated under section 402 of the FD&C Act. Review of the evaluation of hazards in the hazard analysis is sufficient to determine the adequacy of the hazard analysis. Written procedures for conducting the hazard analysis are not necessary. Similarly, the preventive controls identified by the facility can be reviewed fully for adequacy without having a separate procedures document.

5. Facility-Based Nature of the Written Food Safety Plan

The overall framework of section 418 of the FD&C Act is directed to a facility rather than, for example, a corporate entity that may have multiple facilities. For example, under section 418(b) of the FD&C Act the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards *that may be associated with the facility* (emphasis added). Thus, proposed § 507.30 establishes a requirement for every animal food facility to have its own written food safety plan.

Federal HACCP regulations for seafood juice, meat and poultry allow the HACCP plan to group food types or production method types if hazards, critical control points, critical limits, and required procedures such as monitoring, are essentially identical (§ 123.6(b)(2), § 120.8(a)(2), and 9 CFR 417.2(b)(2) respectively.) However, these do provide that any required features of the plan that are unique to a specific product or production method be clearly delineated in the plan and observed in practice. This type of grouping would be allowed under proposed § 507.30, and thus would provide flexibility for facilities in the development of their food safety plans.

B. Proposed § 507.33—Hazard Analysis

1. Requirements of Section 418 of the FD&C Act

Section 418(b)(1) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including: (1) Biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and (2) hazards that occur naturally, or may be unintentionally introduced. Section 418(b)(3) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall develop a written analysis of the hazards.

As discussed in section II.C.2.f, proposed part 507 is not intended to address ''hazards that may be intentionally introduced, including by acts of terrorism.'' Therefore, the Agency would not be implementing section 418(b)(2) of the FD&C Act in this proposed rule.

Section 418(c)(1) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(3) of the FD&C Act specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act, or misbranded under section 403(w) of the FD&C Act.

Section 403(w) of the FD&C Act addresses the labeling of major food allergens, as defined in 201(qq) of the FD&C Act. The misbranding provisions in section 403 of the FD&C Act, when read together with other provisions of the Food Allergen Labeling and Consumer Protection Act, appear to be intended for human food. Therefore, this proposed rule does not address section 403(w) misbranding.

Sections 418(c)(1) and (c)(3) of the FD&C Act, which will be discussed more fully in section X.C.2, are relevant to the discussion of proposed § 507.33(a) regarding the purpose of the hazard analysis required by section 418(b) of the FD&C Act.

2. Proposed § 507.33(a)—Hazard Analysis

a. Proposed § 507.33(a)—Requirement to identify and evaluate hazards. Proposed § 507.33(a) would require that the owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards, for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur. As discussed more fully in the remainder of this section, proposed § 507.33(a) would implement section 418(b)(1) of the FD&C Act.

In developing the proposed requirement for a hazard analysis, the Agency considered the language of section 418(b)(1) of the FD&C Act describing the hazards that a facility would be required to identify and evaluate, i.e., ''known or reasonably foreseeable hazards that may be associated with the facility.'' The Agency considers the ''known or reasonably foreseeable hazards'' in section 418(b) of the FD&C Act to be analogous to the ''potential hazards'' discussed in the NACMCF HACCP guidelines, and the hazards that are required to be identified to determine if they are ''hazards that may be reasonably expected to occur at each step'' in the Codex HACCP Annex, or ''reasonably likely to occur'' in Federal HACCP regulations for seafood, juice, and meat and poultry (Refs. 29 and 36).

Proposed § 507.33(a) would establish the requirement to identify and evaluate hazards by conducting a hazard analysis. The specific requirements for the hazard identification are in proposed § 507.33(b) (see section X.B.3) and specific requirements for the hazard evaluation in proposed § 507.33(c) and (d) (see sections X.B.4 and X.B.5.)

Proposed § 507.33(a) would require that the identification and evaluation of hazards be done ''for each type of animal food manufactured, processed, packed, or held at the facility.'' In developing the proposed requirement

for a hazard analysis, the Agency considered the language of section 418(b)(1) of the FD&C Act. The purpose of sections 418(b)(1) appears clear, i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards that may be associated with the food produced by the facility. The known or reasonably foreseeable hazards associated with the facility's food may differ based on the type of food.

The process of identifying and evaluating the hazards that may occur for specific types of animal food handled in a facility provides an efficient means for keeping track of multiple hazards that may occur in a facility that handles several types of animal food. Such a process also provides an efficient means for ensuring that preventive controls are applied to specific animal food products when required. Thus, a facility may need to conduct multiple hazard analyses. For example, a facility that uses an animal protein blend (by-products derived from meat and animal production industries) as an ingredient in the manufacture of food intended for swine, poultry, dogs and cats, would be required by proposed § 507.33 to identify the *Salmonella* serotypes to which swine, poultry, dogs, and cats are each susceptible (e.g., *Salmonella* Choleraesuis in food for swine; *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis in food for poultry) along with an evaluation of the adverse health effects each Salmonella serotype would cause in each of the animal species for which the food is intended (e.g., diarrhea, fever, or pneumonia in pigs caused by *Salmonella* Choleraesuis; diarrhea, gasping, or depression in poultry caused by *Salmonella* Pullorum) (Ref. 14). In addition, for the animal protein blend used in the manufacture of food for dogs and cats, a hazard analysis would need to include the hazards reasonably likely to occur related to the health of human handlers (e.g., pet owners) who are likely to come in contact with the finished food. In other words, if a facility manufactures food for multiple animal species, the Agency would consider the animal food intended for each animal species to be a type of animal food under proposed § 507.33(a), each requiring its own hazard identification and evaluation, even if the animal food the facility produces for each animal species consists of the same primary ingredients. As with the example above, the same biological, chemical, physical, or radiological agent in different types of food intended for different animal species may lead to varied adverse health effects in each of the animal species consuming the food.

To give another example, a facility that uses corn as a raw material in the manufacture of animal food intended for lactating dairy cows, beef cattle, swine, and poultry, would determine if aflatoxin is a reasonably foreseeable hazard that is reasonably likely to occur in the corn. An evaluation of the hazard would include the adverse health consequences to humans consuming milk and milk products from the dairy cows (See FDA Compliance Policy Guide (CPG) 683.100, Action Levels for Aflatoxins in Animal Feeds) (Ref. 15). This evaluation is likely to differ from the evaluation of aflatoxin in corn used to manufacture food for beef cattle, swine, and poultry, where higher levels of aflatoxin, to a point, would not be likely to cause illness or injury to the animals that consume the food or to humans consuming food products derived from those animals (Ref. 15). As a result, in evaluating the same hazard, the hazard analysis for the food for dairy cattle would lead to a different conclusion than the hazard analysis for the food for beef cattle, swine, and poultry.

Proposed § 507.33(a) would identify the purpose of the hazard analysis, i.e., to determine whether there are hazards that are reasonably likely to occur in animal food. Although section 418(b)(1) of the FD&C Act does not explicitly identify the purpose of the hazard analysis, the Agency interprets the combined requirements of sections 418(b), (c)(1) and (c)(3) of the FD&C Act to reflect a purpose, i.e., to enable the facility to identify and, where necessary, implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and the animal food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act. If, for example, a facility concludes during the hazard analysis that one or more (or even all) reasonably foreseeable hazards are not reasonably likely to occur in the facility, the facility could conclude that there is no need to implement preventive controls for those hazards. The purpose of the hazard analysis identified in proposed § 507.33 is consistent with the purpose identified in the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

b. *Requirement for the hazard analysis to be written.* Proposed § 507.33(a) would require that the hazard analysis ''be written'' as required by section 418(b)(3) of the FD&C Act. A written hazard analysis can help the facility organize the scientific basis for the hazard analysis and would be essential to the facility's food safety team, auditors, and inspectors during review and evaluation of the hazard analysis. The facility's food safety team would need to fully understand the nature of the hazards in order to produce safe animal food. For example, although the facility's food safety plan would include corrective action procedures that address problems that can be anticipated, the food safety team would need to identify appropriate corrective actions when there is an unanticipated problem (see, e.g., the discussion of a proposed requirement (proposed § 507.42) for corrective actions when there is an unanticipated problem in section X.F.3). The written hazard analysis would be useful at these times. Having a written hazard analysis available for auditors and for inspectors is essential for assessing the adequacy of the hazard analysis. A written hazard analysis would also be essential during reanalysis and updates of the hazard analysis, as would be required by proposed § 507.45(e) so that the person doing the reanalysis or update has a baseline from which to start. A written hazard analysis would also be useful for training purposes as a tool to make employees aware of food safety hazards that are reasonably likely to occur.

The written hazard analysis would include the justification for whatever conclusion the owner, operator, or agent in charge of a facility reaches, including a conclusion that no hazards are reasonably likely to occur. Thus, proposed § 507.33(a) would not limit the requirement for a written hazard analysis to those circumstances where the owner, operator, or agent in charge of a facility identifies one or more hazards that are reasonably likely to occur. Under proposed § 507.33(a), a written hazard analysis would be required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur.

3. Proposed § 507.33(b)—Hazard Identification

Proposed § 507.33(b) would require that the hazard analysis consider hazards that may occur naturally or may be unintentionally introduced, including:

- Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of animal or human health significance (proposed § 507.33(b)(1));

- Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances (proposed § 507.33(b)(2));
- Physical hazards (proposed § 507.33(b)(3)) ; and
- Radiological hazards (proposed § 507.33(b)(4)).

Proposed § 507.33(b) would implement section 418(b)(1) of the FD&C Act and would establish four groups of hazards (i.e., biological, chemical, physical, and radiological).

Microbiological Hazards

Proposed § 507.33(b)(1) would include microbiological hazards within the category of biological hazards. Examples of microbiological hazards include:

- Parasites (which are required to be considered by section 418(b)(1)(A) of the FD&C Act). A parasite is an organism that lives on or in an organism of another species (often called the host organism) and receives its nutritional requirements from that other species. *Cryptosporidium* spp., *Giardia* intestinalis, and *Toxoplasma* gondii are examples of parasites.
- Environmental pathogens (e.g., *Salmonella* spp.); and
- Other microorganisms of animal or human health significance, including molds (e.g., *Aspergillus* spp., *Penicillium* spp., and *Fusarium* spp.) and bacteria (e.g., *Salmonella* spp., *Clostridium* spp.)

Chemical Hazards

Proposed § 507.33(b)(2) would include substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances (all of which except nutrient imbalances, are explicitly required to be considered by section 418(b)(1)(A) of the FD&C Act) within the category of chemical hazards. Pesticide residues may be present in animal food at levels in excess of a tolerance level established by the U.S. Environmental Protection Agency (EPA). Natural toxins such as aflatoxin and gossypol are well recognized as hazards in animal food products such as corn and cottonseed, respectively (Refs. 53 and 54. Residues of natural toxins such as aflatoxin may be present in human food (such as milk) derived from dairy cattle consuming animal food contaminated with the toxin in excess of a tolerance or safe level established and enforced by FDA (Ref. 15). Decomposition of animal food consists of microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes. These changes are manifested by abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death. For example, the metabolic activity of *Fusarium* graminearum growing in or on grain and grain products can lead to changes in the levels of grain nutrients such as carbohydrates, proteins, lipids, or vitamins and formation of deoxynivalenol (DON or vomitoxin). DON can cause diarrhea, vomiting and reduced weight gain in animals consuming food contaminated with the toxin. Swine can smell DON and refuse animal food contaminated with the substance (Ref. 55).

Nutrient imbalance hazards can result from excessive levels of a nutrient in animal food leading to toxicity (e.g., copper poisoning in sheep consuming food with excessive levels of copper), or a nutrient deficiency in the food that can compromise the health of animals (e.g., chickens fed riboflavin deficient diets experience curled toe disease) (Refs. 56, 57, 58, and 59). Nutrient imbalances are particularly problematic for animal food, because often one animal food type is the sole source of an animal's diet. A nutrient imbalance hazard in animal food would pose a greater risk to the health of animals fed a sole source diet than animals receiving multiple types of animal food (like humans eat).

Nutrient imbalance hazards can also result from diets containing essential nutrients in inappropriate proportions of essential nutrients. For example, an animal's calcium needs cannot be considered independently of phosphorus. Calcium, an essential mineral, may be adequate in forage (especially legumes) for grazing cattle. Phosphorus, however, can be deficient in the forages, and since calcium and phosphorus work hand in hand for the animal's muscle and metabolic functions, respectively, supplemental phosphorus at an appropriate level would be needed for cattle on forage-based diets. Calcium and phosphorus are also the major mineral constituents of bone. The calcium to phosphorus ratio in the animal food for cattle would need to be maintained in the desired range to prevent negative health effects associated with nutrient imbalance (e.g. rickets in young animals, osteomalacia in adult animals, reduced resistance to disease, overall reduced productivity including reduced food intake, reduced conception rates, or reduced milk production in cattle) (Refs. 60 and 61).

Physical Hazards

Proposed § 507.33(b)(3) would require that the hazard analysis consider physical hazards, which are required to be considered by section 418(b)(1)(A) of the FD&C Act. Examples of physical hazards include pieces of wood, stones, glass, or metal fragments that could inadvertently be introduced into animal food. Physical hazards may be associated with raw materials, especially raw agricultural products. The facility and equipment can also be a source of physical hazards (e.g., pieces of glass from glass container breakage and metal pieces such as nuts and bolts from equipment used during manufacturing/processing).

Radiological Hazards

Proposed § 507.33(b)(4) would require that the hazard analysis consider radiological hazards. Examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium, strontium-90 and iodine-131. Section 418(b)(1)(A) of the FD&C Act requires that radiological hazards be considered, and animal food may be subject to contamination with radiological hazards, e.g., if water used to manufacture the animal food contains a radionuclide.

4. Proposed § 507.33(c)—Hazard Evaluation

Proposed § 507.33(c) would require that the hazard analysis contain an evaluation of the hazards identified in § 507.33(b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur. Proposed § 507.33(c) would implement sections 418(b)(1) and (c)(3) of the FD&C Act. Contamination of animal food with biological hazards often leads to immediate or near-term onset of illness or injury (e.g., gastrointestinal illness in humans after handling pet treats contaminated with *Salmonella*). Exposure to some biological hazards may have long-term consequences as well (e.g., human infections with *Salmonella* may lead to reactive arthritis). The health consequence of exposure to some biological hazards can be severe (e.g., acute enteritis that can cause severe abdominal pain, diarrhea or death in horses exposed to *Salmonella* spp. through consumption of contaminated food) (Refs. 62 and 63). Proposed § 507.33(c) would require that such biological hazards be considered to determine whether they are reasonably likely to occur even if the biological hazard occurs infrequently.

Contamination of animal food with chemical hazards may also lead to immediate or near-term obvious onset of illness, e.g., mycotoxins in large doses can be the primary agent causing acute health or production problems such as diarrhea, metritis, mastitis, or reduced conception rates in a dairy herd (Ref. 64). In other instances, the focus of the evaluation for chemical hazards would be directed to their long term effects, such as liver diseases in animals or humans exposed to aflatoxin over long periods (Refs. 65 and 66). Proposed § 507.33(c) would require that such chemical hazards be considered to determine whether they are reasonably likely to occur even if the chemical hazard occurs infrequently.

Physical hazards such as hard and sharp foreign objects that may be present in animal food can pose a health risk to the animals that consume the food. Hard or sharp foreign objects in animal food may cause traumatic injury, including laceration and perforation of tissues of the throat, stomach and intestine (Ref. 67). Although physical hazards may occur infrequently, under proposed § 507.33(c) the potential for severe consequences would require consideration of these physical hazards to determine whether they are reasonably likely to occur. Factors relevant to an evaluation of the severity of illness or injury caused by a physical hazard include the potential size of the object, the nature of the food, and whether the intended animal species or production class is susceptible to the physical hazard (Ref. 68).

Contamination of animal food with radiological hazards generally is evaluated for long-term effects such as the potential for cancer (Ref. 69). A significant radiation dose could be received as a result of consumption of animal food contaminated as a result of an accident at a nuclear power plant or other types of accidents (Ref. 69) (see also 63 FR 43402, August 13, 1998). Foods may contain unsafe levels of radionuclides (Ref. 70). Thus, although radiological hazards occur infrequently, under proposed § 507.33(c) the potential for severe consequences would require consideration of radiological hazards to determine whether they are reasonably likely to occur for a particular food or facility, especially when circumstances arise that could lead to contamination of food with radiological hazards.

The purpose of section 418(b)(1) and (c)(3) of the FD&C Act seems clear, i.e., that the owner, operator, or agent in charge of a facility identify and evaluate known or reasonably foreseeable hazards for the purpose of identifying and implementing preventive controls to provide assurances that identified hazards will be significantly minimized or prevented and that animal food manufactured, processed, packed or held by the facility will not be adulterated under section 402 of the FD&C Act. The process of evaluating animal food hazards to determine which potential hazards require preventive controls must take into account the consequences of exposure (i.e., severity of illness or injury) as well as the probability of occurrence (i.e., frequency) to provide assurances that the animal food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act. Proposed § 507.33(c) would implement this statutory direction.

5. Proposed § 507.33(d)—Effect on Finished Food

Proposed § 507.33(d) would require that, in conducting the hazard evaluation, the qualified individual must consider the effect of the following on the safety of the finished animal food, including:

- The formulation of the animal food;
- The condition, function, and design of the facility and equipment;
- Raw materials and ingredients;
- Transportation practices;
- Manufacturing/processing procedures;
- Packaging activities and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors.

The Agency tentatively concludes that these are factors that a prudent person who manufactures, processes, packs, or holds animal food would consider when evaluating identified hazards to determine whether they are reasonably likely to occur. As the Agency indicated when proposing FDA's HACCP regulation for juice, a prudent processor should consider factors such as these in doing a hazard analysis (63 FR 20450 at 20468, April 24, 1998).

Proposed § 507.33(d)(1) would require that the hazard evaluation consider the formulation of the animal food. The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, since they may inhibit growth of, or even kill, microorganisms of animal and health significance. This could impact the evaluation of the potential for growth of pathogens in the animal food during manufacturing, processing, packing or holding. A multi-component food may have individual ingredients that on their own do not support growth of undesirable microorganisms, e.g., because of their oil content or salt content that affects a_w, but when these ingredients are combined the finished food may have an a_w that supports microorganism growth. Under proposed § 507.33(d)(1), the interaction of the individual ingredients must be evaluated as part of the formulation of the animal food.

Proposed § 507.33(d)(2) would require that the hazard evaluation consider the condition, function, and design of the facility and equipment. The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into animal food. For example, older equipment (e.g., older belt, bucket elevator, or auger conveying equipment) may be more difficult to clean (e.g., with close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen proliferation in niche environments. Proposed § 507.33(d)(2) would require that facilities with such equipment consider the impact of the equipment on the potential for a pathogen to be a hazard that is reasonably likely to occur; in those situations, a preventive control such as enhanced sanitation controls may be appropriate, particularly if the equipment is used in production of animal food products that would not undergo further processing to eliminate pathogens prior to consumption. Equipment designed such that there is metal-to-metal contact may generate metal fragments. Proposed § 507.33(d)(2) would require that facilities with such equipment consider the impact of the equipment on the potential for generation of such metal fragments to be a hazard that is reasonably likely to occur; if so, a preventive control such as metal detectors may be appropriate.

Proposed § 507.33(d)(3) would require that the hazard evaluation consider the effect of raw materials and ingredients on the safety of the finished animal food. While there is an overlap between raw materials and ingredients, not all raw materials are ingredients. Before being used in the manufacturing process, raw materials are often altered to be used in different processes. For example, molasses, a thick, dark syrup, is a byproduct of sugar refining that is used as an ingredient in animal food for cattle. Briefly, to make molasses from sugar cane, washed cane stalks are shredded into short pieces and cane

juice separated from the stalks by mechanical (pressing through rollers) or solvent (water or lime juice) extraction methods. The juice is then subjected to a series of processes including filtration, vacuum boiling, and centrifugation to clarify the juice, crystallize out, and separate the sugar leaving the thick syrup (molasses). Because the production process transforms sugar cane stalks, the raw materials, into molasses, those raw materials generally would not be viewed as ''ingredients'' of the final product, molasses. Likewise, if a facility that manufactures animal food for cattle mixes molasses with other food products to make the food, the facility would view molasses as an ingredient of its cattle food product, but would not view the sugar cane stalks used to produce molasses as ingredients of its cattle food product. Animal food can become contaminated through the use of contaminated raw materials or ingredients. For example, corn grown under severely hot and dry weather conditions often becomes infected with *Aspergillus* flavus. Under these environmental conditions, this fungus is likely to produce aflatoxins, resulting in aflatoxin contaminated corn. Corn is one of the most frequently used ingredients in animal food, and corn contaminated with aflatoxins can cause illness in animals consuming food made with the corn and in humans consuming milk derived from dairy cattle consuming food made with the contaminated corn (Refs. 71 and 53).

Production and harvesting practices may impact whether raw materials and ingredients contain hazards. For example, machine-harvested forage or hay is more likely to be contaminated with physical hazards than hand-harvested forage or hay, because the machinery often picks up foreign material from the field. For this reason, machine-harvested forage or hay may lead to increased incidence of hardware disease in cattle (e.g., traumatic reticuloperitonitis developing as a result of perforation of the reticulum), which often occurs when animals consume food contaminated with physical hazards. Cattle commonly ingest heavy, sharp foreign objects because they take large mouthfuls of food and do not completely chew food before swallowing. The disease is common when greenchop, silage, and hay are made from fields that contain old rusting fences or baling wire, because these foods are often machine-harvested. The grain ration may also be a source of physical hazards due to accidental addition of metal such as nails, nuts, or bolts during the production process (Ref. 67).

Proposed § 507.33(d)(4) would require that the hazard evaluation consider the effects of transportation practices on the safety of the finished animal food. Animal food can become unsafe as a result of poor transportation practices. For example, failure to adequately control temperature during transportation could make animal food unsafe if the product requires time and temperature controls to ensure safety. Distributing animal food in bulk without adequate protective packaging can make the food susceptible to contamination during transportation, e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination (Ref. 72).

The Sanitary Food Transportation Act of 2005 (SFTA) gives FDA authority to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. The Agency published an Advance Notice of Proposed Rulemaking on April 30, 2010 (75 FR 22713), to request data and information on the food transportation industry and its practices and expects to issue a separate proposed rule to implement the SFTA. FDA does not expect a future rulemaking implementing the SFTA to eliminate the need for the owner, operator, or agent in charge of a facility to consider transportation practices when determining whether a hazard is reasonably likely to occur.

Proposed § 507.33(d)(5) would require that the hazard evaluation consider the effects of manufacturing/processing procedures on the safety of finished animal food. For example, hazards may arise from manufacturing/processing operations such as cooling or holding of certain animal food products due to the potential for germination of pathogenic spore forming bacteria such as *Clostridium* spp. and *Bacillus* spp. (which may be present in animal food ingredients) as a cooked product is cooled and reaches a temperature that would promote germination and outgrowth of the spores. Hazards may also arise from animal food manufacturing/processing activities such as acidification due to the potential for bacterial contamination if the acidification is not done correctly. Physical hazards may occur from metal fragments generated during the manufacture of animal food on equipment in which metal (e.g., a blade, saw, or knife) is used to cut products during manufacturing.

Proposed § 507.33(d)(6) would require that the hazard evaluation consider the effects of packaging activities and labeling activities on the safety of finished animal food. For example, the hazards that are reasonably likely to occur would be different depending on whether the animal food product is distributed in bulk form or packaged in bags. Labels on food for livestock would direct the person feeding animals to use the correct food product for the intended animal species. For example, it is well known that feeding food products to sheep that were intended for other ruminant animal species such as cattle can lead to copper toxicity (poisoning); proper labeling would help to guard against sheep being fed animal food products that are unsafe for sheep.

Proposed § 507.33(d)(7) would require that the hazard evaluation consider the effects of storage and distribution on the safety of finished animal food. For example, biological hazards are more likely to be a hazard that is reasonably likely to occur during storage and distribution in animal food products that require refrigerated storage to maintain safety than in shelf-stable foods. Shelf-stable foods are designed such that biological hazards are controlled.

Proposed § 507.33(d)(8) would require that the hazard evaluation consider the intended or reasonably foreseeable use on the safety of finished animal food. For example, gossypol, a natural toxin commonly occurs in cottonseed food products, can cause severe illness in immature ruminants and young pigs, but the older animals can tolerate low levels of the chemical hazard in their diets. Therefore gossypol would be identified as a hazard of concern if it is reasonably likely to occur at low levels in food for immature ruminants and young pigs but less of a concern in food for older ruminants and for mature pigs.

Proposed § 507.33(d)(9) would require that the hazard evaluation consider the effects of sanitation, including employee hygiene, on the safety of finished animal food. Sanitation measures and practices can impact the likelihood of a hazard being introduced into animal food. For example, the frequency with which a production line in a pet food facility is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw meat products that could carry over into the next production cycle on a line). Practices directed at worker health and

hygiene can reduce the potential for transfer of pathogens such as *Salmonella.* To the extent that these controls are necessary for the safety of the animal food product, they may need to be listed as preventive controls.

Proposed § 507.33(d)(10) would require that the hazard evaluation consider the effect of any other relevant factors that might potentially affect the safety of the finished animal food. For example, an unexpected natural disaster could flood some or all of a facility, creating insanitary conditions and potentially contaminating the facility with harmful microorganisms or chemical residues. Following a natural disaster, environmental contaminants that could be brought into the facility could be hazards reasonably likely to occur in a facility that manufactures, processes, packs, or holds animal food.

Further discussion of the hazard analysis, including comparison to HACCP, can be found in section XII.B of the document for the proposed rule for preventive controls for human food (78 FR 3646).

C. Proposed § 507.36—Preventive Controls for Hazards That Are Reasonably Likely To Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c)(1) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented. Section 418(c)(1)(3) of the FD&C Act, in relevant part, specifies that the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act

Section 418(o)(3) of the FD&C Act defines preventive controls and proposed § 507.3 would include the statutory definition in proposed part 507. Under section 418(o)(3), the procedures, practices, and processes described in the definition of preventive controls may include the following:

- Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment (section 418(o)(3)(A) of the FD&C Act);
- Supervisor, manager, and employee hygiene training (section 418(o)(3)(B) of the FD&C Act);
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment (section 418(o)(3)(C) of the FD&C Act);
- A recall plan (section 418(o)(3)(E) of the FD&C Act);
- CGMPs under part 110 or any successor regulations (section 418(o)(3)(F) of the FD&C Act); and
- Supplier verification activities that relate to the safety of food (section 418(o)(3)(G) of the FD&C Act).

2. Proposed § 507.36(a)—Requirement To Identify and Implement Preventive Controls for Hazards That Are Reasonably Likely To Occur

Proposed § 507.36(a) would require that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points (CCPs), if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the animal food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act.

As discussed in section X.B, proposed § 507.33(a) would require that the owner, operator, or agent in charge of a facility conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are ''reasonably likely to occur.'' Under proposed § 507.36(a), a facility that determines through its hazard analysis that there are hazards that are reasonably likely to occur would then be required to identify and implement preventive controls for those hazards. Preventive controls would be required when applicable hazards are identified as reasonably likely to occur. The types of preventive controls implemented would depend on the facility and the animal food it produces. Most hazards would be addressed through process controls and sanitation controls. For any type of preventive control, a facility would have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes available to it that would provide the assurances that would be required by proposed § 507.36(a).

Proposed § 507.36(a) would implement section 418(c) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for juice, seafood, and meat and poultry, although there are some differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. It differs in part in that preventive controls may be required at points other than at CCPs and critical limits would not be required for all preventive controls. Under proposed § 507.36(a), a processor could address hazards that are reasonably likely to occur through preventive controls that would be applied at CCPs, but doing so would not be the only option available to the facility in all circumstances. In some cases adequate assurances could be achieved via preventive controls implemented through other procedures and practices of a facility, such as its control parameters for the occurrence of nutrient imbalance hazards, which may not have specific CCPs.

Whatever types of preventive controls a facility chooses to apply in its operations, the requirement in proposed § 507.36(a) would be risk-based. Establishing risk-based preventive controls involves consideration of the available scientific data and information related to animal food safety risks. Typically, the hazard evaluation will enable the facility to determine appropriate risk-based preventive controls for the hazard based on the severity of the hazard and the likelihood of its occurrence.

For example, as discussed in section II.F.4 of this document, *Salmonella* spp. is an environmental pathogen that can establish a harborage in the environment such as on a production line used in manufacturing. Once established, *Salmonella* spp. can intermittently contaminate products on the production line. When a hazard analysis identifies *Salmonella* spp. as a hazard that is reasonably likely to occur in an animal food, the facility would establish sanitation controls to prevent *Salmonella* spp. from establishing itself in a harborage site. In addition to such sanitation controls, a facility may consider applying a bactericidal process step (i.e., a process control applied to adequately reduce levels of *Salmonella* spp.) in animal foods that are handled in the home.

3. Proposed § 507.36(b)—Requirement for Written Preventive Controls

Proposed § 507.36(b) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur be written. Proposed § 507.36(b) would implement section 418(h) of the FD&C Act which, as discussed in section X.A.1, requires that the owner, operator, or agent in charge of a facility prepare a written food safety plan that, among other things, identifies the preventive controls

within the plan. Written preventive controls are essential for the facility to implement the preventive controls consistently and essential for the facility's food safety team, auditors, and to inspectors. Written preventive controls also would be essential for training purposes and during reanalysis and updates of the preventive controls.

4. Proposed § 507.36(c)—Requirement for Parameters Associated With the Control of Hazards That Are Reasonably Likely To Occur

Proposed § 507.36(c)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the animal food, parameters associated with the control of the hazard, such as parameters associated with heat processing, irradiating, and refrigerating animal foods. The parameters are those factors that must be controlled to ensure the hazard will be significantly minimized or prevented. The specific parameters required, and how they would be controlled, would depend on the facility and the animal food. For example, for a heat process, parameters such as temperature and time must be controlled. The heating temperature may be controlled through controls on oven temperature (as when heating product in an oven). The heating time may be controlled by the belt speed for the conveyor on a continuous oven. A facility would have flexibility to establish controls on heating temperature and time through these or other mechanisms.

Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal contamination. Sanitation procedures may include scrubbing certain pieces of equipment by hand; this may not require the identification of specific parameters.

Proposed § 507.36(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, as appropriate to the facility and the animal food, the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. Some of the preventive controls a facility may implement may be based upon scientific studies or other information that demonstrate the effectiveness of the control measure at specific values of a biological, chemical, physical, or radiological parameter e.g., the application of heat to animal food at a specific time/temperature combination to adequately reduce pathogens. Proposed § 507.36(c) would also require that a facility that establishes such a preventive control specify values of the essential parameters to be applied in implementing the control. Specifying these values would enable the facility to implement them consistently and would facilitate validation of the preventive controls as would be required by proposed § 507.45(a). Proposed § 507.36(c)(1) and (c)(2) would implement section 418(c) of the FD&C Act and are consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal regulations for seafood, juice, and meat and poultry, although there are some differences related to the differences between HACCP systems and the preventive control system established by section 418 of the FD&C Act. FSMA does not use the term ''critical limit.'' Critical limits may not be appropriate for preventive controls that are not applied at CCPs. Thus, proposed § 507.36(c)(1) and (c)(2) use a broader term, i.e., parameter, to encompass preventive controls that may or may not apply at CCPs.

5. Proposed § 507.36(d)(1)—Process Controls

Proposed § 507.36(d)(1) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include process controls that include those procedures, practices, and processes performed on an animal food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Process controls do not include those procedures, practices, and processes that are not applied to the animal food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards that are reasonably likely to occur but are not applied to the food itself. Specifying that process controls are employed during manufacturing/processing to significantly minimize or prevent hazards that are reasonably likely to occur would distinguish those controls applied in manufacturing/processing that significantly minimize or prevent hazards (e.g., screening, drying, cooking, and, irradiating) from other types of controls that may be applied in manufacturing/processing to provide the desired product (e.g., controls for product size and shape).

As discussed in section X.C.4 of this document, proposed § 507.36(c)(2) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include, when applicable, the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled. (For process controls in particular, the term ''parameter'' used in proposed § 507.36(c)(1), and the value associated with the parameter in proposed § 507.36(c)(2), are associated with the term ''critical limit'' used in HACCP systems.)

For example, a facility that holds shelled corn in bulk storage units for an extended time period until it is sold or mixed into an animal food may identify the potential for growth of aflatoxin-producing molds on the corn as a hazard reasonably likely to occur. As a process control to prevent such molds from growing on the corn during storage, the facility may elect to dry the corn to a specific moisture content (e.g., no more than 15 percent) prior to placing the corn in storage. The process control would be ''drying'' and the associated parameter would be moisture level, with its maximum value, or limit, being 15 percent.

6. Proposed § 507.36(d)(2)—Sanitation Controls

Proposed § 507.36(d)(2)(i)(A) and (B) would establish two requirements for sanitation controls where necessary to significantly minimize or prevent hazards that are reasonably likely to occur. Proposed § 507.36(d)(2)(i)(A) would require that the owner, operator or agent in charge of the facility implement, where relevant to hazards that are reasonably likely to occur, sanitation controls that would include procedures for the cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment. Examples of such sanitation controls include cleaning and sanitizing procedures (including appropriate frequencies for these procedures, concentrations of cleaning and sanitizing compounds, method of application, and contact time). Such controls can prevent contamination of animal food with microorganisms of animal or human health significance, including environmental pathogens that result from inadequate cleaning of animal food-contact surfaces.

Proposed § 507.36(d)(2)(i)(B) would require that the owner, operator or agent

in charge of a facility implement, where relevant to hazards that are reasonably likely to occur, sanitation controls that include procedures for the prevention of cross-contamination from insanitary objects to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product. Examples of such controls to prevent cross-contamination include procedures for ensuring that personnel do not touch insanitary objects such as waste and waste bins and then animal food, animal food contact surfaces, or animal food packaging material; procedures for protecting animal food packaging material from environmental contamination; procedures for protecting exposed animal food products from contamination from the environment; and procedures for controlling traffic (including traffic of people and traffic of equipment such as forklifts) between the raw and finished sides of the operation. Any time an animal food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the animal food to be contaminated. Appropriate sanitation controls can minimize the presence and transfer of contaminants, including environmental pathogens, to animal food. (See section I.D and I.E of the Appendix to this document for a discussion on the importance of controlling environmental pathogens.) Proposed § 507.36(d)(2)(i)(A) and (B) would implement section 418(c) of the FD&C Act. For a discussion on sanitation controls under HACCP, see section XII.C.7 for the proposed rule for preventive controls for human food (78 FR 3646).

Proposed § 507.36(d)(2)(ii) would require that the owner, operator, or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures that would be established in proposed § 507.36(d)(2)(i)(A) or (B) or that result in insanitary conditions that could lead to cross-contamination with a hazard.

Proposed § 507.36(d)(2)(iii) would provide that the owner, operator, or agent in charge of a facility is not required to follow the corrective actions that would be established in proposed § 507.42(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with proposed § 507.36(d)(2)(ii), to correct conditions and practices that are not consistent with the procedures in proposed § 507.36(d)(2)(i) (A) or (B). As discussed in section X.F, proposed § 507.42(a) would require that the owner, operator or agent in charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, and outlines specific components that must be included. Proposed § 507.42(b) would require specific actions in the event of an unanticipated problem when a preventive control is not properly implemented and a specific corrective action procedure has not been established or a preventive control is found to be ineffective. For sanitation controls, proposed § 507.36(d)(2)(ii) would require that the owner, operator or agent in charge of a facility take action to correct, in a timely manner, conditions and practices that are not consistent with the established sanitation control practices.

There are many different ways in which conditions and practices for sanitation can deviate from the established procedures. In many instances the actions taken will be the same, regardless of the deviation. The corrective actions will generally involve re-establishing sanitary conditions (e.g., re-cleaning a piece of equipment) and/or retraining personnel to carry out the procedures correctly. In many instances the procedural deviations are not reasonably likely to impact product (e.g., insanitary animal food-contact surfaces are usually detected by a pre-production inspection of the equipment by plant personnel; deviations in cleaning solution strength rarely result in the production of unsafe product if other cleaning and sanitizing procedures were properly carried out). Thus, there is rarely a need to evaluate the impact of the sanitation failure on animal food and to prevent animal food from entering commerce, as would be required by proposed § 507.42(a)(2) and (a)(3). Because the corrective actions that will need to be taken for most sanitation controls are so general, the Agency sees little benefit in requiring a facility to develop written corrective action procedures for the many sanitation deviations that could occur. The Agency does expect the facility to take action to correct conditions and practices as appropriate to the situation as would be required by proposed § 507.36(d)(2)(ii). The requirement in proposed § 507.36(d)(2)(ii) to take action to correct, in a timely manner, sanitation conditions and practices that are not in accordance with procedures is consistent with proposed § 507.42(a)(1), which would require that appropriate action be taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur.

Proposed § 507.36(d)(2)(iv) would require that all corrective actions taken in accordance with proposed § 507.36(d)(2)(ii) be documented in records that would be subject to verification in accordance with proposed § 507.45(b)(2) and records review in accordance with proposed § 507.45(c)(1)(i) and (c)(2). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

7. Proposed § 507.36(d)(3)—Recall Plan

Proposed § 507.36(d)(3) would require that preventive controls include, as appropriate, a recall plan as would be required by proposed § 507.38. Proposed § 507.36(d)(3) would incorporate the statutory definition of ''preventive controls'' from section 418(o)(3)(E) of the FD&C Act, which establishes that preventive controls may include a recall plan. The Agency includes the details of the recall plan in proposed § 507.38 and discusses it in section X.D of this document.

8. Proposed § 507.36(d)(4)—Other Controls

Proposed § 507.36(d)(4) would require that preventive controls for hazards identified in the hazard analysis as reasonably likely to occur include any other controls necessary to satisfy the requirements of proposed § 507.36(a), i.e., to significantly minimize or prevent hazards identified in the hazard analysis and to provide assurance that the animal food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act.

FDA notes that some of the controls listed in section 418(o) of the FD&C Act are not explicitly identified in proposed § 507.36. As discussed in section X.B, the Agency is not interpreting misbranding under section 403(w), major allergens, to apply to animal food. Therefore, the proposed preventive controls for animal food do not include allergen controls. In section X.K, the Agency requests comment on an environmental monitoring program (which section 418(o)(3)(C) of the FD&C Act indicates is one of the procedures, practices, and processes that preventive controls may include, and which section 418(f)(4) of the FD&C Act identifies as a verification activity.) In section X.L, the Agency also requests comment on a supplier approval and verification program as one of the procedures, practices, and processes

that preventive controls my include (section 418(o)(3)(G)). In section IX.C, the Agency requests comment on supervisor, manager, and employee hygiene training. There is a full discussion on CGMPs in section IX of this document. Further, as discussed in section IX.A of this document, such controls are traditionally considered to be part of prerequisite programs, essential to effective preventive controls but often not part of them. FDA expects that compliance with those requirements in proposed part 507, subpart B will be sufficient. However, a facility may determine that in some circumstances it would be appropriate to include certain Current Good Manufacturing Practice provisions among their preventive controls (i.e., as ''other controls'' in proposed § 507.36(d)(4).

9. Proposed § 507.36(e)—Applicability of Monitoring, Corrective Actions, and Verification

Proposed § 507.36(e)(1)(i) through (iii) would specify that, except as provided by proposed § 507.36(e)(2), the preventive controls required under this section would be subject to monitoring as would be required by proposed § 507.39; corrective actions as would be required by proposed § 507.42; and verification as would be required by proposed § 507.45. Proposed § 507.36(e)(1)(i) through (iii) would restate the requirements of proposed §§ 507.39, 507.42, and 507.45 to clearly communicate the applicability of proposed §§ 507.39, 507.42, and 507.45 to the preventive controls that would be required under proposed § 507.36 and would establish no new requirements.

Proposed § 507.36(e)(2) would provide that the recall plan that would be established in proposed § 507.38 would not be subject to the requirements of proposed § 507.36(e)(1). A recall plan would address animal food that had left the facility, whereas the proposed requirements for monitoring, corrective actions, and verification would all be directed at animal food while it remains at the facility. Thus, as proposed, the requirements for monitoring, corrective actions, and verification have limited applicability to a recall plan. However, a ''mock recall'' (i.e., a simulated recall situation) is a verification activity that could identify problems with a recall plan, enable a facility to correct the problems, and provide reasonable assurance that the recall plan would be effective in removing products from commerce. FDA requests comments on whether to include a requirement for a mock recall as verification activity in the final rule.

D. Proposed § 507.38—Recall Plan for Animal Food With a Hazard That Is Reasonably Likely to Occur

1. Requirements of Section 418 of the FD&C Act

Section 418(c) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented (section 418(c)(1) of the FD&C Act); and
- The food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act (section 418(c)(3) of the FD&C Act).

Under section 418(o)(3)(D), the procedures, practices, and processes described in the definition of preventive controls may include, in relevant part, a recall plan.

2. Proposed § 507.38—Recall Plan for Animal Food With a Hazard That Is Reasonably Likely to Occur

Proposed § 507.38(a) would require that the owner, operator, or agent in charge of a facility establish a written recall plan for animal food with a hazard that is reasonably likely to occur. Although a recall is different from other preventive controls in that it is carried out after a product is distributed, it shares the purpose of significantly minimizing or preventing hazards, which is accomplished by limiting feeding of the affected animal food. Time is critical during a recall. A written recall plan is essential to minimizing the time needed to accomplish a recall; additional time during which the animal food is on the market can result in additional animal (or human) exposure. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked.

Proposed § 507.38(a) would implement sections 418(c)(1) and (3) of the FD&C Act and 418(o)(3)(E) of the FD&C Act. Recommendations for addressing a recall, applicable to both human food and animal food, can be found in FDA's general guidance on policy, procedures, and industry responsibilities regarding recalls in part 7 (21 CFR part 7), subpart C (§§ 7.40 through 7.59). The guidance advises firms to prepare and maintain a current written contingency plan for use in initiating and effecting a recall (§ 7.59). Section 507.38(a) would require that the owner, operator, or agent in charge of a facility develop a written recall plan and assign responsibility for performing all actions in the plan.

Proposed § 507.38(b) would require that the written recall plan include procedures to perform the following actions:

- Directly notify the direct consignees of the product being recalled and how to return or dispose of the affected product (proposed § 507.38(b)(1));
- Notify the public about any hazard presented by the animal food when appropriate to protect animal or human health (proposed § 507.38(b)(2));
- Conduct effectiveness checks to verify that the recall is carried out (proposed § 507.38(b)(3)); and
- Appropriately dispose of recalled product, e.g., through destroying the product, reprocessing, or diverting to a use that does not present a safety concern (proposed § 507.38(b)(4)).

Procedures that describe the action to be taken would enable a facility to act promptly by following its plan when the facility determines that a recall is warranted rather than developing a plan of action after the need for a recall is identified. Procedures that assign responsibility for taking those steps would save the time needed to make such determinations during a recall and enable the owner, operator, or agent in charge of a facility to clearly communicate such responsibilities to applicable managers or staff so that such managers or staff can take action as soon as the decision to conduct a recall is made.

Directly notifying direct consignees about the recall (proposed § 507.38(b)(1)) is the most effective mechanism to ensure direct consignees know that the product is being recalled and is consistent with FDA's general guidance on recall communications in § 7.49(a). Further, instructing direct consignees how to return or dispose of an affected product minimizes the chance the affected product will be disposed of improperly and allows direct consignees to act quickly. Further, it is consistent with FDA's guidance on the content of recall communications in § 7.49(c)(4). FDA has provided guidance to industry on a model recall letter (Ref. 73). This guidance may be useful in developing procedures for directly notifying direct consignees about the recall and on how

to return or dispose of an affected product.

Notification procedures could identify a variety of communication means, including email, telephone, fax, text messaging, and urgent mail delivery. Notification procedures that would establish only a general notification to the public (e.g., through a press release or through information posted on a facility's Web site), without procedures for concurrent contact directly with direct consignees about how to access the general notification, would not satisfy proposed § 507.38(b)(1); a general notification to the public would rely on the chance that the direct consignees would see the information and may not be effective.

Notifying the public about any hazard presented by the animal food when appropriate to protect human or animal health is a common practice (e.g., see FDA's Web site that provides information gathered from press releases and other public notices about recalls of animal food, Animal & Veterinary Recalls & Withdrawals) (Ref. 74). Notifying the public in such circumstances is consistent with the Agency's guidance on a recall strategy that the purpose of a public warning is to alert the public that a product being recalled presents a hazard to human or animal health (§ 7.42(b)). Notifying the public, in addition to direct consignees, may not be necessary to protect the public if, for example, the animal food being recalled was all distributed to animal feeding operations (who were notified as a direct consignee) and not distributed for retail sale. Procedures in the recall plan for notifying the public could include model press releases and procedures for disseminating information to the public though press releases or other means, such as by information posted on the facility's Web site or provided to end users of the animal food using social media. FDA has provided guidance to industry with a model press release for the presence of *Salmonella* in pet food and pet treats (Ref. 75).

An effectiveness check is a procedure designed to verify that all notified consignees have received notification about the recall and have taken appropriate action; procedures to conduct effectiveness checks would be consistent with FDA's guidance on a recall strategy in § 7.42(c)(3). Procedures to conduct an effectiveness check could expand on the procedures used to directly contact consignees about the recall, e.g., to include forms for consignees to provide information about the amount of recalled product on hand, to include information on follow up contacts via phone or email, or to include personal visits to consignees by sales representatives. FDA has provided guidance to industry on conducting effectiveness checks (Ref. 73). This guidance includes a model effectiveness check letter, a model effectiveness check response form that could be sent to a consignee, and a model questionnaire to be used during effectiveness checks conducted by telephone or by personal visit.

A facility that receives recalled product from its customers must appropriately dispose of the product, e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or by destroying the product. These types of disposition actions are similar to the disposition actions that a facility would consider as a corrective action as a result of a problem that is discovered before the product leaves the facility (see, e.g., the discussion of corrective actions in the final rule to establish FDA's HACCP regulation for seafood; 60 FR 65095 at 65127). Procedures for disposition of a product can help the facility ensure that disposition of recalled product will be appropriate and will not present a risk to animals. Implementation of such procedures is part of determining whether a recall can be considered terminated. Thus, having procedures in place can result in more efficient completion of a recall. Under § 7.55, appropriate disposition of recalled product is a consideration in determining whether a recall is terminated.

FDA requests comment on whether the procedures to be included in the recall plan (i.e., to directly notify consignees, to notify the public, to conduct effectiveness checks, and to appropriately dispose of recalled product) are appropriate for all types of facilities or if they should be modified for certain facilities.

FDA requests comment on whether the Agency should require a recall plan to include procedures and assignments of responsibility for notifying FDA of recalls subject to the plan. Notifying FDA could enhance the effectiveness of a recall by allowing FDA to take appropriate steps to minimize the risk of illness or injury related to recalled products. As discussed in section II.E of this document, notifying FDA of a reportable food (including animal food) is required by section 417 of the FD&C Act. Reportable food reports include information about whether a reportable food is being recalled. Thus, in some cases, reporting a recall to FDA could be accomplished by submitting a reportable food report required under section 417. In other cases, facilities could notify the local FDA district office of the recall.

E. Proposed § 507.39—Monitoring

1. Requirements of Section 418 of the FD&C Act

Section 418(a) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the performance of the preventive controls. Section 418(d) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act to provide assurances that the outcomes described in section 418(c) shall be achieved. The outcomes relevant to this proposal are those that provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and that food manufactured, processed, packed or held by a facility will not be adulterated under section 402 of the FD&C Act.

Section 418(g) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act.

Section 418(h) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act.

2. Monitoring, Verification, and Their Relationship

Proposed § 504.3 would define ''monitor'' to mean ''to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.'' Monitoring is essential to managing food safety because it facilitates tracking of the operation (i.e., the ''process, point, or procedure'' that is being controlled). This provides ongoing information about whether the process, point, or procedure is under control (i.e., operating according to plan), and can provide information about shifts away from control. If monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a deviation from a maximum or minimum value (critical limit) occurs. For example, if the minimum oven

temperature needed to ensure pathogen elimination during baking of a particular size pet treat is 300 °F for a specific time and the procedure for baking pet treats calls for an operating temperature of 375 °F, monitoring would detect that the temperature in the oven was dropping and enable the facility to identify and fix the problem with the temperature before the temperature drops to 300 °F. In addition, monitoring is used to determine when a deviation occurs at a critical control point (i.e., exceeding or not meeting a critical limit), indicating there is loss of control. In the previous example, there would be loss of control if the temperature drops to 299 °F. When a deviation occurs, an appropriate corrective action must be taken, e.g., stop the baking process until the temperature in the oven can be maintained above 300 °F and reprocess the pet treats that were not baked at the appropriate temperature. Also, monitoring provides written documentation for use in verification. For example, if the facility monitors the temperature of the oven continuously, using a temperature recording device, the output of the temperature recording device is available during the verification activity of review of records. Under this approach, monitoring is directed to evaluating implementation of the preventive controls, and the written documentation of the monitoring is then used in verification.

Proposed § 507.3 would define ''verification'' to mean those ''activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.'' One aspect of verification, as proposed, is the initial validation of a food safety plan to determine that the plan is scientifically and technically sound, that all hazards have been identified, and that if the food safety plan is properly implemented these hazards will be effectively controlled. Another aspect of verification is evaluating whether the facility's food safety system is functioning according to the food safety plan. Both of these aspects are directed at the effectiveness of a preventive control; they establish that the preventive control is scientifically valid for controlling the hazard and verify that the preventive control is accomplishing its intended purpose. Examples of verification activities include review of monitoring records and review of records for deviations and corrective actions. The Agency discusses verification activities in more detail during its discussion of proposed § 507.45 (Verification) in section X.G.

Monitoring and verification are closely related; both address the performance of preventive controls, and verification relies in part on monitoring records to establish that preventive controls developed to significantly minimize or prevent hazards are being implemented according to plan. Three provisions of section 418(f) of the FD&C Act (Verification) are particularly relevant when considering the role of monitoring. First, section 418(f)(1) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that ''the preventive controls implemented . . . are adequate to control the hazards identified . . . '' Second, section 418(f)(2) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that ''the owner, operator, or agent is conducting monitoring . . .'' Third, section 418(f)(4) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that ''the preventive controls implemented . . . are effectively and significantly minimizing or preventing the occurrence of identified hazards . . .''

3. Monitoring the Performance of Preventive Controls

Section 418(a) requires monitoring the ''performance'' of preventive controls whereas section 418(d) requires monitoring their ''effectiveness.'' The Agency tentatively concludes that the language of section 418 regarding monitoring is ambiguous and that it would be appropriate to require monitoring of the performance of preventive controls. ''Performance'' means ''the execution or accomplishment of an action, operation, or process undertaken or ordered'' (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 2157) and is consistent with use of ''monitoring'' in traditional HACCP. Monitoring the performance of preventive controls would be undertaken to determine whether a facility is implementing its preventive controls and would generate records that would be used to verify implementation of the controls. For example, monitoring performance could include visual observation and measurements of temperature, time, pH, and moisture level. In contrast, ''effectiveness'' refers to the quality of ''having an effect or result'' (Shorter Oxford English Dictionary, Fifth Ed. (2002), p. 794) and is not consistent with use of the term ''monitoring in traditional HACCP. The term ''verification,'' not ''monitoring'' is used to refer to effectiveness in traditional HACCP systems. Monitoring the effectiveness of preventive controls would evaluate whether the preventive controls were working.

Requiring monitoring of the effectiveness of the preventive controls would be redundant with required verification activities. Section 418(f) requires verification that the preventive controls are ''effectively and significantly minimizing the occurrence of the identified hazards . . .'' The activities necessary for such verification are the same as would be required for monitoring the effectiveness of the preventive controls. Requiring monitoring of effectiveness rather than performance of the preventive controls would create a significant gap in the preventive controls system. In contrast, monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately and thereby are effectively and significantly minimizing or preventing hazards.

Section 418(n)(5) of the FD&C Act directs the Secretary, in issuing these regulations, to review hazard analysis and preventive control programs in existence to ensure that this regulation is consistent to the extent practicable with applicable domestic and internationally-recognized standards in existence. Requiring monitoring of the performance of preventive controls is consistent with applicable domestic and internationally recognized standards.

Therefore, the Agency tentatively concludes that this interpretation is reasonable and proposes to adopt it in the proposed requirements implementing section 418(d) of the FD&C Act. The Agency requests comment on this interpretation.

4. Proposed § 507.39—Monitoring

a. Proposed § 507.39(a)—Requirement for written procedures for monitoring. Proposed § 507.39(a) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls. Proposed § 507.39(a) would implement section 418(d) and (h) of the FD&C Act.

Proposed § 507.39(a) would require that the monitoring procedures be written. Under section 418(d) of the FD&C Act, the owner, operator, or agent in charge of a facility must monitor the effectiveness of the preventive controls implemented under section 418(c) of the FD&C Act. Under section 418(h) of the FD&C Act, the procedures used by the

facility to comply with the requirements of section 418 of the FD&C Act must be included in the written plan.

Proposed § 507.39(a) would facilitate tracking the implementation of the preventive controls to provide assurance that they are consistently performed; if monitoring indicates that there is a trend towards loss of control, a facility can take action to bring the process back into control before a preventive control is not properly implemented and potentially unsafe product is produced. Further, if monitoring is conducted with sufficient frequency to ensure preventive controls are consistently performed, it will detect if a preventive control is not properly implemented (e.g., if the temperature of an oven falls below the temperature needed to ensure safety), indicating loss of control and signaling the need for an appropriate corrective action. Finally, the proposed monitoring requirement would result in written documentation for use in verification.

To assist the animal food industry in developing their food safety plan, the Agency, in proposed § 507.39(a)(1) through (a)(6), lists the monitoring procedures that it tentatively considers to be the minimum information needed to provide assurances that the outcomes described in proposed § 507.36, ''Preventive controls for hazards that are reasonably likely to occur,'' are achieved. The owner, operator, or agent in charge of the facility, in their written monitoring procedures would need to include the preventive controls that will be monitored. The procedures would also need to include who will perform the monitoring, how the monitoring will be performed, what parameter will be measured if applicable, the frequency of monitoring, and any additional information needed to endure proper monitoring of the preventive controls.

b. Proposed § 507.39(b)—Frequency of monitoring. Proposed § 507.39(b) would require that the owner, operator, or agent in charge of a facility monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed. Proposed § 507.39(b) does not specify a single monitoring frequency applicable to all facilities and processes. Rather, it requires monitoring with ''sufficient frequency'' to assure that the preventive controls are consistently performed. Proposed § 507.39(b) would implement section 418(d) of the FD&C Act and is consistent with the NACMCF HACCP guidelines and the Codex HACCP Annex.

Continuous monitoring is possible with many types of physical and chemical parameters. For example, the temperature and time for many thermal processes can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the affected product can be retained and evaluated to determine the appropriate disposition. Examples of other parameters that can be monitored continuously include pressure, flow rate, and pH.

Continuous monitoring may not be possible, or even necessary, in all cases. For example, it may not be practical to continuously monitor the size of particles in a food to ensure they do not exceed the maximum dimensions that are required to ensure a process such as cooking, cooling, or acidification can be properly implemented. If monitoring is not continuous, it may be difficult to ensure that the preventive controls are consistently implemented and a problem has not occurred. Thus, according to NACMCF, the frequency of non-continuous monitoring must be sufficient to ensure that a CCP (or, in the case of this proposed rule, a preventive control) is under control (Ref. 31). The Codex HACCP Annex also notes that, if monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control (Ref. 36). The frequency of non-continuous monitoring would depend on factors such as the proximity of operating conditions to the conditions needed to ensure safety and the variability of the process. For example, if the temperature needed to ensure safety of baked pet treats is 300 °F, non-continuous monitoring would need to be more frequent when an oven for baking pet treats is operated at 350 °F than when the oven is operated at 400 °F. As another example, if temperatures vary by 30 °F during processing, monitoring would need to be more frequent than if the variation is only 10–15 degrees.

c. Proposed § 507.39(c)—Requirement for records. Proposed § 507.39(c) would require that all monitoring of preventive controls in accordance with proposed § 507.39 be documented in records that are subject to verification in accordance with § 507.45(b)(1) and records review in accordance with 507.45(c)(1)(i) and (c)(2). Proposed § 507.39(c) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Further discussion monitoring under HACCP systems can be found in section XII.E of the proposed rule for preventive controls for human food (78 FR 3646).

The monitoring records would be used to verify that the preventive controls are adequate, as would be required by proposed § 507.45(a), and to verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, as would be required by proposed § 507.45(d).

Together, proposed §§ 507.39(a), (b), and (c) and 507.45(a), (b), and (d) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented and that food manufactured, processed, packed or held by such facility will not be adulterated under section 402 of the FD&C Act.

F. Proposed § 507.42—Corrective Actions

1. Requirements of Section 418 of the FD&C Act

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act. Section 418(e) specifies that the owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective:

- Appropriate action is taken to reduce the likelihood of recurrence of the implementation failure (section 418(e)(1) of the FD&C Act);
- All affected food is evaluated for safety (section 418(e)(2) of the FD&C Act); and
- All affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (section 418(e)(3) of the FD&C Act).

Section 418(f)(4) of the FD&C Act requires, in relevant part, that the owner, operator, or agent in charge of a facility verify that the preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards.

2. Proposed § 507.42(a)—Corrective Action Procedures

Proposed § 507.42(a) would require that the owner, operator, or agent in

charge of a facility establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. Having written procedures in place would enable facilities to act quickly and appropriately when preventive controls are not properly implemented, e.g., when a parameter associated with heat processing exceeds a maximum value or falls below a minimum value. Proposed § 507.42(a) would implement section 418(e) of the FD&C Act. A discussion on the use of corrective actions in HACCP can be found in section XII.F.2 of the proposed rule for preventive controls for human food (78 FR 3646). As discussed in section X.C.4, the proposed rule would establish requirements for preventive controls (which may be at critical control points), and proposed § 507.36(c)(2) would require that the preventive controls include, as appropriate to the facility and the animal food, the maximum or minimum value, or combination of values, to which any physical, biological, radiological, or chemical parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. For example, if a parameter associated with heat processing falls below a minimum value, corrective action would be triggered.

The benefits from identifying corrective action procedures in advance of the need to actually take corrective action largely derive from having the procedures in written form. Written corrective action procedures would be essential to the facility's animal food safety team, to auditors, and to inspectors. The facility's animal food safety team will be responsible for ensuring that appropriate corrective actions are taken if preventive controls are not properly implemented. Having access to appropriate, written corrective action procedures determined in advance of the need for such action can ensure that correct and complete actions are taken in a timely fashion without the need for the team to meet and decide on the appropriate action. Having written corrective action procedures available for auditors and for inspectors is essential for them to assess the adequacy of the animal food safety plan; the procedures a facility will use to address implementation failures are essential to the production of safe food, and without them a complete assessment cannot be made. Written corrective action procedures also would be useful for training purposes, so that employees who would need to implement the corrective action procedures will be prepared for what they would need to do.

Proposed § 507.42(a) would implement section 418(e) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must establish corrective action procedures) and section 418(h) of the FD&C Act (i.e., that the owner, operator, or agent in charge of a facility must prepare a written plan).

Proposed § 507.42(a) would require that corrective action procedures describe the steps to be taken to ensure that:

- Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur (proposed § 507.42(a)(1));
- All affected animal food is evaluated for safety (proposed § 507.42(a)(2)); and
- All affected animal food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (proposed § 507.42(a)(3)).

The hazard analysis and risk-based preventive controls in this proposed rule are designed to identify hazards that are reasonably likely to occur, and to significantly minimize or prevent the occurrence of such hazards and provide assurances that such animal food is not adulterated under section 402 of the FD&C Act. However, a preventive controls system accounts for the possibility of implementation and effectiveness problems and includes procedures for addressing those problems and any affected food.

Proposed § 507.42(a) would implement section 418(e)(1) through (e)(3) of the FD&C Act. Section 418(e)(1) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. Section 418(e)(1) and proposed § 507.42(a)(1) explicitly require that action be taken to reduce the likelihood of recurrence of the implementation failure. Although not prescribed by proposed § 507.42(a)(1), reducing the likelihood of recurrence of an implementation failure is best accomplished by identifying the root cause of failure and then taking action to address that root cause. If the root cause is not identified and corrected, it is more likely that the failure will recur. For example, if the temperature of a heat process cannot be maintained, a corrective action to raise the temperature using the controller may correct the problem short-term. However, if the root cause is a lack of boiler capacity to run multiple heating units at the same time, corrective action should address replacing the boiler to increase capacity.

Proposed § 507.42(a)(2) and (a)(3), would require that corrective action procedures include an evaluation of all food affected by a problem and procedures for ensuring that affected food is prevented from entering into commerce if the owner, operator or agent in charge of the facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act. Such an evaluation is implicit in the Agency's HACCP regulations for seafood and juice (§§ 123.7(b) and 120.10(a)) in that these sections do not explicitly require that food affected by the problem be evaluated, but do require that steps be taken to ensure that product that is injurious to health or otherwise adulterated does not enter commerce. Although the Agency's HACCP regulations for seafood and juice do not specify the steps that must be described in a corrective action plan, the regulations require that specific steps be taken when a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation (§§ 123.7(c) and 120.10(b), respectively). Under the seafood and juice HACCP regulations, required steps include segregating and holding affected product, performing or obtaining a review to determine the acceptability of the affected product for distribution and taking corrective action, when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.

3. Proposed § 507.42(b)—Corrective Action in the Event of an Unanticipated Problem

Proposed § 507.42(b)(1) through (b)(3) would require that if a preventive control is not properly implemented and a specific corrective action has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility take corrective action to identify and correct the problem, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following the corrective action procedure under proposed § 507.42(a)(3). However, a facility might not anticipate all of the problems that may occur, and a facility may

experience an implementation failure for which a corrective action procedure has not been established. Regardless of whether a problem was anticipated and a corrective action procedure was developed in advance, corrective actions to accomplish the steps that would have been included in a corrective action procedure are necessary. Likewise, a facility might determine (e.g., as a verification activity in accordance with proposed § 507.45(c), discussed in section X.G of this document), that a preventive control is ineffective. For example, detecting a pathogen in pet food may signal that preventive controls for that pathogen are ineffective. As in the case of an unanticipated implementation failure of a preventive control, corrective actions would be necessary if a preventive control is found to be ineffective.

Proposed § 507.42(b)(4) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 507.45(e) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented and a specific corrective action has not been established, or if a preventive control is found to be ineffective. (The Agency uses the term ''reanalyze'' when it refers to a reassessment of the validity of a preventive control or the food safety plan to control a hazard.) Under proposed § 507.45(a), the verification required by section 418(f) of the FD&C Act would include validation of the food safety plan, referring to whether it is effectively controlling the hazards or ''working correctly.'' See section X.G of this document for a discussion of proposed requirements for verification (including validation and reanalysis) under section 418(f) of the FD&C Act. Proposed § 507.42(b)(4) would apply to unanticipated food safety problems, and the unanticipated nature of the problems is relevant to the reanalysis of the food safety plan. If the owner, operator, or agent in charge of a facility has assessed its procedures, practices, and processed and has not identified a specific failure as a foreseeable occurrence, the owner, operator, or agent in charge must assess whether the problem is simply an implementation failure that could be expected to occur in the normal course of manufacturing, processing, packing or holding the food, or the result of a system-wide problem that is not being properly addressed by the plan (e.g., ineffective preventive controls.) If the problem is simply an implementation failure, and such a failure is now a foreseeable circumstance, reanalysis of the food safety plan would be necessary to determine whether a corrective action procedure should be established for that foreseeable failure. Likewise, if the problem is the result of a system-wide problem that is not being properly addressed by the plan (or is otherwise a result of ineffective preventive controls), reanalysis of the food safety plan would be necessary to identify effective preventive controls. Either way, reanalyzing the food safety plan and modifying it as necessary would be necessary to reduce the risk of recurrence of the problem. Proposed § 507.42(b)(4) is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry.

4. Proposed § 507.42(c)—Documentation

Proposed § 507.42(c) would require that all corrective actions taken in accordance with this section be documented in records that are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2). The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken.

G. Proposed § 507.45—Verification

1. Requirements of Section 418 of the FD&C Act

Section 418(f) of the FD&C Act requires that the owner, operator, or agent in charge of a facility verify that:

- The preventive controls implemented under section 418(c) of the FD&C Act are adequate to control the hazards identified under section 418(b) of the FD&C Act (section 418(f)(1) of the FD&C Act);
- The owner, operator, or agent is conducting monitoring in accordance with section 418(d) of the FD&C Act (section 418(f)(2) of the FD&C Act);
- The owner, operator, or agent is making appropriate decisions about corrective actions taken under section 418(e) of the FD&C Act (section 418(f)(3) of the FD&C Act);
- The preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means (section 418(f)(4) of the FD&C Act); and
- There is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f)(5) of the FD&C Act).

In addition, section 418(g) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Further, section 418(i) of the FD&C Act specifies that the owner, operator, or agent in charge of a facility shall conduct a reanalysis under section 418(b) of the FD&C Act (the requirement to identify and evaluate known or reasonably foreseeable hazards) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is operative. The owner, operator, or agent shall revise the written plan required under section 418(h) of the FD&C Act if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under section 418(i) of the FD&C Act to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

2. Proposed Requirements for Validation

a. Proposed § 507.45(a)—Validation that preventive controls are adequate to control the hazard. Proposed § 507.45(a) would require that, except as provided by paragraph (a)(3), the owner, operator, or agent in charge of a facility validate that the preventive controls identified

and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. Proposed § 507.45(a) would implement section 418(f)(1) of the FD&C Act. A discussion on validation and how it is used in HACCP systems can be found in the proposed rule for preventive controls for human food (78 FR 3646).

b. Proposed § 507.45(a)(1)—Validation by a qualified individual prior to implementation and on reanalysis. Proposed § 507.45(a)(1) would require that the validation of the preventive controls be performed (or overseen) by a qualified individual. The preventive controls must be adequate to control the hazards identified in the hazard analysis as reasonably likely to occur. Determining whether specific preventive controls are adequate requires an individual who is knowledgeable in the hazards associated with a product and process and the appropriate preventive controls for those hazards. Such knowledge requires scientific and technical expertise developed through training, experience or both.

Proposed § 507.45(a)(1)(i) would require that validation occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production. The validation of preventive controls includes collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies), as discussed in the next section of this document. The collected data or information, or the studies, would establish a scientific and technical basis for the preventive controls used, in particular those that involve critical control points. This scientific and technical basis largely must be established prior to producing a product to ensure that the animal food produced using those preventive controls will be safe. However, as a practical matter, the scientific and technical basis for some aspects of a preventive control may require production conditions and, thus, would be established by the collection of data or information during, rather than before, producing a product. For example, ensuring that limits for control parameters can be met during production would be done under production conditions. FDA tentatively concludes that preventive controls that require the collection of data or information, or studies, during production conditions are part of validation, and, thus proposed § 507.45(a)(1)(i) would require that the validation of preventive controls be performed, when necessary, during the first 6 weeks of production. The Agency selected six weeks as a time interval that would be adequate to allow facilities to methodically collect data and information during production, yet would be close to implementation of a preventive control.

FDA requests comment on whether the proposed timeframe for validation should be shorter or longer. Comments should provide the basis for an alternative timeframe.

Proposed § 507.45(a)(1)(ii) would require that the validation of the preventive controls be performed whenever a reanalysis of the food safety plan reveals the need to do so. The circumstances under which a reanalysis would be required are addressed in proposed § 507.45(e)(1). Proposed § 507.45(e)(2) would require that the owner, operator, or agent in charge of a facility complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative, or, when necessary, during the first 6 weeks of production. All preventive controls established to address a hazard identified as reasonably likely to occur must have a scientific and technical basis; establishing that scientific and technical basis is a validation activity regardless of whether the preventive control is established in the facility's initial food safety plan or as a result of reanalysis of the food safety plan.

c. Proposed § 507.45(a)(2)—Validation based on scientific and technical information. Proposed § 507.45(a)(2) would require that, except as provided by paragraph (a)(3) of this section, the validation of preventive controls include collecting and evaluating scientific and technical information or, when such information is not available or is insufficient, conducting studies to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur.

The scientific and technical information that would be evaluated to determine whether preventive controls effectively control the hazards that are reasonably likely to occur may include scientific publications, government documents, predictive mathematical models and other risk-based models, and technical information from equipment manufacturers, trade associations, and other sources. If the qualified individual conducting the validation relies on sources such as scientific publications, the qualified individual would need to ensure during validation that the conditions used by the facility are consistent with those described in the publication that is being used to support the adequacy of the preventive control measure to control the hazard. For example, if a study demonstrates adequate inactivation of *Salmonella* spp. during the manufacturing of dry dog and cat food, conditions such as ingredient matrix, temperature, and heating time, that were critical to achieving inactivation in the study must be the same when the facility manufactures the dry dog and cat food (or any change in the critical parameters must be such that the same or greater lethality is achieved). Documents published by FDA, such as the Food Code (Ref. 76), the Pasteurized Milk Ordinance (Ref. 77), and the Fish and Fisheries Products Hazards and Controls Guidance (Ref. 78) may provide scientific and technical information useful in establishing the validity of a preventive control measure, such as times and temperatures for heating animal food in which bacterial pathogens may be eliminated, or minimum water activities (a_w), minimum pH values, and minimum temperatures for the elimination of a variety of pathogens.

Predictive mathematical models that describe the growth, survival, or inactivation of microorganisms in foods may provide scientific and technical information useful in determining whether a process would be adequate to reduce microorganisms of public health concern (Refs. 79 and 80). Other risk-based models may examine the impact of a control measure on a hazard and may be useful if appropriately validated for a specific animal food. If the model is for a different food, it may still provide useful validation information that could be supplemented by additional data. For example, there are many mathematical models for thermal resistance of *Salmonella* spp. If a model for the thermal resistance of *Salmonella* spp. is developed for the same type of food as the animal food being produced, and the animal food being produced has the same critical parameters such as pH and a_w that were used in developing the thermal resistance model, then heat processes based on the model would generally be considered validated. If the model is for thermal resistance of *Salmonella* spp. in a type of animal food that is only similar to the animal food being produced, or has different critical parameters than were used in developing the thermal resistance model, it would be necessary to conduct additional thermal resistance studies in

the animal food being produced to provide the data needed to show that a heat process adequately reduces *Salmonella* spp. in that animal food and to establish the critical parameters for the process. For example, a model for thermal resistance of *Salmonella* spp. on meat and bone meal may not apply to poultry meal, even though the foods are similar in that both are animal by-products. The extent of such studies would, however, be less than the extent of such studies if there were no data on the heat resistance of *Salmonella* spp. in a similar animal food. For example, if the thermal resistance of *Salmonella* spp. in initial studies with canola meal is similar to that for soybean meal then a thermal resistance study used to develop data for canola meal could investigate fewer times and temperatures, or use fewer replicates, than would be the case in the absence of the information about the thermal resistance of *Salmonella* spp. in soybean meal.

A process validation study would establish the relationship between parameters such as process times and temperatures and other factors and the rate at which pathogens are reduced, and a prevalence study would determine the levels at which pathogens may occur in the raw material, ingredient, or animal food product to establish the cumulative amount of pathogen reduction that would be required to adequately reduce the risk of illness from that pathogen. Such studies are typically published or otherwise broadly disseminated within the scientific community and, when properly designed and carried out, are generally regarded by experts as scientifically definitive with respect to the matters addressed by the study. However, if scientific and technical information is not available or is insufficient to support the adequacy of a preventive control measure to control the hazard, the owner, operator or agent in charge of a facility would need to conduct controlled scientific studies to establish that a preventive control measure is adequate to control the hazard.

Information is available in the literature that can assist in the design of studies to support the adequacy of preventive control measures. For example, NACMCF has published information on ''Parameters for Determining Inoculated Pack/Challenge Study Protocols'' (Ref. 80). Studies to validate preventive control measures must be conducted by persons with experience and expertise relevant to the product, process and hazard to be controlled. Under proposed § 507.45(a)(1), any studies needed to provide the scientific and technical information to establish the validity of the plan would either be conducted by a qualified individual (as would be defined in proposed § 507.3) or would be overseen by a qualified individual. In other words, the qualified individual need not have the experience and expertise to conduct validation studies, but must have sufficient expertise in risk-based preventive controls to understand the studies and how they support the validity of the preventive controls with respect to the hazard of concern.

d. Proposed § 507.45(a)(3)—Preventive controls for which validation is not required. Proposed § 507.45(a)(3)(i) and (ii) would provide that validation need not address:

- The sanitation controls that would be established in proposed § 507.36(d)(2); and
- The recall plan that would be established in proposed § 507.38.

According to NACMCF, verification involves activities to determine the validity of the HACCP plan and that the system is operating according to the plan (Ref. 29). Thus, validation is a verification activity. The purpose of validation is to provide the scientific and technical basis for ensuring that the preventive controls implemented are adequate to control the hazards identified as reasonably likely to occur. FDA tentatively concludes that validation, i.e., the evaluation of scientific and technical information, is either not an essential activity, is not practical or is not relevant, for the controls identified in proposed § 507.45(a)(3).

As discussed in section X.C.6, proposed § 507.36(d)(2)(i)(A) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the cleanliness of animal food-contact surfaces, including food-contact surfaces of utensils and equipment. Traditionally, sanitarians employed by the facility, or experts employed by companies that supply cleaning and sanitizing compounds, will establish critical parameters and associated limits for cleaning and sanitation, including the choice and strength of the cleaning and sanitizing chemicals, contact time, and temperature requirements, based on studies conducted by the manufacturers of the products. Antimicrobial solutions applied to animal food processing equipment and utensils to sanitize such objects after they have been washed are included in the definition of ''pesticide chemical'' and therefore, are subject to regulation by EPA under section 408 of the FD&C Act. Chapter 4 (Additional Considerations for Antimicrobial Products) of EPA's ''Pesticide Registration Manual'' (Refs. 81 and 82) outlines EPA's requirements and recommendations for registration of antimicrobial substances, including testing against a validated protocol to be granted EPA-registered claims for pathogen reduction. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the adequacy of the sanitation controls that would be required by proposed § 507.36(d)(2)(i)(A). Monitoring activities to ensure the procedures are followed will provide assurance that the controls are functioning as intended to prevent hazards from insanitary animal food-contact surfaces. The Agency requests comment on this approach.

As discussed in section X.C.6, proposed § 507.36(d)(2)(i)(B) would require that, where relevant to hazards that are reasonably likely to occur, sanitation controls include procedures for the prevention of cross-contamination from insanitary objects and from employees to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product. As already discussed with respect to proposed § 507.36(d)(2)(i)(A), sanitation controls to prevent cross-contamination can be established by companies that supply cleaning and sanitizing compounds without the need for validation.

As discussed in section X.D.7, a recall plan can significantly minimize or prevent hazards by limiting consumption of affected animal food during a recall. Following an existing plan that addresses all necessary elements of a recall helps minimize delay created by uncertainty as to the appropriate actions to take and helps ensure critical actions are not overlooked. The proposed requirement to validate a preventive control by collecting and evaluating scientific and technical information or by conducting studies simply does not apply to such a plan. Thus, FDA tentatively concludes that this proposed rule should not propose to require validation of the recall plan that would be required by proposed § 507.38.

3. Proposed § 507.45(b)(1)—Verification of Monitoring

Proposed § 507.45(b)(1) would require that the owner, operator, or agent in charge of a facility verify that monitoring is being conducted, as would be required by proposed § 507.39. One example of verification

that monitoring is being conducted is a periodic observation of the monitoring activity, e.g., by a supervisor. Another example of such a verification activity is an independent test made by a person other than the person doing the monitoring. For example, if the line operator is verifying the operation of a metal detector by running test pieces through the metal detector every 2 hours to verify it rejects them, a quality assurance technician could periodically run a similar test, e.g., once per shift. Proposed § 507.45(b)(1) does not address the review of monitoring records, which would be required under proposed § 507.45(c)(1)(i) (see the discussion later in this section of the document). Proposed § 507.45(b)(1) would implement section 418(f)(2) of the FD&C Act.

Proposed § 507.45(b)(1) would not specify the verification activities that must be conducted for monitoring. The Agency requests comment on whether proposed § 507.45(b)(1) should do so, and if so, what verification activities should be required.

4. Proposed § 507.45(b)(2)—Verification of Corrective Actions

Proposed § 507.45(b)(2) would require that the owner, operator, or agent in charge of a facility verify that appropriate decisions about corrective actions are being made, as would be required by proposed § 507.42 and by proposed § 507.36(d)(2)(ii). An example of verification that appropriate decisions about corrective actions are being made is observation of the corrective actions being taken, e.g., by a supervisor. Proposed § 507.45(b)(2) would implement section 418(f)(3) of the FD&C Act.

Proposed § 507.45(b)(2) would not specify the verification activities that must be conducted for corrective actions. The Agency requests comment on whether proposed § 507.45(b)(2) should do so, and if so, what verification activities should be required.

5. Proposed § 507.45(b)(3)—Implementation and Effectiveness

Proposed § 507.45(b)(3) would require that the owner, operator, or agent in charge of a facility verify the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, including the requirements in proposed § 507.45(b)(3) and § 507.45(c), as appropriate to the facility and the animal food. Proposed § 507.45(b)(3) and (c) would implement section 418(f)(4) of the FD&C Act, which requires in relevant part verification by ''appropriate means'' that the preventive controls ''are effectively and significantly minimizing or preventing the occurrence of identified hazards.''

a. Proposed § 507.45(b)(4)—Calibration. Proposed § 507.45(b)(4) would require calibration of process monitoring instruments and verification instruments. The combination of monitoring (proposed § 507.39(a)), recordkeeping (proposed § 507.55), and verification (proposed § 507.45(a), (b)(4), and (c)) would establish a system that would provide assurance that hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act would be significantly minimized or prevented and that animal food manufactured, processed, packed, or held by such facility would not be adulterated under section 402 of the FD&C Act. In many instances, monitoring and verification activities rely on instruments (such as a weigh scale or a thermometer) that must be calibrated. Calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance that hazards will be significantly minimized or prevented. If an instrument is calibrated against a known reference, the reference standard may also need periodic calibration (e.g., the standard reference thermometer used to calibrate a thermometer used in processing equipment will itself also need to be calibrated periodically).

Instrument calibration is performed on a regular or periodic basis based upon the type of instrument being used and its sensitivity to factors such as the operating environment and the wear and tear of ongoing use. The type of instruments used in a particular facility and the manner of their use will largely determine the need for, and the frequency of, calibration, and the frequency of calibration is often prescribed by the instrument manufacturer. Therefore, proposed § 507.45(b)(4) would not specify a frequency for calibration.

b. Proposed § 507.45(c)—Records review. Proposed § 507.45(c) would require a review of specific records related to monitoring, corrective actions, and other verification activities within specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. Proposed § 507.45(c)(1)(i) would require review of the monitoring and corrective action records within a week after the records are made. Proposed § 507.45(c)(1)(ii) would require review of the records related to calibration of instruments within a reasonable time after the records are made. (As discussed in section X.J, proposed § 507.55 would list the records that facilities must establish and maintain, including records that document the monitoring of preventive controls as required by § 507.39(c), corrective actions as required by § 507.42(d), and verification activities as required by § 507.45(f)). Proposed § 507.45(c) would implement section 418(f) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry.

Proposed § 507.45(c) would establish that the purpose of the review of records would be to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decision were made about corrective actions. The Agency tentatively concludes that review of the records required by proposed § 507.45(c)(1)(i) and (ii) would accomplish these purposes. Reviewing monitoring records can reveal whether they contain information on all the parameters that were to be monitored to determine whether a process is delivered in accordance with the food safety plan. For example, if the size of the animal food to be baked and the temperature and the time of baking are critical to the safety of the animal food, review of the monitoring records would demonstrate whether all three parameters were monitored and whether the values were within specified parameter values. Reviewing monitoring records can reveal whether a process followed the procedures specified in the facility's food safety plan (e.g., if the monitoring records show the temperature of every other batch of a baked animal food when the plan specified the measurement of every batch). Review of monitoring records also can reveal whether any information is missing, e.g., a designated lot number, so that the missing information can be quickly identified and added to the record if necessary. The Agency seeks comment on this proposal.

If the review of the records reveals that the records do not contain all information specified by the food safety plan, or that the procedure in the food safety plan was not followed, the facility will not be able to conclude that its

preventive controls were implemented in accordance with its food safety plan for those activities. Because the food safety plan establishes the procedures needed to ensure preventive controls are effective, if the records review indicates that the plan is not being followed, e.g., the records are missing critical information or the activities were not performed as specified in the plan, the facility will not be able to conclude its preventive controls were effective. For example, if the records show that animal food particle size is not being determined or that the particles are too large, the minimum temperature of all parts of the particle may not occur to ensure control of pathogens such as *Salmonella* spp. If the plan requires determination of the baking temperature and time of each batch of product but the records do not show that the temperature was measured on all batches, the facility cannot be sure that the internal temperature of those batches is correct, again posing a potential risk from *Salmonella* spp. As a result, the facility would not be able to verify that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by section 418(f) of the FD&C Act.

Review of records can also reveal whether appropriate decisions were made about corrective actions. The review should determine whether all the corrective action procedures required by proposed § 507.42(a) have been followed, e.g., that actions are taken to prevent recurrence of the problem, that affected animal food has been evaluated for safety, and that affected animal food is prevented from entering commerce unless it can be determined that the animal food is not adulterated under section 402 of the FD&C Act. For example, a food safety plan may require that each package of product pass through a properly functioning metal detector and that the operator determine every two hours whether metal test pieces of a specified type and size are rejected when passed through the metal detector. If one of the test pieces was not rejected but production continued until a supervisor doing a verification check noted the problem, then corrective actions should have been taken and a corrective action record produced. A review of the corrective action records should reveal that all packages of product that passed through the metal detector since the last test showing the metal detector was functioning appropriately were held and passed through a functioning metal detector before being released into commerce. The records should also show that the metal detector was adjusted to reject the metal test pieces before it was used again to check product during production.

Proposed § 507.45(c) would require that the review of records be performed by (or under the oversight of) a qualified individual (see the discussion in section X.I regarding the activities that must be performed (or overseen) by a qualified individual as would be established in proposed § 507.50). The review of records is critical to assessing the facility's application of the preventive controls system and, thus, is fundamental to ensuring its successful operation.

Proposed § 507.45(c)(1)(i) would require review of the monitoring and corrective action records within a week after the records are made. Although proposed § 507.45(c)(1)(i) would establish a more frequent review of these records than recommended in the NACMCF guidelines (which recommend monthly verification of monitoring records and corrective action records), it is consistent with the Agency's HACCP regulations for seafood (§ 123.8(a)(3)(i) and (ii)) and juice (§ 120.11(a)(1)(iv)(A) and (B)), which require that the review of monitoring records and corrective action records occur within one week of the day that the records are made. Even for shelf-stable foods (e.g., low-acid canned foods and acidified foods) the Agency's experience has demonstrated that review of these kinds of records is a critical verification tool (60 FR 65096 at 65133, December 18, 1995). As discussed in the seafood HACCP final rule (60 FR 65096 at 65132), review of records needs to occur with sufficient frequency so as to ensure that any problems in the design and implementation of the HACCP plan are uncovered promptly and to facilitate prompt modifications. The concept is roughly that of a ''feedback loop,'' with information coming out of the record review process in such a timely manner that it can have impact on the production of subsequent lots of the product. If a problem with product is discovered during a review of records, all product since the last review could be affected. Although verification prior to shipment provides a valuable added assurance, FDA explained in the preamble to the seafood HACCP final rule (60 FR 65096 at 65132) that with highly perishable products this is not always possible and that a weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records.

Proposed § 507.45(c)(1)(ii) would require review of the records related to calibration, within a reasonable time after the records are made. The review of calibration records will depend in part on the frequency with which calibrations occur, which will be established in the food safety plan. If calibrations occur daily, it would be reasonable to review these records weekly. Where several instruments are calibrated each month, a monthly review of all the calibrations would be reasonable. Consequently, FDA tentatively concludes that setting a specific frequency for review of these records is not warranted.

As noted previously, proposed § 507.45(c) would require a review of records in part to determine whether the preventive controls are effective. A review should determine whether monitoring and corrective actions have been done in accordance with the food safety plan and whether the instruments used in monitoring and verification were properly calibrated. If food safety activities appropriate to the facility have been conducted in accordance with the plan and this is reflected in the records, the facility thus verifies the preventive controls are effective, i.e., that its preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards as required by Section 418(f) of the FD&C Act.

6. Proposed § 507.45(d)—Written Procedures for Verification Activities

Proposed § 507.45(d) would require that the owner, operator, or agent in charge of a facility establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments. The Agency is proposing to require written procedures for the frequency of calibration because the frequency of calibration will vary depending on the instrument and the process or verification activity that it pertains to.

The Agency is not proposing to require that written procedures be developed for all verification procedures. In some instances the records of verification activities provide the information needed to understand how the verification activity has been carried out and to assess whether the verification activity is adequately demonstrating that the preventive controls are effective in significantly minimizing or preventing the hazards reasonably likely to occur. For example, the Agency is not proposing to require

written procedures for validation, verification of monitoring and corrective actions, or calibration of process monitoring instruments and verification instruments (other than for the frequency of calibration). Validation involves a variety of procedures, including evaluation of scientific and technical information and conducting laboratory and in-plant studies that generally do not follow a standardized protocol or approach. Records of monitoring and corrective actions provide the information needed to understand how the verification activity was carried out. In many instances the calibration of process monitoring instruments and verification instruments will be done by contract with other entities and the facility would not have access to the procedures used; having instruments calibrated and documenting the calibration provides the necessary assurance that such instruments will be accurate. However, the frequency of calibration must be specified to ensure that the instruments are calibrated on a schedule appropriate to the instrument and the process it controls.

Section 418(f) of the FD&C Act establishes certain requirements for verification, and section 418(h) of the FD&C Act requires that the procedures used by the facility to comply with the requirements of section 418 be included in the written plan. Requiring verification procedures to be written implements the requirements in section 418 of the FD&C Act and is consistent with the requirements in HACCP regulations for seafood, juice, and meat/poultry. For further discussion, see section XII.B.6 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

7. Proposed § 507.45(e)—Reanalysis

a. Proposed § 507.45(e)—Reanalysis on the initiative of the owner, operator, or agent in charge of a facility. Proposed § 507.45(e)(1) would require that the owner, operator, or agent in charge of a facility conduct a reanalysis of the food safety plan:

- At least once every 3 years (proposed § 507.45(e)(1)(i));
- Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard (proposed § 507.45(e)(1)(ii));
- Whenever the owner, operator or agent in charge becomes aware of new information about potential hazards associated with the animal food (proposed § 507.45(e)(1)(iii));
- Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established (proposed § 507.45(e)(1)(iv));
- Whenever a preventive control is found to be ineffective (proposed § 507.45(e)(1)(v)); and
- Whenever FDA requires a reanalysis in response to newly identified hazards and developments in scientific understanding (proposed § 507.45(e)(1)(vi).

For example, if a facility that conducts baking operations for pet treats makes design changes to its oven to increase product throughput, the facility would be required to reanalyze its food safety plan because a design change to equipment that is used to control a hazard that is reasonably likely to occur would be a significant change in the activities conducted at the facility.

The owner, operator or agent in charge of a facility may become aware of a problem due to the finding of a hazard in an animal food as the result of testing by a regulatory agency (Federal, State, tribal, or foreign government) that would require an analysis of the food safety plan to ensure the hazard is significantly minimized or prevented by appropriate preventive controls. In addition, new hazards can emerge, e.g., as identified through the investigation of outbreaks. For example in 2006–2007 there was an outbreak of salmonellosis due to contamination of peanut butter with *Salmonella* Tennessee (Ref. 83). This was the first outbreak of food borne illness caused by peanut butter consumption in the U.S. and it demonstrated the need for manufacturers to address the hazard of *Salmonella* spp. in this product and in products into which peanut butter is added, such as pet treats. Information about outbreaks and ensuing product recalls is widely disseminated, including on FDA's Web site, and modern communication tools make it possible for the owner, operator, or agent in charge of a facility to receive such information automatically. For additional discussion related to the proposed requirement that the owner, operator, or agent in charge of a facility conduct a reanalysis whenever such owner, operator or agent becomes aware of new information about potential hazards associated with the food, see the discussion in section X.G.7.b of proposed § 507.45(e)(1)(vi), which would provide that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

As noted in section X.F of this preamble, proposed § 507.42(b)(4) would require that the owner, operator, or agent in charge of a facility reanalyze the food safety plan in accordance with proposed § 507.45(e) to determine whether modification of the food safety plan is required if a preventive control is not properly implemented or is found to be ineffective, and a specific corrective action has not been established. If the owner, operator, or agent in charge of a facility has not identified a specific failure as a foreseeable occurrence, the deviation may be the result of a system-wide problem that is not being properly addressed by the food safety plan (e.g., ineffective preventive controls). Thus, an unforeseen failure for which a corrective action was not identified may indicate an ineffective preventive control, and a reanalysis of the food safety plan is warranted. Similarly, when information arises indicating that the preventive control has not been effective in significantly minimizing or preventing a hazard from occurring, a reanalysis must be conducted to determine if the food safety plan should be modified to ensure that the preventive controls implemented are adequate to significantly minimize or prevent a hazard identified as reasonably likely to occur.

Proposed § 507.45(e) would implement section 418(f)(5) and (i) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP guidelines, the Codex validation guidelines, and Federal HACCP regulations for seafood, juice, and meat and poultry. A discussion on ''reanalysis'' (or ''reassessment of the hazard analysis'' as it is called) in HACCP systems can be found in section XII.G.7 of the document for the proposed rule for preventive controls for human food (78 FR 3646).

The requirement in proposed § 507.45(e)(1) that the periodic reanalysis of the food safety plan occur at least once every 3 years is explicitly required by section 418(i) of the FD&C Act. The Agency tentatively concludes that, as a practical matter, the proposed requirement for reanalysis whenever a significant change is made in the activities conducted at a facility if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard makes it likely that reanalysis would occur more frequently than every 3 years because such changes are likely to occur more frequently than every 3 years.

b. Proposed § 507.45(e)(1)(vi)—Reanalysis on the initiative of FDA. Proposed § 507.45(e)(1)(vi) establishes that FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding. Proposed § 507.45(e)(1)(vi) would implement section 418(i) of the FD&C Act, which provides in relevant part that ''[t]he Secretary may require a reanalysis . . . to respond to new hazards and developments in scientific understanding . . . .'' As discussed in section X.G.7.a, new hazards can emerge, e.g., as identified through the investigation of outbreaks of foodborne illness by CDC or other public health agencies. In addition, new developments can occur in the scientific understanding of existing or potential hazards, e.g., if scientists and animal food safety regulatory agencies develop a better understanding of the causes of these events. For example, the outbreak from *Salmonella* Tennessee in peanut butter resulted in a greater understanding of the risks posed by environmental contamination and the importance of control of water in facilities producing low-moisture foods (Refs. 84 and 85. Information submitted to the RFR, which is a relatively recent addition to the regulatory framework for food safety, has the potential to identify new hazards or routes of contamination even before outbreaks occur.

c. Proposed § 507.45(e)(2)—Implementation of additional controls. Proposed § 507.45(e)(2) would require that the owner, operator, or agent in charge of a facility complete the required reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production. The purpose of the reanalysis is to identify the need for, and implement, preventive controls in light of a reasonable potential for a new hazard, or a significant increase in a previously identified hazard, that is reasonably likely to occur. It follows that the preventive controls must be in place before making the change that creates the potential for a new hazard or a significant increase in a previously identified hazard. As with initial validation in proposed § 507.45(a)(1)(i), the Agency is proposing to provide the first 6 weeks of production, when necessary, to implement any additional preventive controls to allow facilities to methodically collect data and information during production to ensure the needed change can be implemented in the facility. The Agency seeks comment on this timeframe. Proposed § 507.45(e)(2) would implement section 418(i) of the FD&C Act.

d. Proposed § 507.45(e)(3)—Revision of the food safety plan. Proposed § 507.45(e)(3) would require that the owner, operator, or agent in charge of a facility revise the written food safety plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. Proposed § 507.45(e)(3) would implement section 418(i) of the FD&C Act, which requires that the written plan be revised ''if . . . a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.'' As discussed in section X.B of this document, the written hazard analysis is required even if the conclusion of the analysis is that there are no hazards reasonably likely to occur. It is also important to document that a reanalysis has been conducted even if no change has been made, as required by section 418(i) of the FD&C Act. Such documentation demonstrates that a facility has considered all relevant information on the safety of the products being produced, including new information that has become available since the last analysis, and determined that current procedures for implementing preventive controls are adequate to significantly minimize or prevent hazards that are reasonably likely to occur.

e. Proposed § 507.45(e)(4)—Requirement for a qualified individual. Proposed § 507.45(e)(4) would require that the reanalysis be performed, or overseen, by a qualified individual. Proposed § 507.45(e)(4) is consistent with proposed § 507.30(b) which would require that the food safety plan be developed by a qualified individual. The Agency tentatively concludes that the same qualifications are needed whether initially conducting a hazard analysis and establishing a food safety plan, or reanalyzing a hazard analysis and plan.

8. Proposed § 507.45(f)—Requirement for Records for Verification

Proposed § 507.45(f) would require that all verification activities taken in accordance with this section be documented in records and would implement section 418(g) of the FD&C Act.

H. Proposed § 507.48—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

1. Requirements of Section 418 of the FD&C Act

Briefly, as relevant to proposed § 507.48, specific provisions of section 418 of the FD&C Act require, in relevant part, that the owner, operator, or agent in charge of a facility:

- Identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility and develop a written analysis of the hazards (section 418(b) of the FD&C Act);
- Identify and implement preventive controls to provide assurances that hazards identified in the hazard analysis will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act (section 418(c) of the FD&C Act);
- Monitor the effectiveness of the preventive controls implemented under section 418 (c) of the FD&C Act to provide assurances that the outcomes described in section 418(c) shall be achieved (section 418(d) of the FD&C Act);
- Establish procedures to ensure that, if the preventive controls implemented under section 418(c) of the FD&C Act are not properly implemented or are found to be ineffective, appropriate action is taken to reduce the likelihood of recurrence of the implementation failure; all affected food is evaluated for safety; and all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 of the FD&C Act (section 418(e) of the FD&C Act);
- Verify that the preventive controls are adequate to control the hazards the owner, operator, or agent is conducting monitoring and is making appropriate decisions about corrective actions and the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards and there is documented, periodic reanalysis of the plan under section 418(i) of the FD&C Act to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats (section 418(f) of the FD&C Act);
- Maintain, for not less than 2 years, records documenting the monitoring of the preventive controls instances of nonconformance material to food safety

and instances when corrective actions were implemented (section 418(g) of the FD&C Act);

- Prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards and identifying the preventive controls adopted to address those hazards section 418(h) of the FD&C Act);
- Conduct a reanalysis under section 418(b) of the FD&C Act whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier (section 418(i) of the FD&C Act).

In addition to these requirements directed to the owner, operator, or agent in charge of a facility, section 418(m) of the FD&C Act provides, in relevant part, that the Secretary may, by regulation, exempt or modify the requirements for compliance under section 418 of the FD&C Act with respect to facilities that are solely engaged in the storage of packaged foods that are not exposed to the environment.

2. Approach to Modified Requirements Under Section 418(m) of the FD&C Act

As discussed in section VIII.E of this document, proposed § 507.10 would both provide that proposed part 507 subpart C does not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment (proposed § 507.10(a)) and establish that such a facility is subject to modified requirements in proposed § 507.48 (proposed § 507.10(b)). In the remainder of the discussion of these modified requirements, the Agency refers to ''packaged food that is not exposed to the environment'' as ''unexposed packaged animal food,'' and to ''unexposed refrigerated packaged animal food that requires time/temperature control for safety'' as ''unexposed refrigerated packaged TCS animal food.'' As noted in section VIII.E, the Agency considers ''not exposed to the environment'' and ''unexposed'' to mean that the animal food is in a form that prevents any direct human contact with the food. The modified requirements in proposed § 507.48 would apply to unexposed refrigerated packaged TCS animal food. In essence, proposed § 507.48 distinguishes between unexposed packaged animal food and unexposed refrigerated packaged TCS animal food. This distinction is based on hazards that are reasonably likely to occur during the storage of unexposed refrigerated packaged TCS animal food, but are not reasonably likely to occur during the storage of unexposed packaged animal food that does not require time/temperature control for safety.

When an unexposed packaged animal food is a refrigerated TCS animal food, the principal hazard for the unexposed refrigerated packaged TCS animal food is the potential for the growth of, or toxin production by, microorganisms of animal or human health significance. Information about this hazard for TCS foods in general (i.e., not limited to unexposed packaged animal food) is widely available (Refs. 39, 40, and 86). In brief, the need for time/temperature control is primarily determined by: (1) The potential for contamination with microorganisms of animal or human health significance and (2) the potential for subsequent growth and/or toxin production. Refrigeration has long been used to retard deterioration of the flavor, color, and texture of foods including animal food. More importantly, refrigeration helps maintain the microbiological safety of potentially hazardous foods (62 FR 8248; February 24, 1997).

Failure to maintain animal food at appropriate temperatures may result in the growth of microorganisms that may have contaminated the food before, or at the time of, harvest or during processing, handling, or storage. The rate of growth of these microorganisms is reduced as the storage temperature is lowered. Proper refrigeration, therefore, prevents or slows the growth of animal and human pathogens and spoilage microorganisms and reduces the likelihood of foodborne illness (62 FR 8248). A review of the factors that influence microbial growth and an analysis of microbial hazards related to time/temperature control of foods for safety can be found in a report (issued by the Institute of Food Technologists (IFT) under contract to FDA) on the Evaluation and Definition of Potentially Hazardous Foods (Ref. 86). The IFT report describes properties of common food commodities and the microbiological hazards that may occur from consuming particular food commodities, emphasizing microbial concerns that would be associated with temperature abuse of the products. The IFT report discusses foods for which time/temperature control may be necessary for safety (Ref. 86). Most types of animal food that are stored refrigerated have not been processed to eliminate pathogenic sporeformers, including *Clostridium botulinum,* and *Bacillus* spp. If refrigerated animal food is exposed to high enough temperatures for sufficient time, these sporeformers may begin to grow and produce toxins. Some strains of *C. botulinum* and *Bacillus* spp. can grow at refrigeration temperatures, e.g., some strains of *B. cereus* grow at 39 °F (4 °C) and some strains of *C. botulinum* grow at 38 °F (3.3 °C) (Ref. 87).

Examples of refrigerated foods that are capable of supporting the growth of pathogenic sporeformers such as *Bacillus,* spp. and *C. botulinum* include many refrigerated food for dogs and cats. Producers of refrigerated animal food minimize the contamination of the food with pathogens to the extent possible, particularly if the pathogen can grow under refrigeration conditions. Growth of pathogens is very slow under refrigeration, and the lower the temperature the longer the time for growth (Ref. 86). Conversely, as refrigeration temperature increases, the growth rate of strains of pathogens that grow slowly under refrigeration increases and animal food temperatures may get high enough that pathogens that cannot grow at normal refrigeration temperatures (generally in the range of 41–45 °F (5 °C–7 °C)) begin to grow (Ref. 86). For example, the strains of *C. botulinum* that have caused most of the outbreaks in the United States do not grow and produce toxin until the temperature reaches 50 °F (10 °C) (Ref. 78). Additional information about the time/temperature control of food to address the potential for microorganisms of animal or human health significance to grow or produce toxins is available in books on food microbiology that are available for purchase.

Such information is sufficiently well-known and accepted that the Agency tentatively concludes that the outcome of each individual hazard analysis for an unexposed refrigerated packaged TCS animal food, conducted by the owner, operator, or agent in charge of each individual facility solely engaged in the storage of unexposed packaged animal food, would be the same. That outcome would be that the potential for the growth of, or toxin production by, microorganisms of animal or human health significance is a hazard reasonably likely to occur in any unexposed refrigerated packaged TCS animal food. Likewise, information about appropriate preventive controls for this hazard is widely available (Refs. 41 and 78). Such information is sufficiently well-known and accepted that the Agency tentatively concludes that the appropriate preventive control

selected by each individual facility solely engaged in the storage of unexposed packaged animal food would be adequate controls on the temperature of any unexposed refrigerated packaged TCS animal food.

In light of the general recognition of the hazard that is reasonably likely to occur in a refrigerated packaged TCS animal food and the appropriate preventive control for that hazard, the Agency tentatively concludes that it is appropriate to specify the hazard and appropriate preventive control in the regulation. Under this approach, it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged animal food to conduct its own hazard analysis and reach its own conclusion about the hazard and the appropriateness of temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance. Instead, what would remain for the facility to do to comply with section 418 of the FD&C Act for the activity of storing an unexposed refrigerated packaged TCS animal food would be a subset of the requirements for hazard analysis and risk-based preventive controls that would be established in proposed subpart C to implement section 418 of the FD&C Act. None of these requirements would require a qualified individual. This subset of requirements would be to:

- Implement temperature controls (section 418(c) of the FD&C Act);
- Monitor temperature (section 418(d) of the FD&C Act);
- Take appropriate corrective actions when there is a problem with temperature control (section 418(e) of the FD&C Act);
- Conduct applicable verification activities (review of records) (section 418(f) of the FD&C Act); and
- Establish and maintain certain records (section 418(g) of the FD&C Act).

The Agency seeks comment on the proposed list of modified requirements.

The Agency also tentatively concludes that it would not be necessary for each individual facility solely engaged in the storage of unexposed packaged animal food to conduct the reanalysis specified in section 418(i) of the FD&C Act with respect to storing an unexposed refrigerated packaged TCS animal food. As discussed in section X.G of this document, reanalysis would apply in determining whether to apply any additional preventive controls and in determining whether to update the written plan. Under this approach, FDA would have identified the preventive control, and it would be FDA's responsibility, through rulemaking, to require any additional preventive control. Likewise, under FDA's approach, the facility would not be required to develop a food safety plan and, therefore, would not need to update the plan. If, for example, the facility changes its procedures for temperature control, the specific activities that the facility would be required to conduct (monitoring temperature; taking appropriate corrective actions if there is a problem with temperature control; conducting applicable verification activities; and establishing and maintaining appropriate records) would be adequate to address the change in procedure for temperature control.

3. Proposed § 507.48—Modified Requirements That Apply to a Facility Solely Engaged in the Storage of Packaged Animal Food That Is Not Exposed to the Environment

Proposed § 507.48(a) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment conduct certain activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance. Briefly, those activities would encompass:

- Establishing and implementing temperature controls (proposed § 507.48(a)(1));
- Monitoring the temperature controls (proposed § 507.48(a)(2));
- If there is a problem with the temperature controls for such refrigerated packaged animal food, taking appropriate corrective actions (proposed § 507.48(a)(3));
- Verifying that temperature controls are consistently implemented (proposed § 507.48(a)(4)); and
- Establishing and maintaining certain records (proposed § 507.48(a)(5)).

More specifically, proposed § 507.48(a)(1) would require that the owner, operator, or agent in charge of a facility subject to proposed § 507.48 establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance in an unexposed refrigerated packaged TCS animal food. There are two fundamental questions that the owner, operator, or agent in charge of a facility subject to proposed § 507.48 would need to know the answers to in order to comply with proposed § 507.48 for any given unexposed refrigerated packaged animal food:

- Is the animal food a TCS food?
- If the animal food is a TCS food, what is the appropriate temperature for storage of the food?

The two primary ways in which the owner, operator, or agent in charge of a facility subject to proposed § 507.48 can obtain the answers to these questions are through: (1) Information provided by the manufacturer, processor, or packer of the animal food, either in documents exchanged between the parties in the course of business or by label statements placed on the animal food by the manufacturer, processor, or packer of the food and (2) applicable scientific and technical support literature.

As discussed in section VIII.E, a citizen petition submitted to FDA (Docket No. FDA–2011–P–0561) asserted that facilities work closely with the food manufacturers to understand the conditions and controls that need to be utilized to ensure the quality of the foods they store and distribute and, in many cases, those conditions and controls are formalized in written contracts. If the conditions for storage are not formalized in written contracts or by other means (e.g., through documents of the trade that travel with a food product when it moves within the supply chain), information relevant to safe storage of the food may be provided by the manufacturer, processor, or packer of the food on the food label. For example, in 1997 FDA published guidelines for labeling food that needs refrigeration by consumers due to the potential for the food to be rendered unsafe due to the growth of infectious or toxigenic microorganisms if ''temperature abused'' (62 FR 8248). FDA recommended that foods requiring refrigeration by the consumer for safety be labeled ''IMPORTANT Must be Kept Refrigerated to Maintain Safety'' (62 FR 8248 at 8251) and that foods that are intended to be refrigerated but that do not pose a safety hazard if temperature abused be labeled more simply, e.g.; ''Keep refrigerated.'' Such labeling can provide facilities with the information to identify TCS animal food. The Agency tentatively concludes that similar food safety principles applied in human food storage would be relevant to animal food. Further, the Agency tentatively concludes that it would be rare for a facility solely engaged in the storage of unexposed packaged animal food to not have information regarding whether a refrigerated packaged food requires time/temperature control for

safety and, if so, what specific temperature controls are necessary for safe storage of the food. The Agency requests comment on this tentative conclusion.

In a situation where the owner, operator or agent in charge of a facility does not have information from the manufacturer, processor, or packer of the food about whether an unexposed refrigerated packaged animal food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food, the owner, operator, or agent in charge of the facility could either consult the scientific and technical literature to determine whether a particular food is a TCS animal food or assume that any unexposed refrigerated packaged food is a TCS animal food. Information about food that is TCS animal food, and about the appropriate temperatures to address the potential for microorganisms of animal or human health significance to grow or produce toxin, in food are well-established in the scientific literature. Documents prepared by or on behalf of FDA regarding appropriate time/temperature controls for safety (Refs. 86 and 87) provide numerous references to the primary scientific literature and serve as the basis for time/temperature controls for a variety of foods including animal food. The two temperatures commonly cited in these documents as maximum temperatures for safe storage of refrigerated food are 41 °F (5 °C) and 45 °F (7 °C). The cited maximum temperature depends on the type of food; in some cases, a maximum storage temperature is established through rulemaking in a regulation. For example:

- FDA regulations for the prevention of *Salmonella* Enteritidis in shell eggs during production, storage, and transportation (§ 118.4(e) (21 CFR 118.4(e))) and for refrigeration of shell eggs held for retail distribution (21 CFR 115.50(b)(2)) require that eggs be held and transported at a temperature not to exceed 45 °F (7 °C).
- The PMO provides for pasteurized Grade ''A'' milk and milk products to be held at 45 °F (7 °C) (Ref. 77).
- The FDA Food Code, which has been widely adopted in state laws, recommends holding most potentially hazardous (TCS) food at 41 °F (7 °C) or lower (Ref. 88).

Storage of refrigerated food at or below one of these two temperatures (i.e., 41 °F (5 °C) or 45 °F (7 °C)) consistent with storage temperatures required by regulation or recommended in widely adopted documents such as the PMO and the FDA Food Code would satisfy proposed § 507.48(a).

The Agency considers frozen animal food to be a subset of refrigerated animal food. The temperature and time required for a frozen animal food to become unsafe would result in significant quality issues for such food. Although there have been occasional problems with frozen animal food being subject to temperatures that allow some thawing in storage and distribution, the Agency is not aware of situations in which frozen animal food has been associated with the food becoming unsafe. Thus, the Agency tentatively concludes that it would be rare for an unexposed frozen packaged animal food to be a TCS animal food.

Proposed § 507.48(a)(2) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged animal food monitor the temperature controls established for unexposed refrigerated packaged TCS animal food with sufficient frequency to provide assurance that they are consistently performed. Monitoring can be done by use of a continuous temperature-recording device (e.g., a recording thermometer) that indicates and records the temperature accurately within the refrigeration compartment with a visual check of the recorded data at least once per day. Monitoring as would be required by proposed § 507.48(a)(2) would provide the owner, operator, or agent in charge of the facility with factual information with which to judge whether the temperature control is operating as intended. Proposed § 507.48(a)(2) is modified relative to the analogous monitoring requirement that would be established in proposed § 507.39(a) in subpart C in that proposed § 507.48(a)(2) would not require written procedures for monitoring. The records of monitoring (which would be required by proposed § 507.48(a)(5)(i)) would demonstrate the frequency of monitoring. The Agency requests comment on whether there would be a benefit to requiring a facility to develop written procedures for monitoring temperature.

Proposed § 507.48(a)(3) would require that, if there is a problem with the temperature controls for unexposed refrigerated packaged TCS animal food, the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged animal food take appropriate corrective actions to correct a problem with the control of temperature for any refrigerated packaged animal food and reduce the likelihood that the problem will recur (proposed § 507.48(a)(3)(i)); evaluate all affected animal food for safety (proposed § 507.48(a)(3)(ii)); and prevent the animal food from entering commerce, if the owner, operator, or agent in charge of a facility cannot ensure the affected animal food is not adulterated under section 402 of the FD&C Act (proposed § 507.48(a)(3)(iii)). Such corrective actions would be necessary if, for example, there was a failure to maintain adequate temperature control. Proposed § 507.48(a)(3) is modified relative to the analogous proposed requirement for corrective actions that would be established in proposed § 507.42(a) in subpart C in that proposed § 507.48(a)(3) would not require written procedures for corrective actions. In essence, there is a single action to correct the problem (i.e., to restore temperature control), followed by the need to evaluate the animal food for safety and to prevent animal food from entering commerce when appropriate. The corrective actions taken, including information to document that product was not exposed to temperatures and times that would compromise the safety of the product, would be documented in records subject to agency review. It may be necessary for the owner, operator, or agent in charge of the facility to consult with the applicable manufacturer, processor, or packer of the animal food to determine the appropriate disposition of the food.

Proposed § 507.48(a)(4)(i) would require that the owner, operator, or agent in charge of a facility solely engaged in the storage of unexposed packaged animal food verify that temperature controls are consistently implemented by calibrating temperature monitoring and recording devices. As discussed in section X.G.5.b of this document, calibration provides assurance that an instrument is measuring accurately. If these instruments are not properly calibrated, the values they provide may not provide the necessary assurance temperatures are adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance in an unexposed refrigerated packaged TCS animal food. Proposed § 507.48(a)(4)(i) is analogous to proposed § 507.45(b)(3)(ii) in subpart C, which would establish a verification requirement for calibration of process monitoring instruments and verification instruments.

Proposed § 507.48(a)(4)(ii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged animal food verify that temperature controls are consistently

implemented by reviewing records of calibration within a reasonable time after the records are made. As discussed in section X.G.5.e of this document, the purpose of the review of records would be to ensure that the records are complete and that the preventive controls are effective. If temperature monitoring and recording devices are not properly calibrated, the temperature controls may not be effective. As discussed in section X.G.5.e, the review of calibration records will depend in part on the frequency with which calibrations occur.

Proposed § 507.48(a)(4)(iii) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged animal food verify that temperature controls are consistently implemented by reviewing the records of monitoring and actions taken to correct a problem with the control of temperature within a week after the records are made. As discussed in section X.G.5.e, the purpose of the review of records would be to ensure that the records are complete, that the temperatures recorded were adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public animal or human significance in an unexposed refrigerated packaged TCS animal food, and that appropriate actions were taken to correct any problem with the control of temperature for any unexposed refrigerated packaged TCS animal food. A weekly review of monitoring and corrective action records would provide for timely feedback of information and limit the amount of product impacted by any problems identified during the review of the records. Proposed § 507.48(a)(4)(iii) is analogous to proposed § 507.45(c)(1)(i) in subpart C, which would establish a verification requirement for review of records of monitoring and corrective action records within a week after the records are made.

Proposed § 507.48(a)(4) is modified relative to the analogous proposed verification requirements in proposed § 507.45 in that proposed § 507.48(a)(4) would not require validation or reanalysis. There is a single control to verify, which limits the need for many of the verification procedures that might otherwise apply. As noted above, the temperatures to control growth of microbial pathogens are well documented and do not require validation that they are effective in controlling the potential for microorganisms of animal or human health significance to grow, or produce toxin, in animal food The reasons for not requiring reanalysis were discussed previously in this section. Proposed § 507.48(a)(4) is also modified relative to the analogous proposed verification requirements in proposed § 507.45 in that proposed § 507.48(a)(4) would not require that a qualified individual perform or oversee the review of records of calibration or records of monitoring and actions taken to correct a problem with the control of temperature. The nature of these records does not require the qualifications that would be required under proposed § 507.50(b).

Proposed § 507.48(a)(5) would require that the owner, operator, or agent in charge of a facility solely engaged in storage of unexposed packaged animal food establish and maintain records documenting the monitoring of temperature controls for any unexposed refrigerated packaged TCS animal food (proposed § 507.48(a)(5)(i)); records of corrective actions taken when there is a problem with the control of temperature for any unexposed refrigerated packaged TCS animal food (proposed § 507.48(a)(5)(ii)); and records documenting verification activities (proposed § 507.48(a)(5)(iii)). The records that document monitoring would be used to verify that the temperature controls are effectively and significantly minimizing or preventing the growth of, or toxin production by, microorganisms of animal or human health significance. The records that document corrective actions would be used to verify that appropriate decisions about corrective actions are being made and appropriate corrective actions are being taken. The records that document verification activities would be used to document that this key element of a food safety plan has been implemented. These records would be necessary to demonstrate compliance with the requirements and as such would be useful to inspectors and auditors. Proposed § 507.48 (a)(5) is analogous to provisions in proposed §§ 507.36(d)(2)(iv), 507.39(c), and 507.45(e) in subpart C, which would require documentation of monitoring, corrective actions, and verification activities, respectively.

Proposed § 507.48(b) would establish that the records that a facility must establish and maintain under proposed § 507.48(a)(5) are subject to the requirements of proposed subpart F. Proposed subpart F would establish requirements that would apply to all records that would be required under part 507. FDA describes the requirements of proposed subpart F in section XII. Proposed § 507.48(b) is analogous to proposed § 507.55(b) in subpart C.

I. Proposed § 507.50—Requirements Applicable to a Qualified Individual

Proposed § 507.50(a) would require that one or more qualified individuals prepare the food safety plan (proposed § 507.30), validate the preventive controls (proposed § 507.45(a)), review records for implementation and effectiveness of preventive controls (proposed § 507.45(c)), and perform reanalysis of the food safety plan (proposed § 507.45(e)). The Agency has discussed the basis for requiring that a trained individual perform or oversee these functions in its discussion of each applicable proposed provision. The Agency is listing the functions that must be performed by a trained individual in § 507.50(a) for simplicity and are not imposing any additional requirement through this list. A single individual with appropriate qualifications could perform all of the listed functions, but there would be no requirement for the same individual to perform all the listed functions.

Proposed § 507.50(b) would establish the qualification requirements applicable to a qualified individual. To be qualified, an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. Training or job experience is essential to the effective development and implementation of a hazard analysis and risk-based preventive controls. Only a trained individual or individual qualified by job experience is capable of effectively executing certain activities, such as identifying hazards that are reasonably likely to occur; identifying preventive controls that will address those hazards; evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the hazards that are reasonably likely to occur; determining the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur; determining whether monitoring procedures and corrective action procedures are appropriate; and determining whether specific corrective actions have been appropriate and effective. In addition, the products produced by the animal food industry are diverse, and the hazards that are

reasonably likely to occur in a particular facility depend on a range of factors that vary from one facility to the next. The Agency requests comment on the scope of the qualifications identified.

FDA will be working with an animal food alliance to develop a standardized curriculum for any final rule establishing requirements for hazard analysis and risk-based preventive controls. Having a standardized curriculum on which facilities, as well as private organizations and academia that conduct training, can base their materials and training would provide a framework to ensure minimum training requirements are met.

Proposed § 507.50(b) also would provide that the qualified individual may be, but is not required to be, an employee of the facility. FDA expects that some facilities may rely on assistance from qualified individuals that are not employees of the facility, such as individuals associated with universities, trade associations, and consulting companies. Proposed § 507.50(b) is consistent with HACCP regulations for seafood and juice, which have virtually identical requirements (§§ 123.10 and 120.13(b), respectively). The option in proposed § 507.50(b) would provide flexibility to facilities subject to the rule. Such flexibility may be particularly important for those facilities that have limited technical expertise.

Proposed § 507.50(c) would require that all applicable training be documented in records, including the date of the training, the type of training, and the person(s) trained. Such records would be a simple mechanism to demonstrate that a person has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, as would be required under proposed § 507.50(b) should the qualified individual not be otherwise qualified through job experience to develop and apply an animal food safety system.

J. Proposed § 507.55—Records Required for Subpart C

1. Requirements of Section 418 of the FD&C Act

Section 418(g) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

Section 418(h) of the FD&C Act, in relevant part, specifies that the owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act, including analyzing the hazards under section 418(b) of the FD&C Act and identifying the preventive controls adopted under section 418(c) of the FD&C Act to address those hazards. Section 418(h) of the FD&C Act also specifies that the written plan, together with the documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

2. Proposed § 507.5—Records Required for Subpart C

Proposed § 507.55(a)(1) through (a)(5) would require that the owner, operator, or agent in charge of a facility establish and maintain the following records:

- The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;
- Records that document the monitoring of preventive controls;
- Records that document corrective actions;
- Records that document verification, including, as applicable, those related to validation; monitoring; corrective actions; calibration of process monitoring and verification instruments; records review; and reanalysis; and
- Records that document applicable training for the qualified individual.

Proposed § 507.55(a) would not establish any new requirements, but merely make it obvious at a glance what records are required under proposed part 507, subpart C.

Proposed § 507.55(b) would provide that the records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of proposed part 507, subpart F. As discussed in section XII, proposed subpart F would provide the general requirements that apply to all records required to be established and maintained by proposed part 507, including provisions for retention of records and for making records available for official review.

K. Request for Comment on Additional Preventive Controls and Verification Procedures Not Being Proposed

1. Overview

As discussed in section II.C.2, section 418(n) requires FDA to establish science-based minimum standards for, among other things, implementing preventive controls. In addition, section 418(f) requires certain verification of those preventive controls. In this section of the preamble, the Agency discusses several preventive controls (i.e., supplier controls) and verification measures (i.e., environmental and product testing programs) that FDA is not including as provisions in proposed part 507, subpart C.

As the Agency discussed in section X.C.1, section 418(c) requires the owner, operator, or agent in charge of a facility to identify and implement preventive controls. Section 418(o)(3) defines ''preventive controls'' to mean ''those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding . . . .'' Section 418(o)(3) indicates that those procedures, practices, and processes may include environmental monitoring, supplier verification activities, and certain sanitation controls. In addition, environmental and product testing programs are set out in section 418(f)(4): Section 418(f)(4) requires that the owner, operator, or agent in charge of a facility ''verify that . . . the preventive controls . . . are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.''

The Agency believes that the preventive controls and verification measures discussed in this section are an important part of a modern animal food safety system. The Agency believes that the preventive controls discussed in this section (i.e., a supplier approval and verification program), when implemented appropriately in particular facilities, are ''risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food

would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding . . . .'' The verification procedures discussed in this section (i.e., environmental and product testing programs), when implemented appropriately in particular facilities, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. The use of and need for these preventive controls and verification measures, which are science-based, are widespread and commonly accepted in many sectors of the food industry. The Agency requests comment on these conclusions.

As discussed (see section I of this document), animal food safety is best assured if each facility understands the hazards that are reasonably likely to occur in its particular product and operation and puts in place scientifically sound preventive controls to significantly minimize or eliminate those hazards. From a regulatory perspective, specifying the circumstances and manner in which these controls and practices are to be applied must take into account the wide array of factors, including the diversity among animal food products, the wide variety of manufacturing and processing methods used to produce the animal food, the variety of sources for raw materials and ingredients, variations in the nature and types of hazards associated with manufacturing, processing, packing, and holding animal food, and the possibility that different mitigation methods may achieve the same end. Further, regulatory requirements should make clear when one of these preventive controls or verification measures is necessary yet also be sufficiently flexible to account for a vast number of animal food and facility combinations and circumstances.

Although the Agency is not including provisions for environmental and product testing programs or a supplier approval and verification program in this proposed rule, the Agency recognizes that these preventive controls and verification measures, when implemented appropriately in particular facilities, can play important roles in effective animal food safety programs. The role and need for these measures varies depending on the type of products and activities of the facility. To facilitate comment and share the Agency's current thinking, the Agency discusses the topics of environmental and product testing programs and a supplier approval and verification program immediately below. See the Appendix to this document for additional background information relevant to these topics.

2. Product Testing

As discussed in section X.G.1, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that ''the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means'' The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to establish a product testing program.

Although finished product testing is rarely considered a preventive control, it plays a very important role as a verification measure in ensuring the safety of animal food, when implemented appropriately in particular facilities. Similarly, testing of raw materials or ingredients by a facility that is receiving the product often plays an important role in verification of hazard control that is performed by its supplier. Thus, an important purpose of testing is to verify that preventive controls, including those related to suppliers and those related to environmental monitoring, are controlling the hazard (Refs. 31 and 32). Testing is used in conjunction with other verification measures in the animal food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan.

Finished product testing is more important and useful when there is a reasonable probability that exposure to an identified hazard will result in serious adverse health consequences or death to humans or animals. FDA believes that there are certain situations in which finished product testing is particularly useful as a verification measure, including the following circumstances:

- The outcome of the hazard analysis conducted under proposed § 507.33 is that a biological hazard is reasonably likely to occur in an ingredient and the preventive controls established and implemented under proposed § 507.36 do not include a process control that will significantly minimize the hazard. An example is a dry blending operation that mixes a variety of ingredients such as seeds, nuts that may be contaminated with *Salmonella* spp., dried fruit, and algae meal to make bird food.
- The outcome of the hazard analysis conducted under proposed § 507.33 is that a biological hazard is reasonably likely to occur in an ingredient that is added during manufacturing after the stage that applies a process control to significantly minimize biological hazards. An example is pet food (such as dry pet food and pet treats) in which untreated flavorings that may contain *Salmonella* spp. are applied after the pet food has undergone a heat treatment.
- The outcome of the hazard analysis conducted under proposed § 507.33 is that a biological hazard is reasonably likely to occur as a result of handling of a product or exposure of a product to the environment after a process control that significantly minimizes a hazard such that a hazard could be introduced or re-introduced into the product. An example is the manufacture of pet treats, such as pig ears, that after heat treating become contaminated with *Salmonella* spp. from the processing environment.

In addition, the frequency of testing and the number of samples tested must be determined and needs to take into account a variety of hazard/commodity/facility considerations. FDA believes that factors to consider include whether ingredients that may contain a hazard have been tested, the extent of any environmental monitoring program, and whether other programs established by the facility provide added assurance that the potential for hazards has been minimized. The frequency of testing and the number of samples tested should have a scientific basis. Sampling plans and their performance have been described in the literature (Refs. 89, 90, and 91) and are included in several Codex documents (Refs. 92 and 93). The Agency discusses likely considerations that could impact finished product verification testing in more detail in section I.F of the Appendix.

Although the Agency is not including a testing provision in this proposed rule, the Agency estimates that a requirement for a finished product testing program, when implemented appropriately in particular facilities, could impose an incremental annual cost of $15,000–$28,000 per facility based on size

(number of employees) that adopts a testing and holding regime. This would result in an estimated aggregate cost of $2.88 million, of which about 73 percent would be for domestic facilities. The facilities that would adopt a testing and holding regime are facilities producing products for which finished product testing would be particularly useful as a verification measure, e.g., the production process does not have a step that will eliminate or reduce hazards to an acceptable level. This estimate excludes facilities that would be exempt under this proposed rule (using a definition of $500,000 for a very small business) and facilities that are already conducting finished product testing. Further details are provided in the ''Analysis of Alternatives'' section of FDA's Preliminary Regulatory Impact Analysis (PRIA) (Ref. 52).

FDA requests comment on when and how product testing programs are an appropriate means of implementing the statutory directives set out above. Although the Agency has not included these provisions in the proposed rule, the Agency requests comment on their inclusion in a final rule. Should a product testing program be limited to finished product testing or include raw material testing? What is the appropriate level of specificity for a product testing program? For example, should the Agency simply require that the owner, operator, or agent in charge conduct, as appropriate to the facility and the animal food, finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur? This would provide flexibility to account for the wide diversity of animal food and animal food manufacturing, processing, packing, and holding systems subject to this rule and be consistent with the discussions within this proposed rule.

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying particular hazards, situations or product types for which finished product testing would be required;
- Specifying the frequency of testing and, if so, whether this frequency should depend on the type of product;
- Identifying appropriate sampling plans for finished product testing;
- Requiring periodic testing for trend analysis and statistical process control; and
- Requiring written procedures for conducting finished product testing and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency.

FDA also requests comment on the impact of product testing requirements on small businesses and on whether any product testing verification requirements should differ based on the size of the operation.

3. Environmental Monitoring

As discussed in section X.G.1 of this document, section 418(f)(4) of the FD&C Act states that the owner, operator, or agent in charge of a facility shall verify that ''the preventive controls implemented under [section 418(c) of the FD&C Act] are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.'' In addition, section 418(o)(3) indicates that preventive controls may include environmental monitoring to verify the effectiveness of pathogen controls is an example of preventive controls. The statute does not indicate the specific circumstances where environmental testing would be required or the specific manner in which such testing should be performed. Nevertheless, FDA believes that this testing can form an important component of a modern animal food safety system. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, is particularly useful as a verification measure for preventive controls (i.e., sanitation controls) when contamination of animal food with an environmental pathogen is a hazard reasonably likely to occur.

As discussed in section X.B.3, proposed § 507.33(b) would require a hazard identification that must consider hazards that may occur naturally or may be unintentionally introduced. The data from recalls and the RFR support a conclusion that *Salmonella* spp. is a hazard in animal pet treats and pet food products. When certain animal food, such as dry pet food, is exposed to the environment prior to packaging, FDA believes that most facilities producing such animal foods would identify *Salmonella* spp. as a known or reasonably foreseeable hazard under proposed § 507.33(b). A robust environmental monitoring program for *Salmonella* spp. can verify the effectiveness of sanitation controls designed to prevent *Salmonella* spp. from contaminating animal food-contact surfaces and animal food (Ref. 94).

As discussed in section I.E.2 of the Appendix to this document, the Agency is also aware that listeriosis occurs in a number of animal species, especially ruminant animals, and is asking for comment on whether *L. monocytogenes* is an environmental pathogen of concern for animal food facilities. FDA's current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes,* because tests for *Listeria* spp. will detect multiple species of *Listeria,* including *L. monocytogenes.* However, FDA's current thinking is that there are no currently available indicator organisms for *Salmonella* spp. The Agency requests comment on these findings and conclusions.

Although the Agency is not including an environmental testing provision in this proposed rule, the Agency estimates that an environmental monitoring program for *Salmonella* spp., when implemented appropriately in certain animal food facilities, could impose an annual cost of about $3,500 per facility. These costs assume that facilities will collect approximately 15 environmental samples per month, based on facility size. FDA used the sampling time, testing time, and capital cost to estimate a cost of $19.20 per sample tested using a quick time test that is performed at the facility. FDA estimates that about 261 facilities (including foreign facilities) would be subject to this requirement. FDA used the current compliance estimates from the human foods manufacturer survey to estimate the total that would need to begin environmental monitoring would be about 184. This would result in estimated total annual testing costs of about $636,000.

The facilities that could adopt environmental monitoring programs are facilities producing animal food products, such as dry pet food, exposed to the environment prior to packaging, whereby they may become contaminated and for which such testing would be particularly useful as a verification measure for sanitation controls.

FDA requests comment on when and how environmental testing is an appropriate means of implementing the statutory directives set out above. Although the Agency has not included these provisions in the proposed rule, the Agency requests comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? For example, should the Agency simply require the performance of environmental monitoring, for an

appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of animal food with an environmental pathogen is a hazard reasonably likely to occur? FDA also requests comment on whether more detail would be appropriate, by, for example:

- Specifying the environmental pathogen or the indicator organism for which the samples must be tested;
- Specifying the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen, such as;
- Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
- Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
- Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated; and
- Conducting finished product testing.
- Specifying the locations within the facility at which samples must be collected;
- Specifying the frequency of collection of environmental samples (e.g., weekly or monthly depending on risk). For example, should the frequency of collection:
- Be greatest for animal foods that are likely to be handled by certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems after a minimal treatment that may not adequately reduce the environmental pathogen?
- Be greater for an environmental pathogen that is frequently introduced into a facility (e.g., *Salmonella* spp., which is ubiquitous in the environment and can be continually introduced into a facility from many routes, including ingredients, people and objects (Ref. 94)) than for an environmental pathogen that is less frequently introduced?
- Be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment?
- Increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction? (Refs. 94 and 95).
- Requiring written procedures for conducting environmental testing and, if so, also requiring that procedures for environmental testing be scientifically valid and include the procedures for sampling and the sampling frequency;
- Requiring data analysis to detect trends.

The Agency further requests comment on whether there is benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.

4. Supplier Approval and Verification Program

Section 418(c) of the FD&C Act specifies, in relevant part, that the owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that:

- Hazards identified in the hazard analysis conducted under section 418(b)(1) of the FD&C Act will be significantly minimized or prevented; and
- The animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the FD&C Act.

Section 418(o)(3)(G) of the FD&C Act indicates that the procedures, practices, and processes described in the definition of preventive controls may include supplier verification activities that relate to the safety of food. While FSMA refers only to supplier verification activities, supplier approval, together with supplier verification, is widely accepted in the domestic and international food safety community. The development of a supplier approval and verification program can be part of a preventive approach. The NACMCF HACCP guidelines describe supplier controls as one of the common prerequisite programs for the safe production of food products and recommend that each facility assure that its suppliers have in place effective CGMP and food safety programs (Ref. 29). Likewise, Codex addresses the safety of ingredients in the General Principles of Food Hygiene and recommends that, where appropriate, specifications for raw materials be identified and applied and laboratory tests be conducted to establish fitness for use (Ref. 34).

Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. Using a preventive approach, a facility receiving raw materials or ingredients from a supplier can help ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program can help ensure that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place to address the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program can help provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

The statute does not indicate the specific circumstances where supplier verification would be required or the specific manner in which supplier verification should be performed, and FDA is not including provisions for such verification in this proposed rule. FDA believes that the role and need for these measures varies depending on the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to determine the specific circumstances and manner where it would be appropriate to perform supplier verification. FDA believes that factors to consider include:

- The nature of the adverse consequences associated with the hazard, such as whether consumption or handling of animal food containing the hazard may result in serious adverse health consequences or death to humans or animals; and
- The establishment that would be controlling the hazard associated with the raw material or ingredient (e.g., the facility that receives the raw material or ingredient, the supplier of that raw material or ingredient, or even a supplier to the supplier of the raw material or ingredient).

The vast majority of costs related to a supplier approval and verification program are due to verification activities such as audits and testing of raw materials and ingredients, which would likely be selected based on the hazard associated with the raw material or ingredient and where the hazard is controlled. Although the Agency is not including a provision for such a program in this proposed rule, the Agency estimates that a requirement for a supplier approval and verification program, if implemented as part of a

preventive approach, could impose an incremental annual cost of $3,300–$4,400 per supplier facility based on size (number of employees) that undergoes an annual audit. This would result in an estimated aggregate cost of $218,000 for domestic facilities and an estimated aggregate cost of $82,000 for foreign facilities. Further details are provided in the ''Analysis of Alternatives'' section of the PRIA (Ref. 52).

FDA requests comment on when and how supplier approval and verification is an appropriate means of implementing the statutory directives set out previously. Although the Agency has not included these provisions in the proposed rule, the Agency requests comment on their inclusion in a final rule. If they are included, what is the appropriate level of specificity? Should the requirement be very general, for example, requiring a supplier approval and verification program as appropriate to the facility and the animal food, when appropriate based on risk? FDA also requests comment on who a supplier approval and verification program should apply to, e.g., should it apply to all facilities that manufacture, process, pack, or hold animal food, or be limited (such as to facilities that manufacture or process animal food)?

FDA also requests comment on whether more detail would be appropriate, by, for example:

- Requiring that the supplier approval and verification program include a written list of approved suppliers;
- Requiring that, in determining appropriate verification activities, the owner, operator, or agent in charge of a facility consider relevant regulatory information regarding the supplier, including whether the raw material or ingredient is the subject of an FDA warning letter or import alert relating to the safety of the animal food.
- Specifying circumstances when a supplier approval and verification program would not be required, e.g., when the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur; or when the receiving facility obtains from its customer written assurance that the customer has established and is following procedures that will significantly minimize or prevent the hazard.
- Specifying that the type of verification activity be linked to the seriousness of the hazard, e.g., whether to:
- Require an onsite audit when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals;
- Provide more flexibility with respect to hazards for which there is not a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, e.g., periodic onsite audits, periodic or lot-by-lot sampling and testing of the raw material or ingredient, and periodic review of the supplier's animal food safety records;
- Specifying requirements for audits, e.g., the qualifications (including training, experience, and conflict of interest) for persons who conduct audits; content of an audit (such as compliance with applicable animal food safety regulations and, when applicable, compliance with a facility's food safety plan);
- Specifying the frequency of verification activities (e.g., initially, annually, or periodically);
- Specifying whether, for some hazards, it will be necessary to conduct more than one verification activity to provide adequate assurances that the hazard is significantly minimized or prevented;
- Providing for alternative requirements if a supplier is a qualified facility, e.g., documenting that the supplier is a qualified facility and obtaining written assurance that the supplier is producing the raw material or ingredient in compliance with sections 402 of the FD&C Act;
- Specifying those records that would be appropriate for a supplier approval and verification program;
- Providing for substitution of a regulatory inspection (e.g., by FDA or a comparable State regulatory agency or foreign animal food safety authority), for an onsite audit; and
- Specifying that a receiving facility take appropriate action (e.g., discontinuing use of a supplier) if the facility determines that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur.

FDA is aware that many firms that could be affected by supplier verification may be importing their ingredients. The Agency believes that these firms are interested in how a supplier verification component of preventive controls will interface with the regulations FDA is required to implement foreign supplier verification under new section 805 of the FD&C Act (21 U.S.C. 384a). Section 805 requires FDA to issue regulations to require importers to implement foreign supplier verification programs (FSVPs) that are adequate to provide assurances that the importer's foreign suppliers produce food, including animal food, in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of animal and human health protection as those required under section 418 (concerning hazard analysis and preventive controls) of the FD&C Act, and in compliance with section 402 (concerning adulteration) of the FD&C Act.

On July 29, 2013, FDA published in the **Federal Register** proposed regulations implementing section 805 (78 FR 45730). FDA intends to align regulations implementing supplier verification under section 418 and regulations implementing FSVP under section 805 to the fullest extent so the Agency does not impose duplicative or unjustified requirements under those two regulations. For example, if a facility imports ingredients, the Agency would not want to subject it to duplicative requirements under a supplier verification provision and an FSVP regulation.

Likewise, FDA is aware that there is great interest from its trading partners on, among other things, the potential overlap between the supplier verification requirements in preventive controls and in FSVP. FDA believes that the approach to harmonization between supplier verification and FSVP described above would adequately address this and comports with its obligations under the World Trade Organization trade agreements, including adherence to the principles of the Sanitary and Phytosanitary (SPS) Agreement.

FDA is committed to meeting the requirements of the SPS Agreement and to complying with its obligations under that Agreement as the Agency implements FSMA. In enacting FSMA, Congress explicitly recognized the importance of compliance with international agreements by providing in section 404 of FSMA that ''[n]othing in [FSMA] shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.'' While the statutory provisions in FSMA governing supplier verification by domestic facilities and foreign supplier verification by importers differ in some respects, they are based on common risk-based principles. Implementation of these risk-based principles will assure a general consistency of approach with respect to foreign and domestic facilities

regarding, for example, when on-site audits are required. Implementation of FSMA's risk-based principles will also ensure that measures applicable to imports are not more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection of the United States, taking into account technical and economic feasibility, as required by paragraph 6 of Article 5 of the SPS Agreement. The Agency invites comments to assist it in issuing final rules that protect animal and human health and satisfy both FSMA and FDA's international obligations.

L. Request for Comment on Other Potential Provisions Not Explicitly Included in Section 418 of the FD&C Act

1. Overview

This section discusses two measures (review of consumer, customer, and other complaints, and submission of a food safety profile) that FDA is not proposing as specific provisions in proposed part 507, subpart C. Although these measures are not explicitly included in section 418, the Agency believes that the preventive controls and verification measures discussed in this section are an important part of a modern food safety system.

2. Complaints

The role of consumer complaints in evaluating the effectiveness of a food safety plan is reflected in the HACCP regulations for seafood and juice. The HACCP regulation for seafood (§ 123.8(a)(2)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points. The HACCP regulation for juice (§ 120.11(a)(1)(i)) requires that verification activities include a review of any consumer complaints that have been received by the processor to determine whether the complaints relate to the performance of the HACCP plan or reveal the existence of unidentified critical control points. FDA notes that the role of consumer complaints is not discussed in the NACMCF guidelines or the Codex guidelines, and their review is not required by the FSIS HACCP regulation for meat and poultry. However, as discussed in the seafood HACCP proposed rule (59 FR 4142 at 4157, January 28, 1994), no system is foolproof, and consumer complaints may be the first alert for a processor that deviations are occurring and are not being prevented or uncovered by the processor's HACCP controls.

Further, although most consumer complaints will be related to quality issues, recent experience has demonstrated the value that consumer and customer complaints can provide in bringing attention to possible problems within a facility's preventive controls activities. FDA has received a number of animal food submissions to the RFR (Ref. 48) that have suggested that environmental pathogens hazards were not adequately addressed in a supplier's food safety plan. Some of these were identified through customer verification testing and others through complaints from consumers to a facility. A facility may also receive alerts as a result of state surveillance and testing programs.

Although this proposed rule does not include a provision regarding a review of complaints, the Agency estimates that a requirement that facility personnel review consumer, customer, or other complaints could impose an additional annual cost of $2,800 per facility. This would result in an estimated total annual cost of $1,767,000 for domestic facilities.

The Agency requests comment on whether and how a facility's review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards.

3. Submission of a Facility Profile to FDA

Proposed § 507.30 would require that the owner, operator, or agent in charge of a facility prepare, or have prepared, a written food safety plan. The food safety plan would include the hazard analysis, preventive controls, and other records. Currently, information of this type is not reviewed by FDA investigators until they are physically present at a facility and have begun an inspection. In light of the large number of facilities that would be covered by this proposal, FDA recognizes several potential benefits to having a facility's food safety plan in advance of an inspection, if the Agency were to require facilities to do so. Having such plans could aid in the efficient oversight of preventive controls by allowing FDA to better target inspectional activities to facilities that produce animal foods that have an increased potential for contamination (particularly with biological hazards) and to improve on-site inspections by focusing attention on hazards and preventive controls for which the facility appears to have deficiencies. Facilities would benefit from the Agency's advance preparation through interaction with better-informed investigators and potentially reduced inspection time. The Agency could also more quickly identify facilities that had not established preventive controls for specific hazards of concern to the Agency and advise them to fill such gaps to prevent a problem before it occurs. Also, FDA could use the plans in evaluating the need for guidance on specific hazards or controls and prioritizing guidance to areas where it is needed most.

FDA believes that there are significant obstacles to realizing these benefits from submission of food safety plans, however. The agency would expect to receive a very large number of plans. Further, these plans would be expected to vary significantly in content and format. Assimilating the underlying information in a way that would be useful to the Agency would be an immense challenge. Moreover, not all of the information in such plans may be essential to realizing the potential benefits described above. Therefore, to most efficiently realize the potential benefits of having certain information prior to an inspection, the Agency requests comment on whether to require submission to FDA of a subset of the information that would be in a food safety plan. This information, which could be referred to as a ''facility profile,'' could be submitted through an electronic form using a menu selection approach. The use of an electronic form would enhance the Agency's ability to store the information in a searchable form. Ideally, a searchable electronic system could allow FDA to assess information when a problem occurs with certain types of foods or controls, so that the Agency could target inspections to facilities that manufacture, process, or pack, animal food types that are at increased risk for a food safety problem; to facilities that appear to have insufficient controls to prevent a problem; or to facilities using a control the Agency concludes is ineffective at controlling hazards. The data elements for a facility profile could include some or all of the following:

- Contact information;
- Facility type;
- Products;
- Hazards identified for each product;
- Preventive controls established for each of the identified hazards;
- Third-party audit information (have you had one and which audit firm(s));
- Preventive control employee training conducted;
- Facility size (square footage);
- Full time operation or seasonal;
- Operations schedule.

This information could be submitted at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration. FDA requests comment on the utility and necessity of such an approach and on the specific types of information that would be useful in developing a facility profile. The Agency also requests comment on any additional benefits that might be obtained from using such an approach and any potential concerns with this approach.

The Agency has previously announced an opportunity for public comment on the proposed collection of additional food facility profile information on a voluntary basis from firms that complete the FDA food facility registration process (77 FR 27779, May 11, 2012). In that notice, the Agency noted that FSMA added section 421 of the FD&C Act (21 U.S.C. 350j), which directed FDA to allocate resources to inspect facilities according to the known safety risks of the facilities. The Agency also noted that food facility profile information voluntarily provided to FDA would help FDA to determine whether a firm is high-risk or non-high-risk and that the Agency will use the profile information to assist in determining the frequency at which it will inspect the firm. In contrast to the voluntary submission of food facility profile information described in that notice, in this document, the Agency is also requesting comment on whether the submission of such information should be required.

XI. Proposed Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

A. Requirements of Section 418 of the FD&C Act

Section 418(l)(3)(A) of the FD&C Act specifies that, in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under section 418(l) of the FD&C Act, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under section 418(l) of the FD&C Act. Section 418 does not expressly prescribe the procedures for withdrawing an exemption provided to a qualified facility under section 418(l). The Agency tentatively concludes that it is appropriate to be transparent about the process it would use to withdraw an exemption and that the Agency should include the process in the proposed rule.

B. Proposed § 507.60—Circumstances That May Lead FDA To Withdraw an Exemption Applicable to a Qualified Facility

1. Proposed § 507.60(a)—Withdrawal of an Exemption in the Event of an Active Investigation of a Foodborne Illness Outbreak

Proposed § 507.60(a) would provide that FDA may withdraw the exemption that would be applicable to a qualified facility under proposed § 507.5(c) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility. Proposed § 507.60(a) would implement the statutory language of section 418(l)(3)(A) of the FD&C Act. An outbreak of foodborne illness is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food (or exposure to a common food in the case of microbiological illness in humans from handling animal food.) Animal food can become contaminated at many different steps: On the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; and at the location of the animal. When foodborne illness is associated with food, a traceback investigation may enable FDA to directly link the illness to the facility or facilities that manufactured, processed, packed, and/or held the animal food. See section XIV.B.1 of the document for the proposed rule for preventive controls for human food (78 FR 3646) for a discussion of an FDA traceback investigation.

2. Proposed § 507.60(b)—Withdrawal of an Exemption Based on Conduct or Conditions Associated With a Qualified Facility

Proposed § 507.60(b) would provide that FDA may withdraw the exemption applicable to a qualified facility under proposed § 507.5(c) if FDA determines that it is necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility. As an example, FDA may receive reports to the RFR under section 417 of the FD&C Act about contamination of an animal food, and the reports may lead the Agency to investigate a qualified facility that manufactured, processed, packed or held the animal food. If the investigation finds conduct or conditions associated with the facility that are material to the safety of the animal food (for example, conduct or conditions that likely led to the contamination of the animal food), FDA would consider withdrawing the exemption applicable to the facility under proposed § 507.5(c) if doing so would be necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak. Likewise, if during a routine inspection of a qualified facility, FDA discovers conditions and practices that are likely to lead to contamination of animal food with microorganisms of animal or human health significance, such as *Salmonella,* the Agency would consider withdrawing the exemption provided to the facility under proposed § 507.5(c) if doing so would be necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak.

C. Proposed § 507.62—Issuance of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.62(a) would provide that, if FDA determines that an exemption applicable to a qualified facility under § 507.5(c) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption. The Agency intends to create and maintain a written record of a determination that the withdrawal of an exemption is warranted and to include the basis for the determination in the written record.

Proposed § 507.62(b) would require that an FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to such Director, must approve an order to withdraw the exemption as part of the withdrawal determination procedure before the order is issued. A Regional Food and Drug Director is an example of an FDA official senior to a District Director. The Deputy Director and Director of the Office of Surveillance and Compliance at the Center for Veterinary Medicine are examples of an FDA official senior to the Director of the Division of Compliance. Requiring prior approval of a withdrawal order by a District Director or an FDA official senior to a District Director is consistent with the approval requirement for a detention order in part 1, subpart K

(Administrative Detention of Food for Human or Animal Consumption). Requiring prior approval of a withdrawal order by the Director of the Division of Compliance in the Center for Veterinary Medicine is consistent with current FDA practices when dealing with foreign firms.

Proposed § 507.62(c) would require that FDA issue an order to withdraw the exemption to the owner, operator, or agent in charge of the qualified facility. The requirements of section 418 of the FD&C Act are directed to the owner, operator, or agent in charge of a facility. The Agency tentatively concludes that the statutory language of section 418 enables FDA to issue an exemption withdrawal order to any of these persons.

Proposed § 507.62(d) would require that FDA issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

D. Proposed 507.65—Contents of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.65(a) through (i) would require that an order to withdraw an exemption applicable to a qualified facility under § 507.5(c) include the following information:

- The date of the order (proposed § 507.65(a));
- The name, address, and location of the qualified facility (proposed § 507.65(b));
- A brief, general statement of the reasons for the order, including information relevant to:
  - An active investigation of a foodborne illness outbreak that is directly linked to the facility; or
  - Conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility (proposed § 507.65(c)).
- A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order (proposed § 507.65(d));
- The text of section 418(l) of the FD&C Act and of this subpart D (proposed § 507.65(e));
- A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter (21 CFR part 16), with certain exceptions described in proposed § 507.73 (proposed § 507.65(f));
- The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); (proposed § 507.65(g)); and
- The name and the title of the FDA representative who approved the order (proposed § 507.65(h)).

FDA tentatively concludes that the requirements that it proposes in § 507.65 would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal with adequate notice of the basis for the Agency's determination to withdraw the exemption and of their opportunity to appeal the Agency's determination and to request an informal hearing. The proposed notification procedures are similar to and consistent with the notification requirements in other regulations involving administrative action, such as administrative detention of food under § 1.393 orders for diversion or destruction of shell eggs under the PHS Act under § 118.12(a)(i), and with procedures for an informal hearing in part 16.

E. Proposed § 507.67—Compliance With, or Appeal of, an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.67(a) would require that the owner, operator, or agent in charge of a qualified facility that receives an order to withdraw an exemption applicable to that facility under § 507.5(c) either comply with applicable requirements of this part within 60 calendar days of the date of the order; or appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 507.69. The Agency tentatively concludes that either of the two circumstances that could result in the determination that an exemption should be withdrawn (as described in proposed § 507.60) warrant prompt compliance with the rule in the interest of animal or human health. The Agency tentatively concludes that 10 calendar days for the submission of an appeal from the date of the receipt of a withdrawal order is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that comes to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.67(b) would establish that submission of an appeal, including submission of a request for an informal hearing, will not delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest. For example, the submission of an appeal of a withdrawal order with a request for an informal hearing under proposed § 507.67(b) would not prevent FDA from simultaneously detaining animal food from the facility under section 304(h) of the FD&C Act, seizing animal food from the facility under section 304(a) of the FD&C Act, or seeking or enforcing an injunction under section 302 of the FD&C Act.

Proposed § 507.67(c) would require that, if the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order. Proposed § 507.67(c) would make clear that the 60 calendar day timeframe for compliance applies regardless of whether the owner, operator, or agent in charge of a facility requests, and FDA grants, a hearing. As already discussed, FDA tentatively concludes that the circumstances that lead to a determination that an exemption should be withdrawn warrant prompt compliance in the interest of animal or human health.

F. Proposed § 507.69—Procedure for Submitting an Appeal

Proposed § 507.69(a) would require that, to appeal an order to withdraw an exemption applicable to a qualified facility under § 507.5(c), the owner, operator, or agent in charge of the facility must: (1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order and (2) respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies.

Allowing the owner, operator, or agent in charge of the facility to submit an appeal in person, by mail, email, or fax would provide for flexibility as well as speed. For example, submitting in person would give the owner, operator, or agent in charge direct knowledge that

the request for appeal had been delivered and received. Email and fax are instantaneous, and overnight mail delivery services are readily available to those who choose to use them; however, the 10 day timeframe for appeal of the order would not require the use of overnight mail delivery. For clarity, proposed § 507.69(a) would repeat the 10 calendar day timeframe that would be established in proposed § 507.67(a)(2) and would not establish any new requirement. Any appeal would need to be written in order for FDA to evaluate the basis for the appeal. The Agency is proposing that a written appeal would need to address with particularity all of the issues raised in the withdrawal order and include all supporting documentation so that the Agency would be able to issue a final determination as to the disposition of the appeal solely on the basis of the materials submitted as part of the written appeal.

Proposed § 507.69(b) would provide that, in a written appeal of the order withdrawing an exemption provided under § 507.5(c), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 507.71. Requesting an informal hearing does not mean that a hearing will be held, because FDA may deny the request (see discussion of proposed § 507.71(b) in the next section of this document). However, if the owner, operator, or agent in charge of the facility does not request an informal hearing at the time the written appeal is submitted, the owner, operator, or agent in charge of the facility will not be entitled to an informal hearing. Instead, FDA will make a final decision based on the written appeal and its supporting materials.

G. Proposed § 507.71—Procedure for Requesting an Informal Hearing

Proposed § 507.71(a)(1) would provide that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility may request an informal hearing. Proposed § 507.71(a)(1) would restate an option that would be included in proposed § 507.69(b) to highlight the opportunity to request an informal hearing. Proposed § 507.71(a)(2) would require that, if the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility must submit any request for an informal hearing together with its written appeal submitted in accordance with § 507.69 within 10 calendar days of the date of the order. The Agency tentatively concludes that requiring submission of a request for an informal hearing in writing at the time that the owner, operator, or agent in charge of the facility would be required to submit a written appeal is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if FDA denies the appeal.

Proposed § 507.71(b) would establish that a request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. Proposed § 507.71(b) would also provide that if the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial. Under proposed § 507.69(a), a written appeal would be required to respond with particularity to the facts and issues contained in the withdrawal order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies. If the materials submitted do not directly address the facts and issues contained in the withdrawal order in a manner that suggests that there is a dispute regarding the material facts contained in the order, the presiding officer may determine that an informal hearing is not warranted. The presiding officer may include written notice of the determination that a hearing is not justified as part of the final decision on the appeal.

H. Proposed § 507.73—Requirements Applicable to an Informal Hearing

Proposed § 507.73(a) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, the hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA. The Agency tentatively concludes that, if it grants a request for an informal hearing, holding the hearing within 10 calendar days, or within an alternative timeframe as agreed upon in writing, is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.73(b) would establish that the presiding officer may require that a hearing conducted under this subpart E be completed within 1 calendar day, if appropriate. The Agency tentatively concludes that, if it grants a request for an informal hearing, limiting the time for the hearing itself to be completed within 1 calendar day is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order and would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.73(c)(1) through (c)(7) would establish that, if the owner, operator or agent in charge of the facility requests an informal hearing, and FDA grants the request, FDA must conduct the hearing in accordance with part 16, except that:

- The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a), provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.
- A request for a hearing under this subpart D must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.
- Section 507.75, rather than § 16.42(a), describes the FDA employees who preside at hearings under this subpart.
- Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.
- Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding

officer's report of the hearing and any comments on the report by the hearing participant under § 507.73(c)(4) are part of the administrative record.

• No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

• If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under part 16, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 (21 CFR 10.45), the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

Under § 16.1(b), the procedures in part 16 apply when a regulation provides a person with an opportunity for a hearing on a regulatory action under part 16. Section 418 of the FD&C Act does not expressly provide for a hearing if circumstances lead FDA to determine that an exemption provided to a qualified facility under proposed § 507.5(c) should be withdrawn. However, the Agency tentatively concludes as a matter of agency discretion that providing an opportunity for a hearing by regulation in this subpart of the proposed rule would provide appropriate process to the owner, operator, or agent in charge of a qualified facility subject to withdrawal of the facility's exemption. The Agency also tentatively concludes that the modified part 16 procedures contained in this proposed rule would provide the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order sufficient fairness and due process while enabling FDA to expeditiously adjudicate an appeal of a withdrawal order for which an informal hearing has been granted.

Section 16.119 provides that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35. Proposed § 507.73(c)(6) would specify that these procedures for reconsideration and stay would not apply to the process of withdrawing an exemption provided under proposed § 507.5(c). The circumstances that may lead FDA to withdraw an exemption include an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility, or the Agency's determination that it is necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility. Such circumstances require prompt action. Under § 16.120, a qualified facility that disagrees with FDA's decision to withdraw an exemption provided under § 507.5(c) has an opportunity for judicial review in accordance with § 10.45.

I. Proposed § 507.75—Presiding Officer for an Appeal and for an Informal Hearing

Proposed § 507.75 would require that the presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director. Under § 16.42(b), an officer presiding over an informal hearing is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action. An order for the withdrawal of an exemption applicable to a qualified facility must be approved by a District Director or an official senior to a District Director. It is therefore necessary that appeals of a decision to issue a withdrawal order should be handled by persons in positions senior to the District Directors. The Regional Food and Drug Director is such a person and could be from the same region where the facility is located, provided that the Regional Food and Drug Director did not participate in the determination that an exemption should be withdrawn and is otherwise free from bias or prejudice. Alternatively, the Regional Food and Drug Director could be from a different region than the region where the facility is located, for example in the event the Regional Food and Drug Director for the region in which the facility is located is the FDA official who approved the withdrawal order.

J. Proposed § 507.77—Timeframe for Issuing a Decision on an Appeal

Proposed § 507.77(a) would require that, if the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the tenth calendar day after the appeal is filed. Under proposed § 507.60, FDA would issue a withdrawal order either in the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility or if FDA determines that an exemption withdrawal is necessary to protect animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the animal food located at the facility. The Agency tentatively concludes that it will need 10 calendar days to review the written appeal and the materials submitted with the written appeal, and that a final decision confirming or revoking a withdrawal order should be issued as quickly as possible in the interest of the public health and to provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal.

Proposed § 507.77(b)(1) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and, if FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within the 10 calendar day period after the hearing is held. The Agency tentatively concludes that it is appropriate to grant the owner, operator, or agent in charge of a qualified facility subject to a withdrawal order the opportunity to review and submit comments to the presiding officer's report because the report is part of the record of a final agency action (see discussion of proposed § 507.83 in this section of the document) that is not subject to further reconsideration by FDA. The presiding officer would have discretion to determine whether to revise the report of the hearing in light of any comments that might be submitted by any of the hearing participants.

Proposed § 507.77(b)(2) would require that, if the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing and if FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or

revoking the withdrawal within 10 calendar days after the date the appeal is filed. The Agency tentatively concludes that ten calendar days for the presiding officer to issue a final decision is appropriate for purposes of the efficient adjudication of the appeal of a withdrawal order, would provide reasonable due process that would come to closure sufficiently in advance of the effective date of the order to provide an opportunity for the facility to come into compliance if the Agency denies the appeal, and is in the interest of animal or human health.

K. Proposed § 507.80—Revocation of an Order To Withdraw an Exemption Applicable to a Qualified Facility

Proposed § 507.80(a) through (c) would establish that an order to withdraw an exemption applicable to a qualified facility under § 507.5(c) is revoked if:

- The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or
- The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or
- The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

The Agency tentatively concludes that an order to withdraw an exemption may be revoked in one of two manners. First, the Agency is proposing that the FDA officer responsible for adjudicating the appeal and presiding over a hearing, if one is granted, may expressly issue a written decision revoking the order within the specified 10 calendar day timeframes. Second, the Agency is proposing that the failure of the FDA officer responsible for adjudicating an appeal to issue a final decision expressly confirming the order within the specified timeframes will also serve to revoke the order. The Agency tentatively concludes that fairness would warrant the revocation of a withdrawal order if FDA is unable to meet the proposed deadlines for expressly confirming an order.

L. Proposed § 507.84—Final Agency Action

Proposed § 507.84 would establish that confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of section 702 of title 5 of the United States Code (5 U.S.C. 702). A confirmation of an order withdrawing an exemption therefore would be reviewable by the courts under section 702 of title 5 and in accordance with § 10.45.

M. Conforming Amendment to 21 CFR Part 16

The Agency proposes to amend § 16.1(b)(2) to include part 507, subpart D, relating to the withdrawal of an exemption applicable to a qualified facility, to the list of regulatory provisions under which regulatory hearings are available.

XII. Proposed Subpart F—Requirements Applying to Records That Must Be Established and Maintained

A. Relevant Statutory Provisions

FDA is proposing to create a new subpart F to establish requirements applying to records that must be established and maintained according to the requirements of this proposed rule. As discussed in section X.J, section 418 of the FD&C Act prescribes several requirements relevant to recordkeeping. The statutory provisions that are most relevant to proposed subpart F are:

- Section 418(a) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain records of monitoring the performance of preventive controls as a matter of routine practice;
- Section 418(b)(3) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility develop a written analysis of the hazards;
- Section 418(g) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility maintain certain records for not less than 2 years. The records identified in section 418(g) include records documenting the monitoring of the preventive controls implemented under section 418(c) of the FD&C Act, instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under section 418(f)(4) of the FD&C Act, instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions;
- Section 418(h) of the FD&C Act, which requires, in relevant part, that the owner, operator, or agent in charge of a facility prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section and that such written plan, together with documentation described in section 418(g) of the FD&C Act, shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request;
- Section 418(n)(1)(A) of the FD&C Act, which provides, in relevant part, that FDA shall issue regulations to establish science-based minimum standards for documenting hazards and documenting the implementation of the preventive controls under this section;
- Section 402(a)(4) of the FD&C Act, which provides that food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- Section 701(a) of the FD&C Act 21 U.S.C. 371(a), which provides FDA with authority to issue regulations for the efficient enforcement of the FD&C Act;
- Section 361(a) of the Public Health Service Act (42 U.S.C. 264(a)), which provides FDA with authority to make and enforce such regulations as in FDA's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession; and
- Section 418(l)(2)(B) of the FD&C Act, which requires a qualified facility to submit documentation to the Secretary related to its qualified status and also submit either documentation of the facility's implementation and monitoring of preventive controls or documentation of its compliance with other appropriate non-Federal food safety laws.

B. Proposed § 507.100—Records Subject to the Requirements of This Subpart F

Proposed § 507.100(a) would establish that, except as provided by proposed § 507.100(d) and (e), all records required by proposed part 507 would be subject to all requirements of proposed subpart F. FDA tentatively concludes that the requirements in proposed subpart F describing how records must be established and maintained, including the general requirements, record retention requirements, and requirements for official review and public disclosure, are applicable to all records that would be required under all subparts, because records that would be required under each of the subparts aid

plants and facilities in compliance with the requirements of proposed part 507; and allow plants and facilities to show, and FDA to determine, compliance with the requirements of proposed part 507.

Proposed § 507.100(b) would establish that all records required by proposed part 507 are subject to the disclosure requirements under part 20 (21 CFR part 20). FDA's regulations in part 20, the Freedom of Information Act (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), and the FD&C Act, govern FDA's disclosures of information, including treatment of commercial confidential information and trade secret information. The Agency's general policies, procedures, and practices relating to the protection of confidential information received from third parties would apply to information received under this rule.

Proposed § 507.100(c) would require that all records required by part 507 be made promptly available to a duly authorized representative of the Secretary upon oral or written request. Proposed § 507.100(c) implements subsection 418(h) of the FD&C Act and is necessary in order for FDA to determine compliance with the requirements of part 507.

Proposed § 507.100(c) does not explicitly require a facility to send records to the Agency rather than making the records available for review at a facility's place of business. FDA requests comments on whether proposed § 507.100(c) should be modified to explicitly address this circumstance, and if so, whether FDA should require that the records be submitted electronically. Obtaining a facility's food safety plan without going to a facility could be useful to FDA in a number of different circumstances, such as to determine whether a recently identified hazard is being addressed by affected facilities.

Proposed § 507.100(d) would establish that the requirements of proposed § 507.100 apply only to the written food safety plan and is discussed in more detail in section XII.D.

Proposed § 507.100(e) would provide that the requirements of § 507.102(a)(2), (a)(4), and (a)(5) and (b) do not apply to the records required by proposed § 507.7(e) pertaining to qualified facilities. As discussed in section VIII.D, proposed § 507.7(e) would require that a qualified facility maintain records relied upon to support the self-certification that would be required by proposed § 507.7(a). Such documentation would be directed to the financial basis (and, when applicable, percentage of sales to qualified end users) as well as to food safety practices at the qualified facility, and could range from invoices to a food safety plan to an operating license issued by a state or local authority. Such records would not be expected to satisfy the provisions of proposed § 507.102(a)(2), (a)(4), and (a)(5) and (b) (which are discussed in the next section). To make clear that a qualified facility need not comply with provisions that do not apply to its records, the Agency is proposing to specify that those provisions do not apply to such records.

C. Proposed § 507.102—General Requirements Applying to Records

Proposed § 507.102 contains general requirements that would apply to records that would be required under proposed part 507, including the format for required records, the recording of actual values and observations obtained during monitoring, when records must be created, and information that must be included in each record.

1. Proposed § 507.102(a)

Proposed § 507.102(a)(1) would require that the records be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. True copies of records should be of sufficient quality to detect whether the original record was changed or corrected in a manner that obscured the original entry (e.g., through the use of white-out). Proposed § 507.102(a)(1) would provide flexibility for mechanisms for keeping records while maintaining the integrity of the recordkeeping system. The proposed requirement allowing true copies provides options that may be compatible with the way records are currently being kept in plants and facilities.

Proposed § 507.102(a)(1) also would require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by part 507 may be retained electronically, provided that they comply with part 11.

FDA tentatively concludes that it is appropriate to apply the requirements of part 11 to the records that would be required to be kept under proposed part 507. However, the Agency requests comment on whether there are any circumstances that would warrant not applying part 11 to records that would be kept under proposed part 507. For example, would a requirement that electronic records be kept according to part 11 mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which the Agency determined to be the case in the regulation ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (69 FR 71562, December 9, 2004 (the BT records regulation)). For the purposes of the records requirements in the BT records regulation, the Agency concluded that it was not necessary for new recordkeeping systems to be established as long as current practices would satisfy the requirements of the Act and, therefore, the Agency exempted the records from the requirements of part 11 (§ 1.329(b)). The Agency also exempted records related to certain cattle materials prohibited from use in human food and cosmetics from part 11 (21 CFR 189.5(c)(7) and 700.27(c)(7), respectively). The Agency also seeks comment on whether it should allow additional time for electronic records to be kept in accordance with part 11. Comments should provide the basis for any view that the requirements of part 11 are not warranted.

2. Proposed § 507.102(a)(2)

Proposed § 507.102(a)(2)would require that records contain the actual values and observations obtained during monitoring. It is neither possible to derive the full benefits of a preventive controls system, nor to verify the operation of the system, without recording actual values and observations to produce an accurate record. Notations that monitoring measurements, such as heat treatment temperatures, are ''satisfactory'' or ''unsatisfactory,'' without recording the actual times and temperatures, are vague and subject to varying interpretations and, thus, will not ensure that controls are working properly. In addition, it is not possible to discern a trend toward loss of control without actual measurement values.

3. Proposed § 507.102(a)(3), (a)(4), and (a)(5)

Proposed § 507.102(a)(3), (a)(4), and (a)(5) would require that records be accurate, indelible, and legible (proposed § 507.102(a)(3)); be created concurrently with performance of the activity documented (proposed

§ 507.102(a)(4)); and be as detailed as necessary to provide a history of work performed (proposed § 507.102(a)(5)). Proposed § 507.102(a)(3) and (a)(4) would ensure that the records are useful to the owner, operator, or agent in charge of a plant or facility in complying with the requirements of proposed part 507, for example, in documenting compliance with monitoring requirements and verifying compliance with the food safety plan. These proposed requirements would also ensure that the records would be useful to FDA in determining compliance with the requirements of proposed part 507. Proposed § 507.102(a)(5) would provide flexibility to plants and facilities to tailor the amount of detail to the nature of the record.

4. Proposed § 507.102(b)

Proposed § 507.102(b)would require that the records include: (1) The name and location of the plant or facility; (2) the date and time of the activity documented; (3) the signature or initials of the person performing the activity; and (4) where appropriate, the identity of the product and the production code, if any. The name and location of the plant or facility and the date and time would allow the owner, operator, or agent in charge of a plant or facility (and, during inspection, an FDA investigator) to assess whether the record is current, to identify when and where any deviation occurred, and to track corrective actions. The signature of the individual who made the observation would ensure responsibility and accountability. In addition, if there is a question about the record, a signature would ensure that the source of the record will be known. Linking a record to a specific product (and, when applicable, the production code) would enable the owner, operator, or agent in charge of a facility to isolate product that has not been processed properly when there has been a problem, thereby limiting the impact of the problem (such as the need to reprocess product or to recall product) to only those lots with the problem.

D. Proposed § 507.106—Additional Requirements Applying to the Food Safety Plan

Proposed § 507.106 would require that the owner, operator, or agent in charge of a facility sign and date the food safety plan upon initial completion and upon any modification. Such a signature would provide direct evidence of the owner, operator, or agent's acceptance of the plan and commitment to implementation of the plan. Additionally, the signature, along with the date of signing, would serve to minimize potential confusion over the authenticity of any differing versions or editions of the document that might exist.

E. Proposed § 507.108—Requirements for Record Retention

Proposed § 507.108 contains requirements on the length of time records that would be required under proposed part 507 must be retained and allowances for offsite storage of records under certain circumstances.

1. Proposed § 507.108(a) and (b)

Proposed § 507.108(a) would require that all records that would be required by proposed part 507 be retained at the plant or facility for at least 2 years after the date they were prepared. Proposed § 507.108(b) would require that records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 507.30) or records that document validation of the written food safety plan (§ 507.45(a)). Proposed § 507.108(a) and (b) implement subsection 418(g) of the FD&C Act, which requires certain records to be maintained for not less than 2 years.

While FDA established shorter records retention requirements for records related to perishable foods in the BT records, seafood HACCP, and juice HACCP regulations, in this case Congress determined and specified in section 418(g) of the FD&C Act that the minimum retention period for the majority of the records required under the implementing regulations for all foods, regardless of perishability, be 2 years. Therefore, FDA tentatively concludes that the same requirement should apply to all records required under this section, regardless of the perishability of the food to which the record relates. This would simplify plants' or facilities' duties in compliance because there would only be one 2-year retention period to apply to any record required under proposed part 507. This 2-year retention period would run either from the date the record was prepared, for day-to-day operational records; or from the date at which use of the record is discontinued, for records relating to the general adequacy or equipment or processes (e.g., the written food safety plan and records that document validation of the written food safety plan). The Agency requests comments on the record keeping requirements for animal food, including whether the Agency should use its authority in section 418(m) of the FD&C Act to modify these requirements with respect to facilities that are solely engaged in the production of food for animals other than man.

2. Proposed § 507.108(c)

Proposed § 507.108(c) would provide that, except for the food safety plan, use of offsite storage for records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan would be required to remain onsite. FDA realizes that the proposed requirements for recordkeeping could require some plants or facilities to store a significant quantity of records, and that there may not be adequate storage space in the plant or facility for all of these records. Providing for offsite storage of most records after 6 months would enable a facility to comply with the proposed requirements for record retention while reducing the amount of space needed for onsite storage of the records without interfering with the purpose of record retention, because the records will be readily available.

Proposed § 507.108(c) would also provide that electronic records are considered to be onsite if they are accessible from an onsite location. Computerized systems within corporations can be networked, allowing for the sending and receiving of information in a secure fashion to all of the different food processing facilities of that corporation worldwide. This type of system can be used to provide access at multiple locations to records from multiple plants or facilities.

3. Proposed § 507.108(d)

Proposed § 507.108(d) would provide that if the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request. Allowing for transfer of records will give practical storage relief to seasonal operations or those closed for other reasons for prolonged periods.

XIII. FSMA's Rulemaking Provisions

Please see this discussion in section XVI of the document for the proposed rule for preventive controls for human food (78 FR 3646).

XIV. Proposed Conforming Changes

FDA is proposing conforming changes to several applicable sections of the CFR that would add a reference to part 507. The affected sections in title 21 CFR are:

- § 225.1 Current good manufacturing practice;
- § 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers; and
- § 579.12 Incorporation of regulations in part 179.

XV. Legal Authority

FDA is proposing the CGMP regulations under the FD&C Act and the Public Health Service Act. FDA is proposing all other requirements under the FDA Food Safety Modernization Act, the FD&C Act, the Public Health Service Act, and the FDAAA of 2007.

A. Current Good Manufacturing Practice Regulations

FDA is proposing CGMP requirements in proposed subparts A, B, and F. FDA's legal authority to require CGMPs derives from sections 402(a)(3), 402(a)(4) and 701(a) of the FD&C Act (21 U.S.C. 342(a)(3), 342(a)(4), and 371(a)). Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. The proposed rule also includes new requirements necessary to prevent food from being adulterated (either because it consists in whole or in part of a filthy, putrid, or decomposed substance, because it is otherwise unfit for food, or because it has been held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health). A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. See, e.g., regulations to require HACCP systems for fish and fishery products (part 123) and juice (part 120), regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* organisms and to require refrigeration of shell eggs held for retail distribution (part 101 and 21 CFR part 115), and regulations for the production, storage, and transportation of shell eggs (21 CFR part 118).

In addition to the FD&C Act, FDA's legal authority for the proposed CGMP requirements derives from the PHS Act to the extent such measures are related to communicable disease. Authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as ''are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State'' (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary.) Many provisions in the proposed rule are necessary to prevent animal food from being contaminated with microorganisms of human health significance, such as *Salmonella,* and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. As discussed in section II.E and X.C.6, lack of adequate sanitation in food establishments can lead to the contamination of food with pathogens, increasing the likelihood of illness in humans consuming products derived from animals (such as milk and eggs) and illness in humans handling animal food, particularly in the household setting. The Agency tentatively concludes that the proposed CGMPs are necessary to prevent the spread of communicable disease and to prevent animal food from containing filthy, putrid, or decomposed substances, being otherwise unfit for food, or being prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

B. Hazard Analysis and Risk-Based Preventive Controls

Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act requires that the Secretary issue regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. Section 418(n)(1)(B) of the FD&C Act requires that the regulations define the terms ''small business'' and ''very small business,'' taking into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act. Section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 of the FD&C Act.

In addition to rulemaking requirements, section 418 contains requirements applicable to the owner, operator, or agent in charge of a facility required to register under section 415. Section 418(a) is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is, in relevant part, to prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 of the FD&C Act. In addition to the general requirements in section 418(a) of the FD&C Act, sections 418(b)–(i) contain more specific requirements applicable to facilities. These include hazard analysis (§ 418(b)), preventive controls (§ 418(c)), monitoring (§ 418(d)), corrective actions (§ 418(e)), verification (§ 418(f)), recordkeeping (§ 418(g)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Proposed requirements (proposed subparts C and F) that would implement these provisions of section 418 of the FD&C Act are discussed in sections X and XII.

The Agency is proposing certain requirements in order to efficiently enforce these requirements of section 418. For example, section 418(g) and (h) of the FD&C Act prescribe certain recordkeeping, maintenance, and access requirements for certain kinds of records. As discussed in section XII, the Agency is proposing to establish one set of requirements that would apply to all records that would be required under the proposed rule. This approach will facilitate compliance with the rule on the part of facilities, and will allow for

efficient enforcement of the requirements of the FD&C Act.

Section 418(j) through (m) of the FD&C Act and section 103(c)(1)(D) and (g) of FSMA provide authority for certain exemptions and modifications to the requirements of section 418 of the FD&C Act. These include provisions related to low-acid canned food (section 418(j)); activities of facilities subject to section 419 of the FD&C Act (Standards for Produce Safety) (section 418(k)); qualified facilities (section 418(l)); facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment (section 418(m)); and facilities engaged only in certain low-risk on-farm activities on certain foods conducted by small or very small businesses (section 103(c)(1)(D) of FSMA). Proposed provisions that would implement these provisions of section 418 of the FD&C Act and section 103 of FSMA are discussed in sections VII, VIII, and X.

FDA tentatively concludes that the provisions in proposed subpart C and related requirements in proposed subparts A, D, and F should be applicable to activities that are intrastate in character. Facilities are required to register under section 415 of the FD&C Act regardless of whether the food from the facility enters interstate commerce (§ 1.225(b)). The plain language of section 418 of the FD&C Act applies to facilities that are required to register under section 415 (section 418(o)(2) of the FD&C Act) and does not exclude a facility because food from such a facility is not in interstate commerce. Section 301(uu) of the FD&C Act provides that ''the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418'', or the causing thereof, is a prohibited act.

FDA also is proposing the provisions in subpart C and related requirements in subparts A, D, and F, under sections 402(a)(3), (a)(4), and 701(a) of the FD&C Act to the extent such requirements are necessary to prevent food from being held under insanitary conditions whereby it may become contaminated with filth or rendered injurious to health, or being unfit for food. FDA is also proposing those provisions under sections 311, 361, and 368 of the PHS Act relating to communicable disease to the extent those provisions are necessary to prevent the interstate spread of communicable disease.

The animal food safety system that the Agency is proposing would require a facility to conduct a hazard analysis to determine those hazards that are reasonably likely to occur and establish and implement preventive controls for those hazards. To ensure that controls are properly implemented and effectively controlling the hazards, the proposed animal food safety system would establish requirements for monitoring, corrective actions, and verification, including validation that the preventive controls are adequate to control the identified hazards. The proposed animal food safety system also would require a recall plan. Certain activities would be required to be conducted (or overseen) by a qualified individual and certain activities would be required to be documented. A written food safety plan would include the hazard analysis, the preventive controls that would be established and implemented to address those hazards determined to be reasonably likely to occur, procedures for monitoring, corrective actions, and verification; and a recall plan. The written plan and other documentation would be required to be made promptly available to a duly authorized representative of the Secretary upon oral or written request. FDA tentatively concludes that, taken as a whole, the animal food safety system described here is necessary to help prevent food safety problems associated with biological, chemical, physical, and radiological hazards in animal foods. Therefore, the proposed system is necessary to prevent animal food from being adulterated because it is unfit for food or because it has been held under insanitary conditions whereby it may become contaminated with filth or may be rendered injurious to health and to prevent the spread of communicable disease.

Finally, FDA is proposing the provisions in subparts B and C and related requirements in subparts A, D, and F, under section 1002(a) of Title X of the FDAAA of 2007 (21 U.S.C. 2102), which requires the Secretary to establish processing standards for pet food. The proposed animal food safety system would require tailored standards for facilities processing animal food (including animal feed, pet food, and their raw materials and ingredients).

XVI. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA has developed a PRIA that presents the benefits and costs of this proposed rule (Ref. 52). FDA believes that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 52) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–N–0922), and is also available on FDA's Web site at *http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM366905.pdf.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new preventive controls, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

E. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) are available to the public in the docket for this proposed rule (Ref. 52).

XVII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the proposed rule have been submitted to OMB for review under section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Food For Animals.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

The analyses that FDA has performed in order to examine the impacts of this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is available to the public in the docket (Docket No. FDA–2011–N–0922) for this proposed rule (Ref. 96).

XVIII. Analysis of Environmental Impact

FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XIX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XX. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

XXI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB's).

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 579

Animal feeds, Animal foods, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1, in paragraph (b)(2) add the following entry in numerical order to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 507.60 through 507.83 (part 507, subpart D) relating to withdrawal of exemption applicable to a qualified facility.

* * * * *

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

■ 3. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 374.

■ 4. In § 225.1, add paragraph (d) to read as follows:

§ 225.1 Current good manufacturing practice.

* * * * *

(d) In addition, non-medicated feed is subject to part 507 of this chapter.

PART 500—GENERAL

■ 5. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 6. Revise § 500.23 to read as follows:

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

Except as provided in § 507.5(b), the provisions of parts 507 and 113 of this chapter apply to the manufacturing, processing, or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

■ 7. Add part 507 to read as follows:

PART 507—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Subpart A—General Provisions

Sec.

507.1 Applicability and status.
507.3 Definitions.
507.5 Exemptions.
507.7 Requirements that apply to a qualified facility.
507.10 Applicability of subpart C to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

Subpart B—Current Good Manufacturing Practice

507.14 Personnel.
507.17 Plant and grounds.
507.19 Sanitary operations.
507.20 Sanitary facilities and controls.
507.22 Equipment and utensils.
507.25 Processes and controls.
507.28 Warehousing and distribution.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

507.30 Requirement for a food safety plan.
507.33 Hazard analysis.
507.36 Preventive controls for hazards that are reasonably likely to occur.
507.38 Recall plan for animal food with a hazard that is reasonably likely to occur.
507.39 Monitoring.
507.42 Corrective actions.
507.45 Verification.
507.48 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.
507.50 Requirements applicable to a qualified individual.
507.55 Records required for this subpart C.

Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.
507.62 Issuance of an order to withdraw an exemption applicable to a qualified facility.
507.65 Contents of an order to withdraw an exemption applicable to a qualified facility.
507.67 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.
507.69 Procedure for submitting an appeal.
507.71 Procedure for requesting an informal hearing.
507.73 Requirements applicable to an informal hearing.
507.75 Presiding officer for an appeal and for an informal hearing.
507.77 Timeframe for issuing a decision on an appeal.
507.80 Revocation of an order to withdraw an exemption applicable to a qualified facility.
507.83 Final agency action.

Subpart E—[Reserved]

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

507.100 Records subject to the requirements of this subpart F.
507.102 General requirements applying to records.
507.106 Additional requirements applying to the food safety plan.
507.108 Requirements for record retention.

Authority: 21 U.S.C. 321, 331, 342, 350c, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 507.1 Applicability and status.

(a) The criteria and definitions in this part will apply in determining whether an animal food is adulterated:

(1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and

Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether an animal food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds animal food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with and is not in compliance with section 418 of the Federal Food, Drug, and Cosmetic Act or subparts C, D, and F of this part and § 507.7 is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Animal food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

(d) Animal food for sale in the United States must be manufactured, processed, packed, and held in accordance with the requirements in this part, subject to the exemptions in § 507.5. If a facility is required to comply with subpart B of this part and is also required to comply with subpart B of part 117 of this chapter because the facility manufactures, processes, packs, or holds human food, then the facility may choose to comply with the requirements in subpart B of part 117, instead of subpart B of part 507, as to the manufacturing, processing, packing, and holding of animal food at that facility. If a facility is required to comply with subpart C of part 507 and is also required to comply with subpart C of part 117 of this chapter, then the facility may choose to comply with the requirements in subpart C of part 117 as to the manufacturing, processing, packing, and holding of animal food at the facility, instead of subpart C of part 507, so long as the food safety plan also addresses all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances. In both instances, when applying the requirements of part 117 of this chapter to animal food, the term ''food'' in part 117 includes animal food.

§ 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Calendar day means every day shown on the calendar.

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Environmental pathogen means a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Farm means farm as defined in § 1.227(b) of this chapter.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact animal food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food-contact surfaces'' include food-contact surfaces of utensils and equipment.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg). Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm or another farm under the same ownership are examples of harvesting.

Hazard means any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in animals or humans in the absence of its control.

Hazard reasonably likely to occur means a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

Lot means the food produced during a period of time indicated by a specific code.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-

type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having animal or human health significance. The term ''undesirable microorganisms'' includes those microorganisms that are of animal or human health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a ''farm mixed-type facility,'' which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or establishment, or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of animal food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Qualified end-user, with respect to an animal food, means the consumer of the food (where the term does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227(b) of this chapter) that:

(1) Is located:

(i) In the same State as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all animal food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified individual means a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Reasonably foreseeable hazard means a potential biological, chemical, physical, or radiological hazard that may be associated with the facility, or the food.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of animal or human health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for animals or humans.

Should is used to state recommended or advisory procedures or identify recommended equipment. Should denotes non-binding guidance.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Small business means, for purposes of this part, a business employing fewer than 500 persons.

Subsidiary means any company that is owned or controlled directly or indirectly by another company.

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

Option 1 for Definition of ''Very Small Business''

Very small business means, for purposes of this part, a business that has less than $500,000 in total annual sales of animal food, adjusted for inflation.

Option 2 for Definition of ''Very Small Business''

Very small business means, for purposes of this part, a business that has less than $1,000,000 in total annual sales of animal food, adjusted for inflation.

Option 3 for Definition of ''Very Small Business''

Very small business means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of animal food, adjusted for inflation.

Water activity (a_w) means a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 507.5 Exemptions.

(a) This part does not apply to establishments (including ''farms'' as defined in § 1.227(b) of this chapter) that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(b) Activities in animal food facilities that are regulated under, and are in compliance with, § 500.23 and part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) are exempt from subpart C of part 507 only with respect to those microbiological hazards regulated under part 113. The facilities must comply with subparts C and F of this part regarding all other potential hazards and must comply with subparts A and B of this part.

(c) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(d) Except as provided in subpart D of this part, qualified facilities are exempt from subpart C of this part if they comply with the requirements in § 507.7.

(e) Subpart C of this part does not apply to on-farm packing or holding of animal food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/animal food combinations on animal food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership:

(1) Conveying, weighing, sorting, culling, or grading (incidental to storing):

(i) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(ii) Oilseed (e.g., cottonseed, linseed, rapeseed, soybean, sunflower);

(iii) Grain or oilseed byproducts;

(iv) Forage (e.g., hay or ensiled material); or

(v) Other plants or plant byproducts (e.g., almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(2) Storing:

(i) Dried grain;

(ii) Dried oilseed;

(iii) Byproducts of dried grain or dried oilseed;

(iv) Forage; or

(v) Other plants or plant byproducts.

(3) Packing:

(i) Grain;

(ii) Oilseed;

(iii) Grain or oilseed byproducts;

(iv) Forage; or

(v) Other plants or plant byproducts.

(4) Mixing (incidental to packing or storing):

(i) Grain, whole; or

(ii) Forage.

(f) Subpart C does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts consists of the following:

(1) When conducted on a farm mixed-typed facility's own raw agriculture commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, (those grown or raised on that farm mixed-type facility or another farm/farm mixed-typed facility under the same ownership) for distribution into commerce:

(i) Cracking, crimping, or flaking:

(A) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(B) Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or

(C) Grain or oilseed byproducts.

(ii) Crushing, grinding, milling, pulverizing, or dry rolling:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts;

(D) Forage (e.g., hay or ensiled material); or

(E) Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(iii) Making silage.

(iv) Chopping or shredding hay.

(v) Extracting (mechanical) or wet rolling:

(A) Grain; or

(B) Oilseed.

(2) When conducted on animal food other than the farm mixed-typed facility's own raw agriculture commodities for distribution into commerce:

(i) Cracking, crimping, flaking, or shelling:

(A) Grain (e.g., barley, corn, rice, oat, sorghum, triticale, wheat);

(B) Oilseed (e.g., cotton seed, linseed, rapeseed, soybean, sunflower); or

(C) Grain or oilseed byproducts.

(ii) Crushing, grinding, milling, pulverizing, or dry rolling:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts;

(D) Forage (e.g., hay or ensiled material); or

(E) Other plants or plant byproducts (e.g., such as almond, peanut, or soybean hulls, citrus, other fruit including culled fruit, potatoes, or other vegetables including culled vegetables).

(iii) Making silage.

(iv) Chopping or shredding hay.

(v) Extracting (mechanical) or wet rolling:

(A) Grain; or

(B) Oilseed.

(vi) Labeling:

(A) Grain whole; or

(B) Oilseed whole.

(vii) Sifting, separating, or sizing:

(A) Grain;

(B) Oilseed;

(C) Grain or oilseed byproducts; or

(D) Other plants or plant byproducts.

(g) Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(h) Subpart B of this part does not apply to the holding or transportation of one or more raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

§ 507.7 Requirements that apply to a qualified facility.

(a) A qualified facility is exempt from subpart C of this part provided that for the calendar year in which it is to be considered a qualified facility, the facility has submitted to FDA documentation that:

(1) Demonstrates the facility is a qualified facility as defined in § 507.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) Demonstrates the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the animal food being manufactured, processed, packed, or held at the facility, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) Demonstrates the facility is in compliance with state, local, county, or other applicable non-Federal food safety law. This documentation may include inspection reports, certification by an appropriate agency (such as a State department of agriculture), or other documentation deemed appropriate by FDA.

(b) The documentation required by paragraph (a) of this section must be submitted to FDA by any one of the following means:

(1) To submit electronically, go to *http://www.access.fda.gov* and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) To submit documents in a paper format or in an electronic format on a CD–ROM, mail these to the U.S. Food and Drug Administration, ATTN: Qualified Facility Coordinator, 10903 New Hampshire Ave., Silver Spring, MD 20993. We recommend that an owner, operator, or agent in charge of a facility submit by mail only if the facility does not have reasonable access to the Internet.

(c) The documentation required by paragraph (a) of this section must be:

(1) Submitted to FDA initially within 90 days of the applicable compliance date of this part; and

(2) Resubmitted at least every 2 years, or whenever there is a material change to the information described in paragraph (a) of this section. For the purpose of this section, a material change is one that changes whether or not a facility is a ''qualified facility''.

(d) A qualified facility that does not submit documentation under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address (the street address, city, state, and ZIP code for domestic facilities, and comparable full address information for foreign facilities) of the facility where the animal food was manufactured or processed as follows:

(1) Such notification must appear in a prominent and conspicuous location on the label for animal food required to bear a package label under any other provision of the Federal Food, Drug, and Cosmetic Act.

(2) For animal food that is not required to bear a food packaging label, the notification must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(e) A qualified facility must maintain those records relied upon to support the documentation required by § 507.7(a)(2). These records are subject to the requirements of subpart F of this part.

§ 507.10 Applicability of subpart C to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) Subpart C of this part does not apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and does not require time/temperature control to ensure the safety of the animal food.

(b) A facility solely engaged in the storage of packaged animal food that is not exposed to the environment but requires time/temperature control is subject to the modified requirements in § 507.48.

Subpart B—Current Good Manufacturing Practice

§ 507.14 Personnel.

(a) Plant management must take all reasonable measures and precautions to ensure that:

(1) Any person who, by his own acknowledgement, by medical examination, or by supervisory observation, is shown to have, or appears to have any illness, open skin lesion, or other source of abnormal microbial contamination by which there is a reasonable possibility of animal food, animal food-contact surfaces, or animal food-packaging materials becoming contaminated, is excluded from any operations which may be expected to result in such contamination until the condition is resolved;

(2) Personnel have been instructed to report such health conditions to their supervisors;

(3) All persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices while on duty to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include:

(i) Maintaining adequate personal cleanliness;

(ii) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work and at any other time when the hands may have become soiled or contaminated;

(iii) Removing all unsecured jewelry and other objects that might fall into animal food, equipment, or containers;

(iv) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are washed; and

(v) Taking any other necessary precautions to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials with microorganisms or foreign substances.

(b) Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

(c) Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 507.17 Plant and grounds.

(a) The grounds about an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food by seepage, foot-borne filth, or providing a breeding place for pests; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a)(1) through (a)(3) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of animal food contamination.

(b) The plant's buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for animal food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe animal food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of animal food, animal food-contact surfaces, or animal food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect animal food in outdoor bulk vessels by any effective means, including:

(i) Using protective coverings;

(ii) Controlling areas over and around the vessels to eliminate harborages for pests;

(iii) Checking on a regular basis for pests and pest infestation; and

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate animal food, animal food-contact surfaces, or animal food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating animal food, animal food-contact surfaces, or animal food-packaging materials.

(5) Provide adequate lighting in hand-washing areas, toilet rooms, areas where animal food is examined, processed, or stored, and areas where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, or otherwise protect against animal food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate animal food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food, animal food-packaging materials, and animal food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 507.19 Sanitary operations.

(a) Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition and must be kept in repair sufficient to prevent animal food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(b) Cleaning compounds and sanitizing agents must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a supplier's guarantee or certification or examination of these substances for contamination.

(c) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in a plant where animal food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(d) Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of animal food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(e) All animal food-contact surfaces, including utensils and animal food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of animal food.

(1) Animal food-contact surfaces used for manufacturing, processing or holding low-moisture animal food must be in a clean, dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and animal food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(f) Non-animal food-contact surfaces of equipment used in the operation of an animal food plant should be cleaned in a manner and as frequently as necessary to protect against contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(g) Cleaned and sanitized portable equipment with animal food-contact surfaces and utensils should be stored in a location and manner that protects animal food-contact surfaces from contamination.

§ 507.20 Sanitary facilities and controls.

(a) The water supply must be sufficient for the operations intended and must be derived from an adequate source. Any water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee sanitary facilities.

(b) Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid constituting a source of contamination to animal food, water supplies, equipment, or utensils or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing.

(c) Sewage must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) Rubbish must be conveyed, stored, and disposed of in a way to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces.

§ 507.22 Equipment and utensils.

(a)(1) All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) The design, construction, and use of equipment and utensils must preclude the adulteration of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) All equipment should be installed and maintained in such a way to facilitate the cleaning of the equipment and all adjacent spaces;

(4) Animal food-contact surfaces must be made of materials that resist corrosion when in contact with animal food;

(5) Animal food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of animal food, and, if applicable, the action of cleaning compounds and sanitizing agents; and

(6) Animal food-contact surfaces must be maintained to protect animal food from being contaminated.

(b) Seams on animal food-contact surfaces must be maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms.

(c) Equipment in the animal food manufacturing or handling area that does not come into contact with animal food must be constructed in such a way that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold animal food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, a_w, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be treated in such a way that animal food is not contaminated.

§ 507.25 Processes and controls.

(a) Plant management must ensure that:

(1) All operations in the manufacturing, processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with adequate sanitation principles;

(2) Containers holding animal food, raw materials, or ingredients are labeled to accurately identify the contents;

(3) The labeling for the finished animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species;

(4) Appropriate quality control operations are employed so that animal food-packaging materials are safe and suitable;

(5) The overall sanitation of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(6) All reasonable precautions are taken so that production procedures do not contribute to contamination from any source;

(7) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination; and

(8) All animal food that has become contaminated to the extent that it is adulterated is rejected, or if permissible, treated or processed to eliminate the contamination.

(b) Raw materials and ingredients:

(1) Must be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into animal food and must be stored under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Raw materials must be washed or cleaned as necessary to remove soil or other contamination;

(ii) Water used for washing, rinsing, or conveying animal food must be safe and of adequate sanitary quality;

(iii) Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food; and

(iv) Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of animal food.

(2) Must not contain levels of microorganisms that may render the food injurious to the health of animals or humans, or they must be treated (e.g., heat) during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated;

(3) Susceptible to contamination with aflatoxin or other natural toxins must comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished animal food;

(4) Including rework, must be held in bulk, or in containers designed and constructed in a way that protects against contamination, and must be held at a temperature and relative humidity and in a manner that prevents the animal food from becoming adulterated. Material scheduled for rework must be identified as such;

(5) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and ingredients from becoming adulterated; and

(6) Whether liquid or dry, received and stored in bulk form must be held in a manner that protects against contamination.

(c) For the purposes of manufacturing operations, the following apply:

(1) Equipment, utensils, and finished animal food containers must be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. When necessary, equipment must be taken apart for thorough cleaning;

(2) All animal food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of animal food;

(3) Animal food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding;

(4) Measures taken to destroy or prevent the growth of undesirable microorganisms, such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w, must be adequate under the conditions of manufacture, handling, and distribution to prevent animal food from being adulterated;

(5) Work-in-process and rework must be handled in a manner that protects against contamination and the growth of undesirable microorganisms;

(6) Effective measures must be taken to protect finished animal food from contamination by raw materials, ingredients, or refuse. When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated animal food. Animal food transported by conveyor must be protected against contamination as necessary;

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or animal food must be constructed, handled, and maintained during manufacturing, processing, packing, or holding in a manner that protects against contamination of animal food;

(8) Effective measures must be taken to protect against the inclusion of metal or other extraneous material in animal food;

(9) Adulterated animal food, raw materials, and ingredients must be disposed of in a manner that protects against the contamination of other animal food or, if the adulterated animal food, raw materials, or ingredients are capable of being reconditioned, they must be reconditioned using a method that has been proven to be effective;

(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, defatting, and forming must be performed in a way that protects animal food against contamination. Animal food should be protected from contaminants that may drip, drain, or be drawn into the animal food;

(11) Heat blanching, when required in the preparation of animal food, should be effected by heating the animal food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the animal food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning;

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations must be treated or maintained in such a manner that they are protected against contamination;

(13) Filling, assembling, packaging, and other operations must be performed in such a way that the animal food is protected against contamination and growth of undesirable microorganisms;

(14) Animal food, including dry mixes, nuts, intermediate moisture animal food, and dehydrated animal food, that relies on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;

(15) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(16) When ice is used in contact with animal food, it must be made from water that is safe and of adequate sanitary quality, and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 507.28 Warehousing and distribution.

Storage and transportation of animal food must be conducted under conditions that will protect against biological, chemical, physical, and radiological contamination of animal food as well as against deterioration of the animal food and the container.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.30 Requirement for a food safety plan.

(a) The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan.

(b) The written food safety plan must be prepared by (or its preparation overseen by) a qualified individual.

(c) The written food safety plan must include:

(1) The hazard analysis as required by § 507.33;

(2) The preventive controls as required by § 507.36;

(3) The recall plan as required by § 507.38;

(4) The procedures and the frequency with which these procedures will be conducted for monitoring the performance of the preventive controls as required by § 507.39;

(5) The corrective action procedures as required by § 507.42; and

(6) The verification procedures and the frequency with which they will be performed as required by § 507.45.

§ 507.33 Hazard analysis.

(a) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur and develop a written hazard analysis.

(b) The hazard analysis must consider hazards that may occur naturally or may be unintentionally introduced including:

(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of animal or human health significance;

(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances;

(3) Physical hazards; and

(4) Radiological hazards.

(c) The hazard analysis must contain an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

(d) The hazard analysis must consider the effect of the following on the safety of the finished animal food:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors.

§ 507.36 Preventive controls for hazards that are reasonably likely to occur.

For hazards identified in the hazard analysis as reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b) Preventive controls must be written.

(c) Preventive controls must include, as appropriate to the facility and animal food:

(1) Parameters associated with the control of the hazard, such as parameters associated with heat processing, irradiating, and refrigerating animal foods; and

(2) The maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

(d) Preventive controls must include, as appropriate:

(1) Process controls that include those procedures, practices, and processes performed on an animal food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur;

(2) Sanitation controls:

(i) Where necessary to significantly minimize or prevent hazards that are reasonably likely to occur, procedures for the:

(A) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(B) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

(ii) The owner, operator, or agent in charge must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section.

(iii) The owner, operator, or agent in charge of the facility is not required to follow the corrective actions described in § 507.42(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(2)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraph (d)(2)(i)(A) or (d)(2)(i)(B) of this section.

(iv) All corrective actions taken in accordance with paragraph (d)(2)(ii) of this section must be documented in records that are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

(3) A recall plan as required by § 507.38; and

(4) Any other controls necessary to satisfy the requirements of paragraph (a) of this section.

(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:

(i) Monitoring as required by § 507.39;

(ii) Corrective actions as required by § 507.42; and

(iii) Verification as required by § 507.45.

(2) The recall plan established in § 507.38 is not subject to the requirements of paragraph (e)(1) of this section.

§ 507.38 Recall plan for animal food with a hazard that is reasonably likely to occur.

(a) The owner, operator, or agent in charge of a facility must develop a written recall plan for animal food with a hazard that is reasonably likely to occur and assign responsibility for performing all actions in the plan.

(b) The written recall plan must include procedures for:

(1) Directly notifying direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notifying the public about any hazard presented by the animal food when appropriate to protect animal and human health;

(3) Conducting effectiveness checks (as described in part 7 of this chapter) to verify the recall has been carried out; and

(4) The proper disposition (e.g., destroying, reprocessing, or diverting to another use that would not present a safety concern) of the recalled animal food.

§ 507.39 Monitoring.

(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures for monitoring the preventive controls. These procedures must include:

(1) What preventive controls will be monitored;

(2) Who will perform the monitoring;

(3) How the monitoring will be performed;

(4) What parameter will be measured, if applicable;

(5) Frequency with which the monitoring will be performed; and

(6) Any additional information needed to ensure appropriate monitoring of the preventive controls.

(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that the preventive controls are consistently performed.

(c) Monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 507.45(b)(1) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

§ 507.42 Corrective actions.

(a) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented. The corrective active procedures must describe the steps to be taken to ensure:

(1) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;

(2) All affected animal food is evaluated for safety; and

(3) All affected animal food is prevented from entering into commerce if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under

section 402 of the Federal Food, Drug, and Cosmetic Act.

(b) If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:

(1) Take corrective action to identify and correct the problem to reduce the likelihood that the problem will recur;

(2) Evaluate all affected animal food for safety;

(3) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(3) of this section; and

(4) Reanalyze the food safety plan in accordance with § 507.45(e) to determine whether modification of the food safety plan is required.

(c) When corrective actions are taken, they must be documented in written records. These records are subject to verification in accordance with § 507.45(b)(2) and records review in accordance with § 507.45(c)(1)(i) and (c)(2).

§ 507.45 Verification.

(a) Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(1) Must be performed (or overseen) by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and

(3) Need not address:

(i) The sanitation controls in § 507.36(d)(2); and

(ii) The recall plan in § 507.38.

(b) The owner, operator, or agent in charge of a facility must verify that:

(1) Monitoring is conducted as required by § 507.39;

(2) Appropriate decisions about corrective actions are being made as required by § 507.42;

(3) The preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur; and

(4) The activities conducted must include, as appropriate to the facility and the animal food, calibration of process monitoring and verification instruments.

(c) The owner, operator, or agent in charge of a facility must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur by ensuring that a qualified individual is conducting (or overseeing):

(1) A review of the following records in the timeframe specified:

(i) Monitoring and corrective action records within 1 week after the records are made; and

(ii) Records of calibration of instruments within a reasonable time after the records are created.

(2) A review of the records in paragraphs (c)(1)(i) and (c)(1)(ii) of this section to ensure:

(i) The records are complete;

(ii) The activities reflected in the records occurred in accordance with the food safety plan;

(iii) The preventive controls are effective; and

(iv) Appropriate decisions were made about corrective actions.

(d) The owner, operator, or agent in charge of a facility must establish and implement written procedures, as appropriate to the facility and the animal food, for the frequency of calibrating process monitoring and verification instruments.

(e) The owner, operator, or agent in charge of a facility must:

(1) Conduct a reanalysis of the food safety plan:

(i) At least once every 3 years;

(ii) Whenever a significant change is made in the activities conducted at the facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(iii) Whenever the owner, operator, or agent in charge becomes aware of new information about potential hazards associated with the animal food;

(iv) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established;

(v) Whenever a preventive control is found to be ineffective; and

(vi) Whenever FDA requires a reanalysis in response to newly identified hazards and developments in scientific understanding.

(2) Complete the reanalysis and implement any additional preventive controls needed to address the hazard identified before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production;

(3) Revise the written food safety plan if a significant change is made, or document the basis for the conclusion that no additional or revised preventive controls are needed; and

(4) Ensure the reanalysis is performed (or overseen) by a qualified individual.

(f) All verification activities taken in accordance with this section must be documented in records.

§ 507.48 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) Take appropriate corrective actions if there is a problem with the temperature controls for such refrigerated packaged animal food to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a

problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

§ 507.50 Requirements applicable to a qualified individual.

(a) One or more qualified individuals must do or oversee the following:

(1) Prepare the food safety plan (§ 507.30));

(2) Validate the preventive controls (§ 507.45(a));

(3) Conduct a review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 507.45(c));

(4) Perform a reanalysis of the food safety plan (§ 507.45(e)).

(b) To be qualified, an individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(c) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Records required for this subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan;

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Monitoring;

(iii) Corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Records review; and

(vi) Reanalysis; and

(5) Records that document applicable training for the qualified individual.

(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D—Withdrawal of an Exemption Applicable to a Qualified Facility

§ 507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

FDA may withdraw the exemption applicable to a qualified facility under § 507.5(d):

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(b) If FDA determines that it is necessary to protect the animal or human health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

§ 507.62 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) If FDA determines that an exemption applicable to a qualified facility under § 507.5(d) should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.

(b) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to such Director, must approve an order to withdraw the exemption.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 507.65 Contents of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 507.5(d) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conduct or conditions associated with a qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart D;

(f) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 507.73;

(g) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(h) The name and the title of the FDA representative who approved the order.

§ 507.67 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) The owner, operator, or agent in charge of a qualified facility that receives an order under § 507.60 to withdraw an exemption applicable to that facility under § 507.5(d) must either:

(1) Comply with applicable requirements of this part within 60 calendar days of the date of the order; or

(2) Appeal the order within 10 calendar days of the date of the order in accordance with the requirements of § 507.69.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part within 60 calendar days of the date of the order.

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 507.5(d), the owner, operator, or agent in charge of the facility must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of the order;

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator, or agent in charge of the facility relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 507.5(d), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 507.71.

§ 507.71 Procedure for requesting an informal hearing.

(a) If the owner, operator, or agent in charge of the facility appeals the order, the owner, operator, or agent in charge of the facility:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 507.69 within 10 calendar days of the date of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial.

§ 507.73 Requirements applicable to an informal hearing.

If the owner, operator, or agent in charge of the facility requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under §§ 507.62 and 507.65, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

(3) Section 507.75, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 507.73(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 507.75 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 507.77 Timeframe for issuing a decision on an appeal.

(a) If the owner, operator, or agent in charge of a facility appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a facility appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 507.80 Revocation of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 507.5(d) is revoked if:

(a) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the facility appeals the order and requests an informal hearing, FDA

denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 507.83 Final agency action.

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

Subpart E—[Reserved]

Subpart F—Requirements Applying to Records That Must Be Established and Maintained

§ 507.100 Records subject to the requirements of this subpart F.

(a) Except as provided by paragraphs (d) and (e) of this section, all records required by this part are subject to all requirements of this subpart F.

(b) Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

(c) All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request.

(d) The requirements of § 507.106 apply only to the written food safety plan.

(e) The requirements of § 507.102(a)(2), (a)(4), and (a)(5) and (b) do not apply to the records required by § 507.7(e) pertaining to qualified facilities.

§ 507.102 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(2) Contain the actual values and observations obtained during monitoring;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§ 507.106 Additional requirements applying to the food safety plan.

The food safety plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

§ 507.108 Requirements for record retention.

(a) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.

(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained at the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 507.30) or records that document validation of the written food safety plan (§ 507.45(a)).

(c) Except for the food safety plan, offsite storage of records is permitted after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.

(d) If the plant or facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location, but must be returned to the plant or facility within 24 hours for official review upon request.

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

■ 8. The authority citation for 21 CFR part 579 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

■ 9. In § 579.12, add the following sentence to the end of the paragraph to read as follows:

§ 579.12 Incorporation of regulations in part 179.

* * * Any facility that treats animal feed and pet food with ionizing radiation must comply with the requirements of part 507 of this chapter and other applicable regulations.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

Although the proposed rule that is the subject of this document does not include provisions for environmental monitoring or finished product testing, the Agency believes that these regimes can play a critical role in a modern food safety system. In sections XI.K and XI.L, the Agency requests comment on when and how these types of testing are an appropriate means of implementing the statutory directives set out in section 418 of the FD&C Act. In this Appendix, the Agency provides background material on these testing measures.

I. The Role of Testing as a Verification Measure in a Modern Food Safety System

A. Verification of Preventive Controls

In some respects, animal food safety is a more complex subject than human food safety in that the feeding of multiple and diverse animal species is involved, many of which are associated with human food in the form of meat, milk and eggs. However, the core principles and approaches used to assess and prevent hazards that are reasonably likely to occur in animal food are similar to those used during the manufacture of food for humans, despite differences in production practices and levels of sanitation involved (Ref. 1).

The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref. 2) (Ref. 3). Prevention of hazards in animal food is much more effective than trying to differentiate safe from unsafe animal food using testing. Although testing is rarely considered a control measure, it plays a very important role in ensuring the safety of animal food. An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard (Ref. 4) (Ref. 5). Testing is used in conjunction with other verification measures in the food safety system, such as audits of suppliers, observations of whether activities are being conducted according to the food safety plan, and reviewing records to determine whether process controls are meeting specified limits for parameters established in the food safety plan. Although testing may be conducted for biological, chemical, physical, or radiological hazards, the most common testing is for microbiological hazards. Thus, much of the testing described below focuses on microbial testing, but many of the issues discussed apply to testing for other hazards as well. The Agency focuses more of its discussion below on verification testing of the environment because of the increasing recognition of the benefits of such testing in identifying conditions that could result in environmental pathogens contaminating animal food; thus such verification testing is important in preventing contamination in animal food, whereas verification testing of raw materials,

ingredients, and finished products is used to detect contamination that has already occurred.

As discussed in sections I.C, I.E, and I.F of this Appendix, microbial testing may include:

- Testing raw materials and ingredients to verify that suppliers have significantly minimized or prevented hazards reasonably likely to occur in the raw materials and ingredients;
- Testing the environment to verify that sanitation controls have significantly minimized or prevented the potential for environmental pathogens to contaminate animal food; and
- Testing finished product to verify that preventive controls have significantly minimized or prevented hazards reasonably likely to occur in the animal food.

Further discussion of verification of preventive controls can be found in section I.A of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

B. Scientifically Valid Sampling and Testing

Consistent with the Agency's discussion of the term ''scientifically valid'' in the proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements for humans (68 FR 12158 at 12198), the Agency uses the term ''scientifically valid'' with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research. A scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12158 at 12198). Sampling and testing used for verification in a food safety system must be scientifically valid if they are to provide assurance that preventive controls are effective.

C. Verification Testing of Raw Materials and Ingredients

Raw materials and ingredients are often tested as part of a supplier approval and verification program, as one of the verification activities when a preventive control that is adequate to significantly minimize or prevent the hazard is not applied at the receiving facility. The utility and frequency of raw material and ingredient testing for verification of supplier controls depend on many factors, including:

- The hazard and its association with the raw material or ingredient;
- The likelihood that the animal, or person handling the animal food, would become ill if the hazard were present in the raw material or ingredient;
- How that raw material or ingredient will be used by the receiving facility (e.g., the effect of processing on the hazard); and
- The potential for contamination of the facility's environment with the hazard in the raw material or ingredient.

Further discussion of verification testing of raw materials and ingredients can be found in section I.C of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

D. Verification of Sanitation Controls to Significantly Minimize or Prevent the Potential for an Environmental Pathogen To Contaminate Animal Food

1. Environmental Pathogens in Animal Food

Animal food can become contaminated with pathogenic microorganisms at many different steps: on the farm; in packing, manufacturing/processing, or distribution facilities; during storage or transit; at retail establishments; and at the location of the animal. Any time animal food is exposed to the environment during a manufacturing, processing, packing, or holding activity, there is the potential for the food to be contaminated with pathogenic microorganisms. As discussed in section VIII.B of the preamble, proposed § 507.3 would define the term ''environmental pathogen'' to mean a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. The environmental pathogens most frequently involved in the contamination of animal food leading to foodborne illness are *Salmonella* spp.

2. *Salmonella* spp. as an Environmental Pathogen

The Agency discusses *Salmonella* spp. in section II.E of the preamble of this document and in section I.D.2 of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646). *Salmonella* has been isolated from a variety of foods and it can get into food by a variety of mechanisms. The focus here is on *Salmonella* contamination from the environment, particularly as a hazard associated with low-moisture animal food such as protein meals and dry animal food (Ref. 6). In the first RFR Annual Report, 86 of the primary RFR entries reported for human and animal food were a result of *Salmonella* contaminations. Almost half of these were from low-moisture foods and 13 of these were animal food (Ref. 7).

3. Environmental Pathogens in the Plant Environment

Environmental pathogens may be introduced into a facility through raw materials or ingredients, people, or objects. Once in the facility, environmental pathogens can be a source of contamination of animal food. Further discussion of ''Environmental pathogens in the plant environment'' can be found in section I.D.4 of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

4. Contamination of Animal Food With *Salmonella* spp. From the Plant Environment

The available data and information associate insanitary conditions in animal and human food facilities with contamination of a number of foods with the environmental pathogen *Salmonella* spp. Such contamination has led to recalls and to outbreaks of foodborne illness.

In 2007, FDA identified S. Schwarzengrund, a rare serotype of *Salmonella* associated with human illness, in a pet food. The Center for Disease Control and Prevention (CDC) traced this rare strain of *Salmonella* to a pet food manufacturing facility located in Pennsylvania. Analytical tests conducted by the FDA confirmed S. Schwarzengrund at the Pennsylvania facility. A recall was issued for two brands of dry dog food and the manufacturing facility ceased operations for 5 months for cleaning and disinfecting. Despite the facility's efforts, additional S. Schwarzengrund illnesses in humans were reported to CDC. After further investigations by FDA, the pet food manufacturing facility issued a nationwide voluntary recall of all dry dog and cat food products produced at the facility over a 5 month period. This recall involved approximately 23,109 tons of dry pet foods, representing 105 brands. While no pets were reported sick, 79 people in 21 states were reported as becoming ill due to the handling of pet food contaminated with this Salmonella strain (Ref. 8).

In 2008–2009, an outbreak was linked to *Salmonella* Typhimurium in peanut butter and peanut paste (Ref. 9) (Ref. 10). This outbreak resulted in an estimated 714 illnesses, 166 hospitalizations, and 9 deaths (Ref. 10). Inspections conducted by FDA at the two implicated ingredient manufacturing facilities (which shared ingredients) revealed lack of controls to prevent product contamination from pests, from an insanitary air-circulation system, from insanitary food-contact surfaces, and from the processing environment (Ref. 11) (Ref. 12). Several strains of *Salmonella* spp. were found in multiple products and in the plant environment (Ref. 12). This outbreak led to the recall of more than 3900 animal (including pet food) and human food products containing peanut-derived ingredients (Ref. 11).

E. Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Sanitation Controls in Significantly Minimizing or Preventing the Potential for an Environmental Pathogen To Contaminate Animal Food

1. Purpose of Environmental Monitoring

The purpose of monitoring for environmental pathogens in facilities where animal food is manufactured, processed, packed, or held is to verify the implementation and effectiveness of sanitation controls intended to significantly minimize or prevent the potential for an environmental pathogen to contaminate animal food. In so doing, environmental monitoring can find sources of environmental pathogens that remain in the facility after routine cleaning and sanitizing so that the environmental pathogens can be eliminated by appropriate corrective actions (e.g., intensified cleaning and sanitizing, sometimes involving equipment disassembly). For further discussion, see section I.E. of the Appendix of the document for the proposed rule for preventive controls for human food (78 FR 3646).

2. Indicator Organisms

The term ''indicator organism'' can have different meanings, depending on the

purpose of using an indicator organism. As discussed in the scientific literature, the term ''indicator organism'' means a microorganism or group of microorganisms that is indicative that (1) a food has been exposed to conditions that pose an increased risk for contamination of the food with a pathogen or (2) a food has been exposed to conditions under which a pathogen can increase in numbers (Ref. 13). This definition in the scientific literature is consistent with a definition of indicator organism established by NACMCF as one that indicates a state or condition and an index organism as one for which the concentration or frequency correlates with the concentration or frequency of another microorganism of concern (Ref. 14). FDA considers the NACMCF definition of an indicator organism to be an appropriate working definition for the purpose of this document.

Listeria spp. is an appropriate indicator organism for *L. monocytogenes.* The Agency is aware that listeriosis occurs in a number of animal species, especially ruminant animals, and is asking for comment on whether *L. monocytogenes* is an environmental pathogen of concern for animal food facilities. FDA's current thinking is that there is no currently available indicator organism for *Salmonella* spp. The Agency requests data, information, and other comment bearing on whether there is a currently available indicator organism for *Salmonella* spp. that could be used for environmental monitoring.

For additional discussion on indicator organisms, monitoring procedures, and corrective actions, see section I.E.2 through 5 of the Appendix for the proposed rule for preventive controls for human food (78 FR 3646).

F. The Role of Finished Product Testing in Verifying the Implementation and Effectiveness of Preventive Controls

Although FDA is not including a provision for finished product testing in this proposed rule, here the Agency sets out some considerations regarding the appropriate use of such testing. The utility of finished product testing for verification depends on many factors that industry currently considers in determining whether finished product testing is an appropriate approach to reducing the risk of: animals consuming contaminated food, humans handling contaminated food, and humans consuming food derived from animals that consumed contaminated food. The first such consideration is the nature of the hazard and whether there is evidence of adverse health consequences from that hazard in the animal food being produced or in a similar animal food. If the hazard were to be present in the animal food, how likely is it that illness will occur and how serious would the consequences be? The more likely and severe the illness, the greater the frequency of conducting verification testing should be. For example, *Salmonella* spp. is a hazard that could cause serious illness, particularly in children and the elderly who might get exposed to it through handling pet food products contaminated with the organism. In contrast, in situations where unlawful pesticide residues are considered reasonably likely to occur, the presence of a pesticide residue that is not approved for a specific commodity, but that is within the tolerance approved for other commodities, while deemed unsafe as a matter of law, may not actually result in illness. Thus, a firm is more likely to conduct finished product testing to verify *Salmonella* spp. control than to verify control of pesticides.

Another consideration in determining whether finished product testing is appropriate is the intended ''consumer'' of the animal food and whether indirect exposure of a susceptible population may occur. The greater the sensitivity of the intended ''consumer'' (as would be the case, for example, for dioxin contamination), the greater the likelihood that finished product testing would be used as a verification activity.

Another consideration in determining whether finished product testing is appropriate is the impact of the animal food on the contaminant. For example, depending on the animal food, pathogens may survive in the food, increase in number, or die off. Finished product testing generally is not conducted if pathogens that may be in an animal food would die off in a relatively short period of time (e.g., before the food reaches the ''consumer'').

Additional considerations in determining whether finished product testing is appropriate are the intended use of the animal food; the types of controls the supplier has implemented to minimize the potential for the hazard to be present (e.g., whether the supplier has a kill step for a pathogen); the effect of processing on the hazard; and whether a hazard can be reintroduced into a food that has been treated to significantly minimize the hazard (e.g., *Salmonella* in dry or low-moisture pet food when a flavoring is applied after heat treatment).

For an extensive discussion on finished product testing and metrics for microbiological risk management, see sections I.F and I.G of the Appendix for the proposed rule for human food (78 FR 3646).

II. The Role of Supplier Approval and Verification Programs in a Food Safety System

An animal food can become contaminated through the use of contaminated raw materials or ingredients as evident by the large recall of pet food as a result of contamination of wheat gluten with melamine (see discussion in section II.E.1of the preamble).

The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. To ensure safe animal food and minimize the potential for contaminated animal food to reach the consumer, each supplier in the chain must implement preventive controls appropriate to the animal food and operation for hazards reasonably likely to occur in the raw material or other ingredient. A facility receiving raw materials or ingredients from a supplier must ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program provides initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

Supplier approval and verification is widely accepted in the domestic and international food safety community. The NACMCF HACCP guidelines describe Supplier Control as one of the common prerequisite programs for the safe production of food products and recommend that each facility should ensure that its suppliers have in place effective GMP and food safety programs (Ref. 14). Codex specifies that no raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing (Ref. 15). Codex also specifies that, where appropriate, specifications for raw materials should be identified and applied and that, where necessary, laboratory tests should be made to establish fitness for use (Ref. 15).

Supplier verification activities include auditing a supplier to ensure the supplier is complying with applicable food safety requirements, such as requirements under proposed part 507. Audit activities may include a range of activities, such as on-site examinations of establishments, review of records, review of quality assurance systems, and examination or laboratory testing of product samples (Ref. 16). Other supplier verification activities include conducting testing or requiring supplier certificates of analysis (COAs), review of food safety plans and records, or combinations of activities such as audits and periodic testing.

An increasing number of establishments that sell food are independently requiring, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements (Ref. 16). There are many established third-party certification programs designed for various reasons that are currently being used by industry. Many third party audit schemes used to assess the

industry's food safety management systems incorporate requirements for manufacturers and processors to establish supplier approval programs. An example of a food safety standard that was specifically developed for the animal food industry is Publicly Available Specification (PAS) 222:2011 (Ref. 1). This standard was developed for the animal food industry by the British Standards Institution (BSI) to specify requirements for prerequisite programs (PRPs) to assist in controlling hazards in animal food. The PAS 222:2011 requirements can be used either in conjunction with ISO 22000, food safety management systems, or as a stand-alone document.

To ensure confidence in the delivery of safe food for animals and humans worldwide, the Global Food Safety Initiative (GFSI), a benchmarking organization, was established in 2000 to drive continuous improvement in food safety management systems. Their objectives include reducing risk by delivering equivalence and convergence between effective food safety management systems and managing cost in the global food system by eliminating redundancy and improving operational efficiency (Ref. 17). GFSI has developed a guidance document as a tool that fulfills the GFSI objectives of determining equivalency between food safety management systems (Ref. 17). The document is not a food safety standard, but rather specifies a process by which food safety schemes may gain recognition, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation) in relation to food safety (Ref. 17). This benchmark document has provisions relevant to supplier approval and verification programs. For example, it specifies that a food safety standard must require that the organization control purchasing processes to ensure that all externally sourced materials and services that have an effect on food safety conform to requirements. It also specifies that a food safety standard must require that the organization establish, implement, and maintain procedures for the evaluation, approval and continued monitoring of suppliers that have an effect on food safety. Thus, all current GFSI-recognized schemes require supplier controls to ensure that the raw materials and ingredients that have an impact on food safety conform to specified requirements. The GFSI guidance document also requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization's facility (Ref. 17).

Because GFSI is a document that outlines elements of a food safety management system for benchmarking a variety of standards, it does not have details about how facilities should comply with the elements. This type of information is found in the food safety schemes that are the basis for certification programs. For example, the Safe Quality Food (SQF) 2000 Code, a HACCP-based supplier assurance code for the food industry, specifies that raw materials and services that impact on finished product safety be supplied by an Approved Supplier. SQF 2000 specifies that the responsibility and methods for selecting, evaluating, approving and monitoring an Approved Supplier be documented and implemented, and that a register of Approved Suppliers and records of inspections and audits of Approved Suppliers be maintained. SQF 2000 requires that the Approved Supplier Program contain, among other items, agreed specifications; methods for granting Approved Supplier status; methods and frequency of monitoring Approved Suppliers; and details of certificates of analysis if required.

According to SQF, the monitoring of Approved Suppliers is to be based on the prior good performance of a supplier and the risk level of the raw materials supplied. The monitoring and assessment of Approved Suppliers can include:

- The inspection of raw materials received;
- The provision of certificates of analysis;
- Third party certification of an Approved Supplier; or
- The completion of 2nd party supplier audits.

III. References

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7. FDA, ''FDA Foods Program, The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration. First Annual Report: September 8, 2009–September 7, 2010,'' January, 2011.
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9. Centers for Disease Control and Prevention (CDC), ''Multistate Outbreak of *Salmonella* Infections Associated with Peanut Butter and Peanut Butter-Containing Products-United States, 2008–2009,'' In: *Morbidity and Mortality Weekly Report* February 2009, (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5804a4.htm*), Date Last Reviewed: February 4, 2009 (accessed on August 27, 2013).
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15. Codex Alimentarius Commission, ''Recommended International Code of Practice General Principles of Food Hygiene, CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
16. FDA, ''Guidance for Industry—Voluntary Third-Party Certification Programs for Foods and Feeds,'' January 2009.
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Dated: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25126 Filed 10–25–13; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 78 Tuesday,

No. 209 October 29, 2013

Part VI

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Endangered Status for Vandenberg Monkeyflower; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2013–0078; 4500030113]

RIN 1018–AY27

Endangered and Threatened Wildlife and Plants; Endangered Status for Vandenberg Monkeyflower

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to list Vandenberg monkeyflower as an endangered species under the Endangered Species Act. If we finalize this rule as proposed, it would extend the Endangered Species Act's protections to this plant. The effect of this regulation will be to add Vandenberg monkeyflower to the List of Endangered and Threatened Plants under the Endangered Species Act.

DATES: We will accept all comments received or postmarked on or before December 30, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by December 13, 2013.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov* and search for FWS–R8–ES–2013–0078, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R8–ES–2013–0078; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all information received on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the *Information Requested* section below for more information).

FOR FURTHER INFORMATION CONTACT: Stephen P. Henry, Acting Field Supervisor, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003; telephone 805–644–1766; facsimile 805–644–3958. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, et seq.) (Act), if a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designations and revisions of critical habitat can only be completed by issuing a rule.

This rule consists of a proposed rule to list Vandenberg monkeyflower (previously identified as a candidate for listing by the name *Mimulus fremontii* var. *vandenbergensis,* currently known as *Diplacus vandenbergensis,* and hereafter referred to as Vandenberg monkeyflower, with the exception of the *Description and Taxonomy* section below) as an endangered species. This plant occurs in nine locations exclusively on Burton Mesa, a distinct geographic region in Santa Barbara County, California.

The basis for our action. Under the Act, we can determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence.

We have determined Vandenberg monkeyflower faces threats under Factors A, D, and E. The greatest threat to Vandenberg monkeyflower is the presence and expansion of invasive, nonnative plants that are abundant on Burton Mesa, particularly occurring within or adjacent to all known occurrences of Vandenberg monkeyflower. Vandenberg monkeyflower habitat includes sandy openings (canopy gaps) within the dominant vegetation. Ground-disturbing activities (including wildfires) create additional open areas that are invaded by nonnative plants, which precludes establishment of Vandenberg monkeyflower. Furthermore, the availability of habitat for Vandenberg monkeyflower and its small overall population size may be affected by a suite of threats (including stochastic events such as wildfire and a changing climate) acting synergistically on the species. Based on the best available scientific and commercial information, we find that the species has a restricted range, faces ongoing and future threats across its range, and is in danger of extinction throughout all of its range.

We will seek peer review. We are seeking comments from knowledgeable individuals with scientific expertise to review our analysis of the best available science and application of that science and to provide any additional scientific information to improve this proposed rule. Because we will consider all comments and information received during the comment period, our final determination may differ from this proposal.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from the public, other concerned governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The species' biology, range, and population trends, including:

(a) Habitat requirements for establishment, growth, and reproduction;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat, or both.

(2) The factors that are the basis for making a listing determination for a species under section 4(a) of the Act (16 U.S.C. 1533(a)), which are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to Vandenberg monkeyflower and regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of Vandenberg monkeyflower, including the locations of any additional occurrences of this species.

(5) Current or planned activities in the areas occupied by Vandenberg monkeyflower and possible impacts of these activities on this species and its habitat.

(6) Information on the projected and reasonably likely impacts of climate change on Vandenberg monkeyflower and its habitat.

(7) Information related to our interpretation and analysis of the best scientific and commercial data and our proposed status determination for the species.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information may not meet the standard of information required by section 4(b)(1)(A) of the Act, which requires that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov*. Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection at *http://www.regulations.gov,* or by appointment during normal business hours at the U.S. Fish and Wildlife Service, Ventura Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Previous Federal Actions

We first identified Vandenberg monkeyflower as a candidate species in a notice of review published in the **Federal Register** on November 10, 2010 (75 FR 69222). Vandenberg monkeyflower was given a listing priority number of 3, which denotes a subspecies [or variety] facing an imminent threat of high magnitude. Notices of review reconfirming its candidate status were also published in the **Federal Register** on October 26, 2011 (76 FR 66370), and November 21, 2012 (77 FR 69994). Candidate taxa are plants and animals for which the Service has sufficient information on their biological status and threats to propose them as endangered or threatened under the Act, but for which development of a proposed listing regulation is precluded by other higher priority listing activities. We may identify a taxon as a candidate for listing after we conduct an evaluation of its status on our own initiative, or after we make a positive finding on a petition to list a species. No petitions seeking the listing of Vandenberg monkeyflower have been submitted nor have other Federal reviews been conducted for Vandenberg monkeyflower.

On May 10, 2011, we filed a multiyear work plan as part of a proposed settlement agreement with Wild Earth Guardians and others in a consolidated case in the U.S. District Court for the District of Columbia. On September 9, 2011, the court accepted our agreement with plaintiffs in *Endangered Species Act Section 4 Deadline Litig.,* Misc. Action No. 10–377 (EGS), MDL Docket No. 2165 (D. DC) (known as the ''MDL case'') on a schedule to publish proposed rules or not-warranted findings for the 251 species designated as candidates in 2010 no later than September 30, 2016. We are submitting this proposed rule in compliance with the MDL settlement agreement.

Elsewhere in today's **Federal Register**, we propose to designate critical habitat for Vandenberg monkeyflower under the Act.

Status Assessment for Vandenberg Monkeyflower

Background

It is our intent to discuss below only those topics directly relevant to the listing of Vandenberg monkeyflower as endangered in this section of the proposed rule.

Description and Taxonomy

Vandenberg monkeyflower is a small, annual herbaceous plant that grows from 0.5 to 10 inches (in) (1.2 to 25.4 centimeters (cm)) tall. The stems are glandular and usually green with purplish tinting. Leaves are obovate (narrowly elliptic) and reach 1.2 in (3 cm) in length. Plants produce a single flower or plants are branched producing multiple flowers. The tubular yellow flowers are bilaterally symmetrical, with the distal ends of the petals forming a unique structure that is likened to a face; hence the common name monkeyflower. Seed capsules are ovoid and reach 0.5 in (1.3 cm) in length. The capsule splits open longitudinally from the tip to release approximately 20 to 100 seeds.

Vandenberg monkeyflower was first described as *Mimulus fremontii* (Benth.) A. Gray var. *vandenbergensis* D.M. Thompson (Thompson 2005, p. 134) as a member of the Scrophulariaceae (figwort family). This is the name and family placement we have previously followed. Molecular systematics studies examining members of the Scrophulariaceae, including *Mimulus,* determined that this genus and a few others constituted a separate monophyletic group warranting recognition at the family rank as Phrymaceae (Beardsley and Olmstead 2002, pp. 1193–1101; Olmstead 2002, p. 18). Placement of *Mimulus* in the family Phrymaceae is recognized by species experts, is used in the recent flora of California (Thompson 2012, pp. 988–998), and will be treated as such in the upcoming volume of the *Flora of North America.*

In 2012, Barker *et al.* (2012) recognized a redefined genus *Diplacus* that includes 46 taxa previously segregated as *Mimulus,* including Vandenberg monkeyflower as *Diplacus vandenbergensis* (D.M. Thompson) Nesom (Barker *et al.* 2012, p. 29). The citation in Barker *et al.* (2012, p. 29) attributes the nomenclatural combination at the species rank to Nesom in Phytoneuron 2012–47: 2, which was published electronically on the same day as Barker *et al.* (2012). The

current citation for Vandenberg monkeyflower is at the species rank as *Diplacus vandenbergensis* (D.M. Thompson) G.L. Nesom. This combination is accepted by species and genus experts and will be used in the upcoming treatment in the *Flora of North America.* Accordingly, we will use the correct name (*Diplacus vandenbergensis*) and family attribution (Phrymaceae) throughout this and subsequent documents.

Life History

The life history of Vandenberg monkeyflower has not been thoroughly studied, but certain characteristics appear similar to other small annual herbs. Vandenberg monkeyflower is shallow-rooted (Thompson 2005, p.131; Consortium of California Herbaria (Consortium 2010)) and has seeds that germinate during winter rains, typically between November and February (Thompson 2005, p. 23), which is similar to other small annual species that grow in sandy openings in chaparral and are adapted to the Mediterranean climate zone of California. For instance, *Lessingia glandulifera* (lessingia) is an annual herb that grows in sandy openings in chaparral, is shallow-rooted, and is commonly associated with Vandenberg monkeyflower (Davis and Mooney 1985, p. 528). Rooting depth is positively related to above-ground size, with annuals having the smallest above-ground size and rooting depth in the soil (Schenk and Jackson 2002, pp. 484–485).

Vandenberg monkeyflower is sensitive to annual levels of rainfall (Thompson 2005, p. 23), and, therefore, germination of resident seed banks may be low or nonexistent in unfavorable years, with little or no visible aboveground expression of the species. Many annual monkeyflower species, including Vandenberg monkeyflower, need early rainfall along with continued rains in late winter or early spring for a substantial number of seeds to germinate, and do not respond well when only later rainfall is available (Thompson 2005, p. 23; Fraga *in litt.* 2012). Vandenberg monkeyflower flowers mostly from late March through June with fruits maturing from late April through July (Thompson 2005, p. 130).

Seed banks develop when a plant produces more viable seeds than germinate in any given year. Seed banks contribute to the long-term persistence of a species by sustaining them through periods when conditions are not conducive to adequately germinate, reproduce, and replenish the seed bank (such as when there is not sufficient rainfall for plants to germinate, grow, and produce enough seeds to maintain the population at the same size from year to year) (Rees and Long 1992, entire; Adams *et al.* 2005, pp. 432–434; Satterthwaite *et al.* 2007, entire). The annual differences in the numbers and location of aboveground plants indicate the presence of a seed bank.

The reproductive biology of Vandenberg monkeyflower has not been specifically studied; however, it is likely similar to closely related *Diplacus* species that occur in similar habitats. In general, annual species of *Diplacus* are self-compatible (able to be fertilized by its own pollen) but are also visited by a wide array of pollinators, which results in a mixed mating system that utilizes both self-fertilization and cross-fertilization (Sutherland and Vickery 1988, p. 334; Leclerc-Potvin and Ritland 1994, pp. 201–204; Fraga *in litt.* 2012). The large size of the flower relative to the size of the plant suggests that Vandenberg monkeyflower is allocating significant resources into attracting pollinators; therefore, this species is thought to typically breed through outcrossing, and is dependent on pollinators to achieve seed production (Fraga *in litt.* 2012).

Species of *Diplacus* are predominantly bee-pollinated, although the genus also includes species that are pollinated by hummingbirds, hawk moths (Sphingidae), beeflies (Bombyliidae), and other flies (order Diptera) (Wu *et al.* 2008, p. 224). Species of bees that have been observed to visit flowers of Vandenberg monkeyflower include sweat bees (*Dufourea versatilis rubriventris*), miner bees (*Perdita nitens, Caliopsis* [*Nomadopsis*] *fracta* and *C. Nomadopsis trifolii*), mason bees (*Hoplitis product bernardina*), and leaf-cutter bees (*Anthidium collectum, Chelostoma cockerelli, C. minutum, C. phaceliae, Chelostomopsis rubifloris,* and *Ashmeadiella timberlakei timberlakei*) (Krombein *et al.* 1979, pp. 1863–2030; Bugguide 2012; The Xerces Society 2012). Additionally, Inouye (*in litt.* 2012) observed that small solitary bees were the most common pollinators on three other species of small annual monkeyflower species from dry and mesic habitats (*D. androsaceus, D. angustatus,* and *D. douglasii*); and Fraga (*in litt.* 2012) has observed halictid bees (Halictidae) on other small monkeyflower species.

Seeds of Vandenberg monkeyflower are small and light in weight, dispersing primarily by gravity and also by water and wind over relatively short distances (Thompson 2005, p. 130; Fraga *in litt.* 2012). The small size of the seed makes it likely that short-distance dispersal could also be facilitated by ants, as has been noted for other small-seeded plant taxa (Cain *et al.* 1998, pp. 328–330). Given that the Burton Mesa area is subject to occasional high winds (see discussion in *Climate* section below), long-distance dispersal likely occurs during these wind events. Wind dispersal results in a random dispersal of seeds, some of which fall into suitable habitat and some do not.

Geographic Setting

Vandenberg monkeyflower occurs only at low elevations and close to the coast in a distinct region in western Santa Barbara County known as Burton Mesa (Wilken and Wardlaw 2010, p. 2). Burton Mesa is a physiographic region situated between the Purisima Hills to the north and the Santa Ynez River to the south. The topography of Burton Mesa comprises a low, flat-topped series of hills averaging 400 feet (ft) (133 meters (m)) in elevation (Ferren *et al.* 1984, p. 3; Dibblee 1988). Level upland expanses from 328 to 394 ft (100 to 120 m) above sea level are dissected by streams that have formed wide valleys with short steep slopes (Davis 1987, p. 318). Underlying this region is the Burton Mesa dune sheet, which extends from Shuman Canyon on Vandenberg Air Force Base (AFB) in the north, roughly southeast along the southern slopes of the Purisima Hills and eastward to a point approximately 22 mi (35 km) from the present shoreline in the Santa Ynez River Valley (Cooper 1967, pp. 89–91; Hunt 1993, pp. 8–9).

Climate

Burton Mesa experiences a Mediterranean climate, with mild, moist winters and moderately warm, rainless summers. The region is strongly influenced by the prevailing westerly transoceanic air currents. Late afternoon and early evening are often characterized by onshore breezes or winds during most of the year, but winds are strongest and persistent in late spring and early summer. A marine layer or fog characterizes this coastal region and is heaviest during late spring and early summer mornings. Frost is also a regular occurrence in winter, especially in low-lying areas (Gevirtz *et al.* 2007, p. 39).

Habitat

Burton Mesa supports a mosaic of several native vegetation types, including maritime chaparral, maritime chaparral mixed with coastal scrub, oak woodland, and small patches of native grasslands (Wilken and Wardlaw 2010,

p. 2). The maritime chaparral on Burton Mesa is referred to as Burton Mesa chaparral (Odion *et al.* 1992, pp. 5–6; Sawyer *et al.* 2009, p. 376), and is dominated by evergreen shrubs and scattered multi-trunked *Quercus agrifolia* (coast live oak) that form open stands to almost impenetrable thickets over large areas of Burton Mesa, with heights reaching up to 13 ft (4 m) (Gevirtz *et al.* 2007, pp. 95–96). The dominant endemic species of Burton Mesa chaparral include *Ceanothus* (*Ceanothus impressus* var. *impressus* (Santa Barbara ceanothus) and *C. cuneatus* var. *fascicularis* (Lompoc ceanothus)) and *Arctostaphylos* (*Arctostaphylos purissima* (Purisima manzanita) and *A. rudis* (shagbark manzanita)), along with the more widespread *Adenostoma fasciculatum* (chamise), *Heteromeles arbutifolia* (toyon), *Cercocarpus betuloides* (birchleaf mountain mahogany), *Salvia mellifera* (black sage), and *Rhamnus californica* (California coffeeberry).

Coast live oak is an important dominant in many places on Burton Mesa, attaining 40 to 70 percent crown cover in older undisturbed patches of habitat. *Ericameria ericoides* (mock heather), with its wind-dispersed seeds, is most often observed at trail edges in dense chaparral, but appears in greater numbers in large open areas and coastal scrub (Gevirtz *et al.* 2007, p. 96). Annual grassland and coastal sage scrub characterized by mock heather, *Artemisia californica* (California sagebrush), and *Baccharis pilularis* (coyote brush) occur on formerly cleared sites and on xeric (dry) slopes. Some poorly drained upland sites in the central and western portions of Burton Mesa form seasonal wetlands characterized by native perennial grasses such as *Elymus glaucus* (blue wildrye) and vernal pool species including *Eryngium armatum* (coastal button-celery) (Davis *et al.* 1988, p. 172). The vegetation transitions to coastal sage scrub habitat as it nears the ocean and into other terrestrial habitats east of Purisima Canyon on the eastern side of La Purisima Mission State Historic Park (SHP) (Gevirtz *et al.* 2005, p. 86). The edaphic (soil) variable with the greatest effect on vegetation composition is the depth of soil overlying the bedrock or subsoil pan (Davis *et al.* 1988, p. 188). Soils on Burton Mesa become very shallow toward the north and west, and chaparral shrubs decrease in height and density with decreasing soil depth (Odion *et al.* 1992, p. 6).

Vandenberg monkeyflower does not grow beneath the canopy of shrubs or oaks, but rather in the sandy openings (canopy gaps) that occur in-between shrubs. Sandy openings have been noted for their high abundance and diversity of annual and perennial herbaceous species, compared to those found in the understory of the shrub canopy (Hickson 1987, Davis *et al.* 1989; Keeley *et al.* 1981; Horton and Kraebel 1955). Vandenberg monkeyflower is currently known to occur within sandy openings at nine extant locations; one additional location is potentially extirpated (see *Distribution of Vandenberg Monkeyflower* below). Because portions of Burton Mesa are inaccessible and difficult to survey, Vandenberg monkeyflower has the potential to occur in areas where it has not yet been observed within sandy openings. However, not all sandy openings within the shrub canopy appear to be currently suitable for Vandenberg monkeyflower because some of the sandy openings consist of sands that structurally seem more consolidated and currently do not support this species (Rutherford *in litt.* 2012). To date, all of the extant occurrences of Vandenberg monkeyflower are within sandy openings where the structure of the sands appears loose (Rutherford *in litt.* 2012).

The amount of Vandenberg monkeyflower suitable habitat currently available has changed over time. Prior to 1938, approximately 23,550 ac (9,350 ha) of maritime chaparral was present on Burton Mesa (Hickson 1987, p. 34). For the purposes of this analysis, we determined in 2012 that approximately 10,057 ac (4,070 ha) of maritime chaparral habitat remain on Burton Mesa, which represents a loss of 53 percent of the original upland habitat (Figure 1; Service 2012a, unpublished data). We then estimated the amount of Burton Mesa considered as sandy openings where Vandenberg monkeyflower could potentially occur. Based on inspection of color imagery (National Agriculture Imagery Program (NAIP) 2009) of areas within Burton Mesa where this species occurs, we used the range of image pixel values among 20 point locations to define bare ground while all other pixel values defined vegetated areas. We calculated the total area encompassed by bare ground and vegetation by multiplying the number of bare ground and vegetated pixels by 1 square meter (the ground resolution of a pixel in the NAIP data). Roads, buried pipeline rights-of-way, and building footprints were removed to estimate the percent of Burton Mesa that currently comprise sandy openings.

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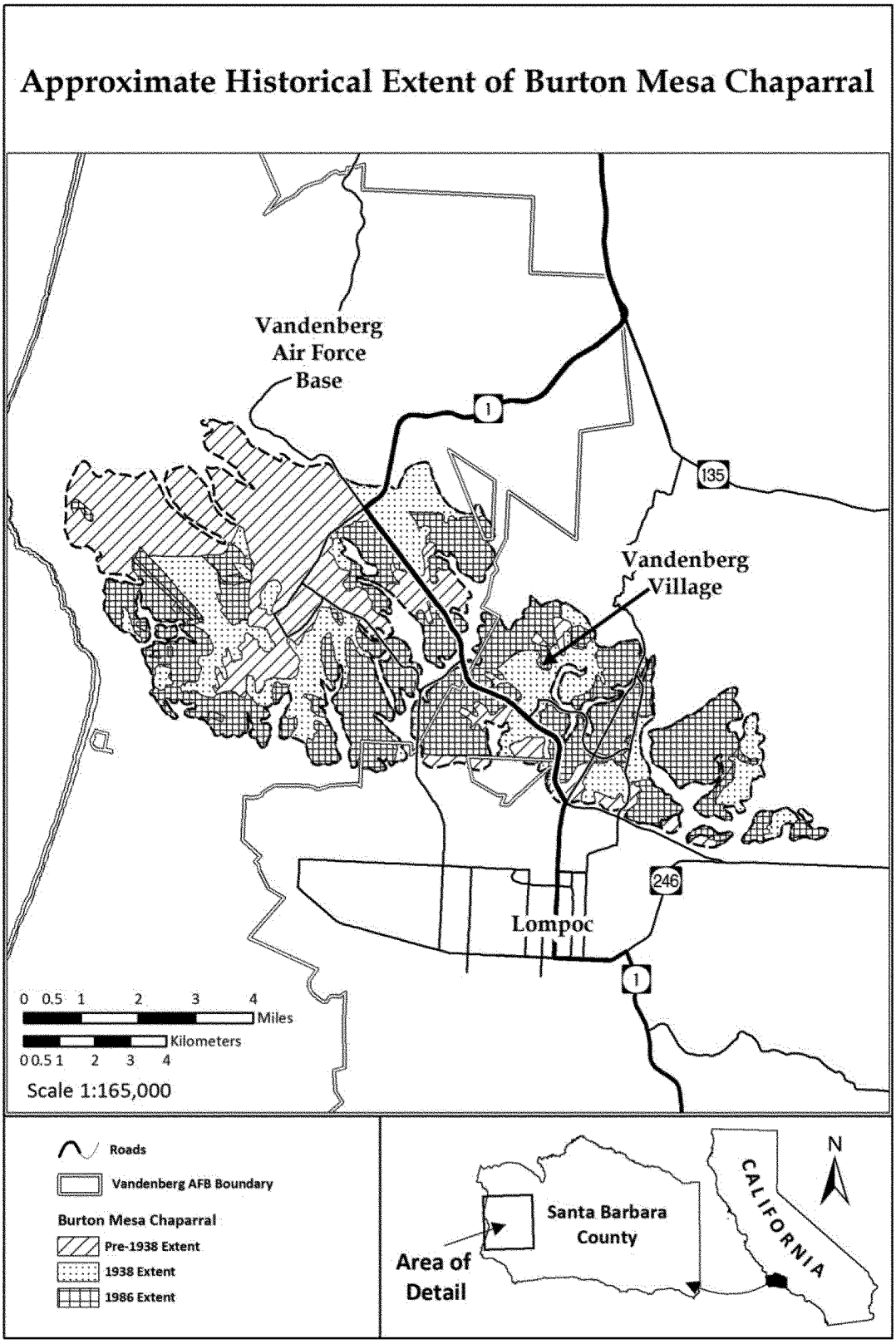


FIGURE 1. Approximate historical extent of Burton Mesa chaparral.

Results indicate up to approximately 20 percent of the total area of remaining Burton Mesa chaparral comprises sandy openings, which is a high estimate because this may include areas of bare ground that are not sandy openings suitable for Vandenberg monkeyflower, such as walking trails (Service 2012b, unpublished data). The percentage

would likely change over time depending on whether chaparral stands continue to age and increase in canopy cover, or are burned to temporarily increase the amount of sandy openings. Additionally, the location of sandy openings on Burton Mesa would likely shift over time because individual shrubs continue to mature and increase in cover or die, creating temporary gaps in the shrub canopy.

The structure of Burton Mesa chaparral comprises a mosaic of vegetation patches interspersed with sandy openings that varies from place to place. Within a given substrate, the chaparral composition is a reflection of stand age or shrub canopy cover, disturbance history (whether the area was cleared in the past or nonnative species were planted), history of wildfire, and distance from the coast (Davis *et al.* 1988, p. 188; Gevirtz *et al.* 2007, p. 97). Although the sandy openings that Vandenberg monkeyflower occupies are only a small percent of the total amount of Burton Mesa chaparral habitat, because the sandy openings and vegetation form a mosaic vegetation community that structurally may vary over time, it is impossible to separate out the sandy openings from the rest of the Burton Mesa chaparral vegetation. Therefore, for the purposes of this rule, we consider suitable Vandenberg monkeyflower habitat to consist of Burton Mesa chaparral, which would include the sandy openings and the dominant vegetation that characterize this vegetation community.

Other low-growing native annual species that often co-occur with Vandenberg monkeyflower in sandy openings include: *Mucronea californica* (California spineflower); *Castillleja exserta* (purple owl's clover); *Logfia filaginoides* (California filago); *Lessingia glandulifera* (lessingia); *Layia glandulosa* (white tidy tips); *Chaenactis glabriuscula* (pincushion); and *Plantago erecta* (plantain). Frequently co-occurring herbaceous native perennial species include *Horkelia cuneata* (horkelia) and *Croton californicus* (croton) (Meyer *in litt.* 2010a). Nonnative annual and perennial species are also known to occur in Vandenberg monkeyflower habitat. Nonnative annual species include (but are not limited to) *Bromus diandrus* (ripgut brome) and *Hypochaeris glabra* (smooth cat's-ear) (Meyer *in litt.* 2010a). Nonnative perennial species include: *Ehrharta calycina* (South African perennial veldt grass (veldt grass)), *Carpobrotus edulis* (iceplant), *Brassica tournefortii* (Sahara mustard), and *Cortaderia jubata* (pampas grass).

Land Ownership

The western portion of Burton Mesa is Federal land within Vandenberg AFB (Davis *et al.* 1988, p. 170). Vandenberg AFB contains approximately 99,000 acres (ac) (40,064 hectares (ha)); approximately 8,114 ac (3,284 ha) is maritime chaparral mixed with coastal sage scrub, veldt grass, pampas grass, herbs, and coast live oak on Burton Mesa within Base boundaries (Air Force 2011c, Appendix A—Figure 5–3; Lum *in litt.* 2012d). Vandenberg AFB is managed by the U.S. Air Force.

To the east of Vandenberg AFB, the State of California received 5,078 ac (2,055 ha) from Union Oil Company in 1990 as part of a settlement of two antitrust lawsuits (Gevirtz *et al.* 2007, p. 2). The land acquired by the State formed the Burton Mesa Ecological Reserve (Reserve) and encompasses most of the maritime chaparral that occurs to the east of Vandenberg AFB (Odion *et al.* 1992, p. 6). The western boundary of the Reserve abuts the eastern boundary of Vandenberg AFB and is delineated by a 100-ft (30-m) wide fuel break (a gap in vegetation designed to act as a barrier to slow progress of a potential wildfire). Additional lands have since been added to the Reserve since 1990, bringing its total acreage to 5,186 ac (2,099 ha) (Gevirtz *et al.* 2007, p. 3). The Reserve contains five management units (Vandenberg, Santa Lucia, Purisima Hills, Encina, and La Purisima) and is situated on the eastern Burton Mesa and foothills of the Purisima Hills (Gevirtz *et al.* 2007, p. 7). The Reserve is managed by the California Department of Fish and Wildlife (CDFW). CDFW was formerly California Department of Fish and Game (CDFG), and because historic documents prior to 2013 use this old name, the abbreviations CDFG and CDFW will both be used interchangeably for references cited throughout the remainder of this document.

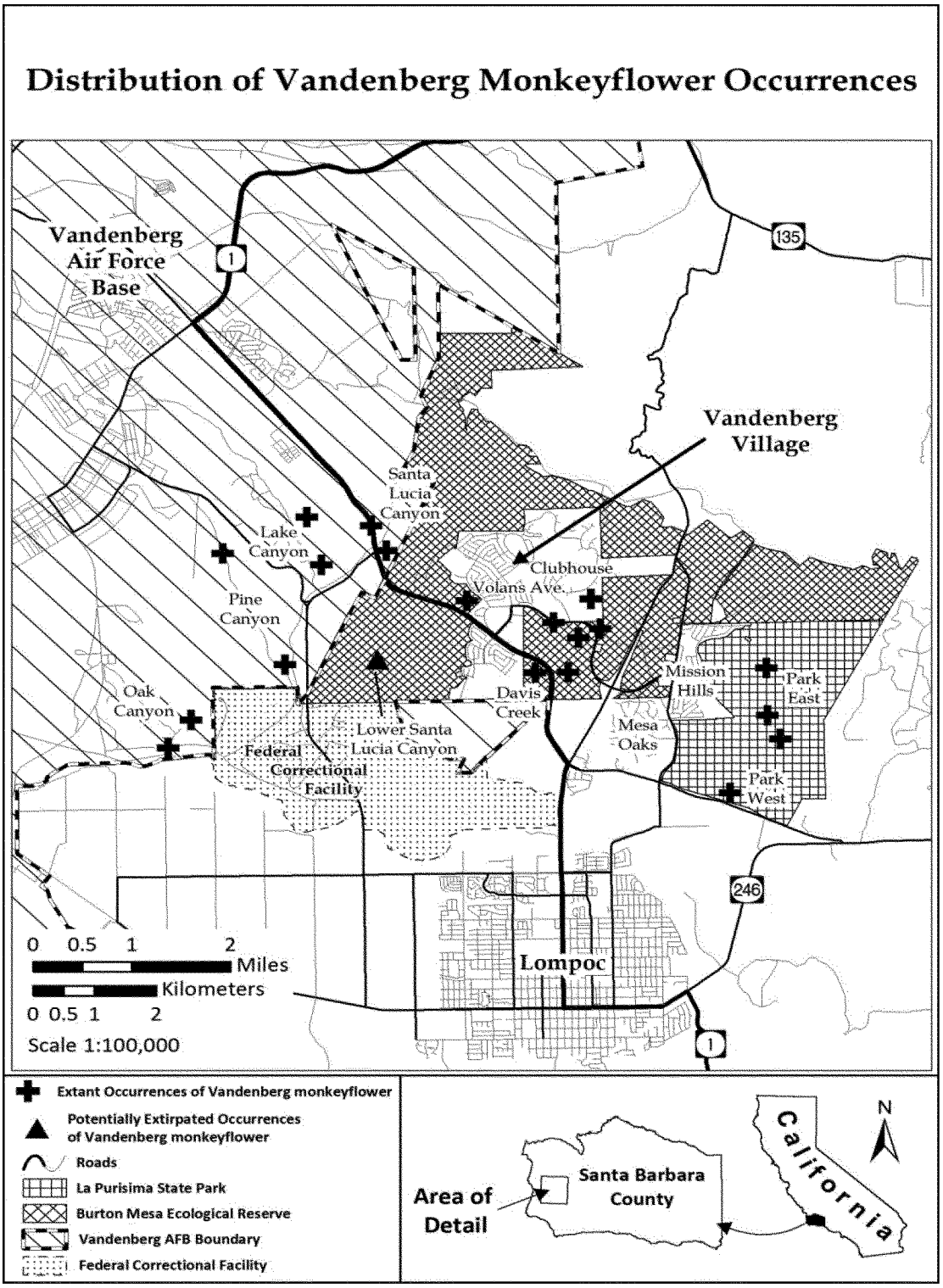
Residential communities such as Vandenberg Village, Clubhouse Estates, Mesa Oaks, and Mission Hills fragment (divide into small noncontiguous pieces) the Reserve and other non-Federal lands on Burton Mesa. The southern portion of the mesa and beyond the southern boundary of the Reserve comprises agricultural lands as well as land owned by the Department of Justice (which houses the U.S. Bureau of Prisons Federal Penitentiary Complex at Lompoc (Lompoc Penitentiary)). The jagged northern perimeter of Burton Mesa is adjacent to an active oil field operated by Plains Exploration and Production Company (PXP).

To the east of the Reserve, La Purisima Mission State Historic Park (SHP) contains 980 ac (397 ha) (California State Parks 1991, p. 9) and is separated from the Reserve by the residential communities of Mesa Oaks and Mission Hills. La Purisima Mission SHP also abuts the southern boundary of the La Purisima Management Unit of the Reserve. California State Parks manages La Purisima Mission SHP.

Distribution of Vandenberg Monkeyflower

For the purposes of this rule, we define the following terms to refer to individuals of Vandenberg monkeyflower and where they occur. We use the term ''occurrence'' (consistent with the definition for ''element occurrence'' used by the California Natural Diversity Data Base (CNDDB)) to be a grouping of plants (individuals) within 0.25 mi (0.4 km) proximity (CNDDB 2010). There may be one or more discrete groupings of plants (individuals) within a single occurrence. We use the term ''location'' to refer only to a particular site, area, or region, as in ''at that location,'' with no relation to an assemblage of plants (e.g., polygon, occurrence, population).

We generally describe the area on Burton Mesa where Vandenberg monkeyflower currently occurs as a crescent-shaped area approximately 7 mi (10.7 km) long by 2 mi (3.0 km) wide. All extant individuals of Vandenberg monkeyflower are located within this area (Consortium) 2010), almost exclusively occurring on thin layers of aeolian- (wind-) deposited sands between approximately 100 and 400 ft (30 to 122 m) in elevation (Wilken and Wardlaw 2010, p. 2). We based the description of suitable habitat on viewing U.S. Geological Survey maps and Google Earth©, and looking at how the occurrences of Vandenberg monkeyflower were spread across the landscape. We did not analyze biological factors such as vegetation or soil type when describing this general area where the species occurs. A discussion of where Vandenberg monkeyflower has been historically observed and where it is currently known to occur follows below. Additionally, Figure 2 includes the known distribution of Vandenberg monkeyflower across its range based on the most recent survey data; Table 1 lists the names of the occurrences, land ownership, and status of each known and historical occurrence.



*Santa Rita Valley occurrence (extirpated) is to the east of the area shown on the map.

FIGURE 2. Distribution of Vandenberg monkeyflower occurrences.

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Historical Locations

We are aware of historical herbarium collections of Vandenberg monkeyflower from two locations; one of these (Santa Rita Valley) no longer supports habitat for this species (Consortium 2010), and we consider it to be extirpated. The second collection was made from Lower Pine Canyon; although plants have not been relocated at lower Pine Canyon, we consider this collection to be a part of the Pine Canyon occurrence, which is extant. In addition to these two collections, an

historical occurrence of Vandenberg monkeyflower was observed, but not collected, from Lower Santa Lucia Canyon; we consider it to be potentially extirpated. Additional detail on the occurrence of Vandenberg monkeyflower at these three historical locations is provided below.

The first historical collection of Vandenberg monkeyflower was made in 1931 from the Santa Ynez Valley approximately 5 mi (8 km) west of Buellton along State Highway 246 and east of La Purisima (Consortium 2010; Santa Barbara Botanic Garden (SBBG) 2005). This site was surveyed multiple times in 2006 (Wilken and Wardlaw 2010, Appendix 2); however, no Vandenberg monkeyflower were seen. At some point prior to 1931, seed from Burton Mesa may have blown downwind to this location, but it appears that Vandenberg monkeyflower has been extirpated at this location because no suitable habitat remains due to agricultural conversion (including vineyards and berries (Elvin 2009, pers. obs.) and heavily grazed pastureland (Wilken and Wardlaw 2010, Appendix 2). Therefore, we consider the occurrence of Vandenberg monkeyflower to be extirpated from this location.

The second historical collection of Vandenberg monkeyflower was made in 1960 near lower Pine Canyon (part of the existing Pine Canyon occurrence) on the eastern edge of Vandenberg AFB (Jepson Herbarium 2006; Rancho Santa Ana Botanic Garden 2006). Vandenberg monkeyflower had not been documented since it was collected there in 1960; however, it was observed in 2010 and 2012 up-canyon from this historical location (Lum *in litt.* 2012a, Rutherford *in litt.* 2012) where suitable habitat remains. (See further discussion of Pine Canyon in *Current Locations* section below). The description of the location of this historical occurrence is not precise enough to determine that the location is distinct from, and not part of, the location where an extant occurrence was observed in 2010 and 2012 in upper Pine Canyon (See *Occurrences Located on Vandenberg AFB* section below). Therefore, we consider the historical occurrence of Vandenberg monkeyflower to be part of the extant Pine Canyon occurrence.

The third historical location of Vandenberg monkeyflower was observed, but not collected, in 1985 in the southwestern portion of the Vandenberg Management Unit on the Reserve (Hickson *in litt.* 2007). Although no collection was made, we have a high confidence in the accuracy of the observation (known as the Lower Santa Lucia Canyon occurrence; Figure 2) because it was made during the course of a vegetation study for a master's thesis (Hickson *in litt.* 2007). The location had not been searched for the species between 1985 and 2011; in 2012 (a low rainfall year), CDFW staff (Meyer) conducted a cursory survey and was unable to relocate the species (Meyer *in litt.* 2012c). Because it has been approximately 30 years (albeit with little survey effort between 1985 and 2011) since it was last observed, and suitable habitat remains but is overcrowded with invasive, nonnative plants (see *Factor A—Invasive, Nonnative Plants*), we consider the occurrence of Vandenberg monkeyflower at this historical location to be potentially extirpated.

Current Status of Vandenberg Monkeyflower

Because we do not have a wealth of survey data over multiple years to analyze a trend in the long-term persistence of Vandenberg monkeyflower, we consider it most appropriate to use suitable habitat trends as a surrogate for the species' trend. Thus, an increase or decrease in the amount of suitable habitat likely results in a respective increase or decrease in the Vandenberg monkeyflower population.

Surveys for Vandenberg monkeyflower have occurred across this species' range on Burton Mesa during recent years, although the level of effort and precision of the surveys varied between the different biologists who conducted surveys. In 2006, the first year that a concerted effort was made to survey most of the known locations, approximately 2,700 individuals were observed during surveys throughout the known range of the species (Ballard 2006; Wilken and Wardlaw 2010, pp. 2–3, Appendices 1, 2). In 2010, the Air Force observed approximately 5,200 individuals during surveys conducted on 376 ac (152 ha) within Vandenberg AFB (Air Force 2012).

In other years, individuals and agencies (including Air Force, CDFW, and our biologists) have conducted opportunistic surveys of specific sites where this species occurs, but rangewide surveys have not been conducted since 2006. Ballard (*in litt.* 2009) searched for Vandenberg monkeyflower in areas between extant occurrences and on the periphery of the plant's known distribution but found no plants. Additionally, the species has not been observed in some areas with sandy openings that appear to be suitable habitat (Ballard *in litt.* 2009). These areas: (1) Appear slightly degraded, even though many species commonly associated with Vandenberg monkeyflower were often abundant; (2) contain small pockets of sandy openings, but the sands did not appear to contain a loose enough structure to support Vandenberg monkeyflower; or (3) harbor a dominant amount of invasive, nonnative plants within sandy openings. The ability for Vandenberg monkeyflower to grow in sandy openings may depend upon the stand age and disturbance history of the location, as well as edaphic factors (Davis *et al.* 1988, p. 188), along with the amount of rainfall, size of the seed bank, and competition with invasive, nonnative plants.

The following sections provide a description of nine specific locations (which contain all extant occurrences identified in Figure 2) where Vandenberg monkeyflower is known to occur, hereby referred to as nine occurrences. All known occurrences are on the following lands: Vandenberg AFB (four occurrences), Burton Mesa Ecological Reserve (three occurrences), and La Purisima Mission SHP (two occurrences) (See Figure 2; Table 1).

TABLE 1—VANDENBERG MONKEYFLOWER LOCATIONS, LAND OWNERSHIP, AND CURRENT STATUS

Vandenberg monkeyflower locations	Land ownership	Current status
Current Locations		
1. Oak Canyon	Vandenberg AFB	Extant.
2. Pine Canyon (includes historical location in lower Pine Canyon).	Vandenberg AFB	Extant.
3. Lake Canyon	Vandenberg AFB	Extant.
4. Santa Lucia Canyon	Vandenberg AFB	Extant.
5. Volans Avenue	Burton Mesa Ecological Reserve	Extant.

TABLE 1—VANDENBERG MONKEYFLOWER LOCATIONS, LAND OWNERSHIP, AND CURRENT STATUS—Continued

Vandenberg monkeyflower locations	Land ownership	Current status
6. Clubhouse Estates	Burton Mesa Ecological Reserve and Private lands.	Extant.
7. Davis Creek	Burton Mesa Ecological Reserve	Extant.
8. La Purisima West	La Purisima Mission State Historic Park	Extant.
9. La Purisima East	La Purisima Mission State Historic Park	Extant.
Historical Locations		
Santa Rita Valley	Private lands	Extirpated.
Lower Santa Lucia Canyon	Burton Mesa Ecological Reserve	Potentially Extirpated.

Occurrences Located on Vandenberg AFB

There are four locations on Vandenberg AFB that are known to support occurrences of Vandenberg monkeyflower. We refer to these four locations as the Oak, Pine, Lake, and Santa Lucia Canyons occurrences.

(1) *Oak Canyon.* Vandenberg monkeyflower was reported as common in the late 1980s or early 1990s (Odion *in litt.* 2006) at the mouth of Oak Canyon on the eastern edge of the Base. Four individuals were found in 2006 (Ventura Fish and Wildlife Herbarium (VFWO) 2013). Although no plants were found in 2010 or 2012 (Air Force 2012, p. 1; Lum *in litt.* 2012b; Rutherford *in litt.* 2012), as discussed above in the *Background—Life History* section, we consider the species to be extant at this location because it has only been 7 years since individuals were last seen, and it is likely that a residual seed bank is still present.

(2) *Pine Canyon.* Approximately 365 individuals were present in multiple scattered occurrences in upper Pine Canyon in 2010 (Lum *in litt.* 2012b), and approximately 100 individuals were observed in 2012 (Rutherford *in litt.* 2012).

(3) *Lake Canyon.* This occurrence contains the greatest number of individuals throughout this species' range and accounts for most of the individuals on Vandenberg AFB. Approximately 1,500 individuals were observed in 2006 and 1,000 individuals in 2007 (Elvin *in litt.* 2009; VFWO 2013). The most recent surveys in Lake Canyon occurred in 2010 and documented approximately 4,817 individuals (Lum *in litt.* 2012b), although these surveys likely included a larger portion of the canyon than surveys conducted in 2006 and 2007. Even though surveys have not occurred at this location since 2010, plants were also observed at several sites in Lake Canyon in 2012. Therefore, we consider the species to be extant at this location (Rutherford *in litt.* 2012). A seed bank is likely present.

(4) *Santa Lucia Canyon.* This canyon is located on the eastern edge of Vandenberg AFB at the junction of Santa Lucia and Lakes Canyons and abuts the Reserve that lies to the east. Approximately 25 individuals were observed in 2006 (Ballard 2006), and 1 individual was observed in 2010 (Lum *in litt.* 2012b). Although surveys have not occurred at this location since 2010, we consider the species to be extant at this location because it has only been 3 years since the species was last seen, and it is likely that a residual seed bank is still present.

Occurrences Located on Burton Mesa Ecological Reserve

Vandenberg monkeyflower occurs or partially occurs (i.e., part of the occurrence is on the Reserve and part of the occurrence is off the Reserve) at three locations within the Reserve. We refer to these locations as the Volans Avenue, Clubhouse Estates, and Davis Creek occurrences.

(5) *Volans Avenue.* Individuals of Vandenberg monkeyflower have been observed in the Santa Lucia Management Unit of the Reserve immediately west of Volans Avenue, between a portion of Vandenberg Village and California State Highway 1. The Santa Lucia Management Unit abuts the eastern boundary of Vandenberg AFB. Five plants were observed in 2003, and one plant was observed in 2007 (Meyer *in litt.* 2007). In the other years between 2004 and 2006, and in 2009, no plants were found (Meyer *in litt.* 2007; Ballard *in litt.* 2007; Meyer *in litt.* 2009a). Although no surveys have occurred since 2009, we consider the species to be extant at this location because it has only been 6 years since individuals were last seen, and it is likely that a residual seed bank is still present.

(6) *Clubhouse Estates.* Vandenberg monkeyflower occurs east of Vandenberg Village on both the privately owned Clubhouse Estates residential development project site, which has ongoing but differing levels of development since 2006, and an adjacent portion of the Encina Management Unit of the Reserve. Prior to 2006, most of the plants occurred on private property at the Clubhouse Estates project site (Scientific Applications International Corporation (SAIC) 2005b, Figure 4.3–2). Approximately 100–285 individuals were observed in 2006 (Wilken and Wardlaw 2010, Appendices 1, 2), and approximately 350–400 individuals were observed in 2009 (McGowan *in litt.* 2009). Although no surveys have occurred since 2009, we consider the species to be extant at this location because it has only been 4 years since individuals were last seen, and it is likely that both plants and a residual seed bank are present.

(7) *Davis Creek.* Vandenberg monkeyflower is located along the western border of the Encina Management Unit of the Reserve and a right-of-way (ROW) for California State Highway 1 managed by the California Department of Transportation. Davis Creek is east of Vandenberg Village and less than 1 mi (1.6 km) south of the Vandenberg monkeyflower individuals at Clubhouse Estates.

The Davis Creek occurrence comprises four locations where Vandenberg monkeyflower has been observed. At ''west of Highway 1,'' researchers reported 3 individuals in 2006 (Ballard 2006), approximately 100 in 2009 (Rutherford and Ballard *in litt.* 2009), and 60 in 2010 (Meyer *in litt.* 2010a). At ''north of Burton Mesa Boulevard,'' four individuals were observed in 2006 (Ballard 2006), and seven individuals were observed in 2010 (Meyer *in litt.* 2010a). Subsequently, 180 individuals were observed in 2010 at a third location east of the Vandenberg Village Community Services District Pump Station and between Highway 1 and Burton Mesa Boulevard (Meyer *in litt.* 2010a). Similarly, approximately 500

individuals were observed in 2010 at a fourth location northwest of the location where 180 individuals were observed in 2010, and to the west of the 7 individuals observed in 2010 that were located north of the Burton Mesa Boulevard. Individuals were also observed at several of these locations in 2012 and 2013. We consider the species to be extant at this location because individuals have been seen as recently as 2013 (Meyer *in litt.* 2013).

Occurrences Located on La Purisima Mission SHP

Vandenberg monkeyflower occurs at two separate locations within La Purisima Mission SHP. We refer to these locations of Vandenberg monkeyflower as the La Purisima West and La Purisima East occurrences.

(8) *La Purisima West.* Vandenberg monkeyflower that occur on the west side of the park are located in a discrete location. Approximately 300 individuals were observed in 2006 (Ballard 2006), and approximately 1,500 individuals were observed in 2009 (Rutherford and Ballard *in litt.* 2009). Subsequently, individuals were observed here in 2010 and 2011 but not counted (Rutherford *in litt.* 2012). Although no observations have occurred since 2011, we consider the species to be extant at this location because it has been only 2 years since individuals were last observed (although not counted), and it is likely that both plants and a residual seed bank are present.

(9) *La Purisima East.* Vandenberg monkeyflower that occur on the east side of the park are made up of hundreds of scattered individuals. Approximately 850 individuals were observed in 2006 (Ballard 2006) and approximately 400 individuals were observed in 2009 (Rutherford and Ballard *in litt.* 2009). Although no surveys have occurred since 2009, we consider the species to be extant at this location because it has been only 4 years since individuals were last seen, and it is likely that both plants and a residual seed bank are present.

Summary—Distribution and Status of Vandenberg Monkeyflower

In summary, we identified one extirpated location where Vandenberg monkeyflower no longer exists, one location that is considered potentially extirpated, and nine locations where Vandenberg monkeyflower is currently considered extant on Burton Mesa. Most of these extant locations contain multiple scattered individuals, and thus we refer to these areas as nine occurrences, as defined above. We generally characterized the size of Vandenberg monkeyflower occurrences based on multiple observations over a period of years. Two of the nine occurrences (22 percent; Lake Canyon and La Purisima West) each contained over 1,000 individuals in multiple years and are the two largest known occurrences of this species. These largest occurrences include a high of approximately 1,500 individuals at Lake Canyon in 2006 (Elvin *in litt.* 2009; VFWO 2013) and 1,500 individuals at La Purisima West in 2009 (Rutherford and Ballard *in litt.* 2009). Four occurrences (44 percent; Pine Canyon, Clubhouse Estates, Davis Creek, and La Purisima East) each contained hundreds of plants ranging between 100 and 850 individuals in multiple years. Finally, three occurrences (33 percent; Oak Canyon, Santa Lucia Canyon, and Volans Avenue) are the smallest, with a range of no individuals observed in most years surveyed (Volans Avenue) to a high of 25 individuals observed in 2006 (Santa Lucia Canyon). Although trend data are not available, these data indicate that the aboveground expression of Vandenberg monkeyflower for 7 of the 9 occurrences (78 percent) harbor 850 or fewer individuals.

Because we have only one rangewide survey for this species, and because based on our current data and the likelihood that Vandenberg monkeyflower forms a seed bank and expresses variable numbers of aboveground individuals from year to year (see *Background—Life History* section above), we are unable to determine a trend in the Vandenberg monkeyflower population. Therefore, we will use trends in the amount of suitable habitat as a surrogate for the species' trend.

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on any of the following five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Each of these factors is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Factor A threats to Vandenberg monkeyflower habitat include development (military, State lands, and residential), utility maintenance and miscellaneous activities, invasive, nonnative plants, anthropogenic (influenced by human-caused activity) fire, recreation, and climate change. These impact categories overlap or act in concert with each other to adversely affect Vandenberg monkeyflower habitat.

Development—Military

Development of Vandenberg AFB military facilities within the last century directly removed approximately 6,104 ac (2,470 ha) of Burton Mesa chaparral habitat. Approximately 40 percent of the chaparral that historically occurred on Vandenberg AFB remains, mostly south and east of the primary developed area on Vandenberg AFB (Odion *et al.* 1992, p. 12). West of the developed area has been impacted by numerous trails, roads, and other ground disturbances. Much of the chaparral habitat that once existed to the north of the primary developed area was cultivated or type-converted (disturbance resulting in a new dominant plant community) to rangeland prior to military use. Areas that historically consisted of chaparral vegetation have regenerated to nonnative grassland, usually with shrubs, and are no longer considered suitable habitat for Vandenberg monkeyflower. This nonnative grassland is dominated by veldt grass and several species of nonnative annual grasses including *Bromus* spp. (bromes), *Avena* spp. (oatgrass), and *Vulpia* spp. (silvergrass) (Odion *et al.* 1992, p. 11).

The Air Force maintains multiple launch facilities at Vandenberg AFB to accomplish their mission (Air Force 2011c, p. 7). There are no launch facilities in suitable habitat for Vandenberg monkeyflower, and the Air Force is not likely to construct new launch facilities within suitable habitat because potential construction would likely occur near the coastline and away from more inland, human-populated areas (Air Force 2009a, p. 16). Additionally, the siting of future facilities is expected to capitalize on existing infrastructure; therefore, disturbance in undeveloped areas would be minimized (Air Force 2009a, p. 32).

Development—State Lands

Prior to the State Lands Commission acquisition of the Reserve lands in 1990, four land uses were identified in the Reserve area, including agricultural operations, military operations, extractive industries, and urban development (Gevirtz *et al.* 2007, p. 54). The Reserve encompasses 5,186 ac (2,099 ha) and there has been no threat from new development. However, local governmental agencies and public utility companies maintain existing utilities and easements throughout the Reserve (see *Factor A—Utility Maintenance and Miscellaneous Activities* below).

La Purisima Mission SHP has operated as a State Park since 1937 (California State Parks 1991, p. 107). The current park boundaries encompass a total of 1,900 ac (769 ha). The park unit consists of the historical area, natural area with riding and hiking trails, agriculture, and the maintenance/service and residential area. The total amount of native vegetation is approximately 1,770 ac (716 ha) (Service 2013, unpublished data). There is no current or future threat of habitat destruction from development at La Purisima Mission SHP because the park was established to preserve cultural and natural features of the area.

Development—Private Lands

Three residential communities exist on Burton Mesa east of Vandenberg AFB's boundary including Vandenberg Village, Mission Hills, and Mesa Oaks. These communities harbor associated infrastructure (including major roads such as California State Highway 1, Harris Grade Road, Rucker Road, and Burton Mesa Boulevard), all of which fragment the Burton Mesa chaparral. Vandenberg Village and associated golf course comprise approximately 720 ac (291 ha). Thus, at least 2,000 ac (809 ha) of Burton Mesa chaparral habitat were removed as a result of past development of these three residential communities and their associated infrastructure.

Presented below are three currently approved or proposed projects on private lands that harbor suitable Vandenberg monkeyflower habitat. Data are not available on the specific acreage of sandy openings expected to be lost as a result of these projects, but data are provided on the loss of Burton Mesa chaparral and the number of individuals of Vandenberg monkeyflower observed at, or adjacent to, these project sites.

(1) Clubhouse Estates is a private development located east of Vandenberg Village (LFR, Inc. 2006, p. 1). Santa Barbara County approved the Clubhouse Estates housing development in August 2005 (County of Santa Barbara Planning Commission 2005, p. 4). Approximately 33 ac (13 ha) were proposed to be developed into residential lots; the remaining 120 ac (49 ha) was proposed as open space (LFR, Inc. 2006, p. 1). Most of the Vandenberg monkeyflower individuals known to occur at this location were inside or within 10 ft (3 m) of the approved development footprint that was graded (SAIC 2005b, Figure 4.3–2). Additionally, the ground disturbance increased the extent of invasive, nonnative species at this location, particularly Sahara mustard and veldt grass (Meyer *in litt.* 2010b).

(2) The Burton Ranch Specific Plan site (Burton Ranch) is located south of the Encina Management Unit of the Reserve. The project was approved in 2006 (City of Lompoc 2012) and totals 149 ac (60 ha). Approximately 83 ac (34 ha) of Vandenberg monkeyflower suitable habitat would be removed (SAIC 2005a, p. 175). Vandenberg monkeyflower has not been observed at this site, although the habitat contains many species commonly associated with Vandenberg monkeyflower (SAIC 2005a, p. 174), and veldt grass is present within the project site. Ground disturbance expected as a result of this approved project would remove native vegetation and may create open areas where veldt grass could invade (see *Factor A—Invasive Nonnnative Species* below*).*

A 100-ft (30-m) buffer at the northern boundary of the project site and 8 ac (3 ha) of onsite open space were proposed as part of the Burton Ranch project (SAIC 2005a). Preserving chaparral may reduce the potential of nonnative plants to invade the intact Burton Mesa chaparral in the Reserve directly to the north of this project site. Additionally, the project proponent completed a conservation agreement with the Land Trust for Santa Barbara County (Land Trust) to mitigate for the removal of native vegetation (Feeney *in litt.* 2012). The conservation area is known as the Burton Ranch Chaparral Preserve and encompasses 95 ac (38 ha) of Burton Mesa chaparral near Vandenberg Village.

(3) Allan Hancock College proposed to develop a public safety complex adjacent to their existing facilities and south of the Davis Creek corridor (Allan Hancock College 2009, p. 28). The project site would remove approximately 59 ac (16 ha) of Burton Mesa chaparral (Allan Hancock College 2009, pp. 134–135). Vandenberg monkeyflower has not been observed within this project site, although a few individuals were observed in 2009 within the chaparral vegetation (Allan Hancock College 2009, p. 113). Therefore, ground disturbance would remove suitable Burton Mesa chaparral and may create open areas for veldt grass to invade. As part of this project, Allan Hancock College proposed to preserve approximately 65 ac (26 ha) of Burton Mesa chaparral near the Davis Creek drainage that is contiguous with the northern portion of the project site (Allan Hancock College 2009, pp. 9, 135). Preserving chaparral in this area may reduce the potential of nonnative plants to invade the intact Burton Mesa chaparral in the Reserve to the north of this project site.

In summary, the majority of development on Vandenberg AFB and the residential communities of Vandenberg Village, Mission Hills, and Mesa Oaks, and the existing infrastructure at La Purisima Mission SHP have existed for decades. Most of Burton Mesa is either State or Federal land on which future development is unlikely; therefore, most of the remaining habitat for Vandenberg monkeyflower would not be directly impacted by future development. However, three recent private developments on the periphery of the State or Federal land either have resulted in or will result in the direct loss of Burton Mesa chaparral. Development within or adjacent to suitable chaparral habitat increases the likelihood of introducing invasive, nonnative species to spread, which is the most significant threat to Vandenberg monkeyflower (see *Factor A—Invasive, Nonnative Plants*). Available conservation measures to minimize the threat of development are discussed below, see *Factor A—Conservation Measures Undertaken.*

Utility and Pipeline Maintenance

Utility and pipeline structures occur within the Reserve on Burton Mesa. These existing facilities or structures at times require maintenance to ensure proper operation. As a result, vehicles and foot traffic could occur at or adjacent to these structures and potentially result in trampling of habitat and other soil surface disturbance, which in turn could result in ground disturbance that removes Burton Mesa chaparral and creates open areas in the vegetation that act as pathways for nonnative plants to expand or invade.

Plains Exploration and Production Company (PXP) owns an oil processing plant surrounded by the La Purisima Management Unit of the Reserve (see *Land Ownership* section above), and requires access to their operation across Reserve lands north of the La Purisima

and Santa Lucia Management Units. Eighteen separate easements and 5 connector easements are used to maintain, repair, replace, and install roads and access power lines, utility lines, and pipelines (Gevirtz *et al.* 2007, p. 12). These easements are generally 50 ft (15 m) wide and vary in length. Additionally, PXP operates a triplet pipeline that is located within the 100-ft- (30-m-) wide fuel break between the Vandenberg AFB boundary and the western edge of the Reserve. Plains Exploration & Production routinely conducts maintenance of this pipeline that includes excavating trenches alongside the pipeline to perform the necessary inspections and repairs. The Oak Canyon occurrence of Vandenberg monkeyflower on Vandenberg AFB is partially located within the pipeline's footprint. No monkeyflower individuals have been observed in Oak Canyon recently, and veldt grass has filled almost every opening in the scrub in Oak Canyon (Rutherford *in litt.* 2012) (see *Factor A—Invasive, Nonnative Species*). The Santa Lucia Canyon occurrence is adjacent to, but not within the pipeline corridor. Actions within PXP's pipeline footprint may result in ground disturbances that create openings for nonnative plants to invade and outcompete native vegetation. However, there is no indication that maintenance of PXP's pipeline in this area has affected Vandenberg monkeyflower or its habitat.

The Reserve contains a limited number of existing structures, most of which are remnants of previous land uses. Local land use agencies and public works agencies retain utilities and pipelines, and easements for access; routine maintenance of the utilities is conducted as needed. The Vandenberg Village Community Services District (VVCSD) has several structures (including water tanks, a water processing plant, wells, and water lines and sewer lines) located within the Reserve (Gevirtz *et al.* 2007, p. 63). The occurrence of Vandenberg monkeyflower at Volans Avenue is adjacent to a sewer line easement held by the VVCSD. A portion of the Vandenberg monkeyflower occurrence located at Davis Creek is within a water line easement, also held by the VVCSD. There is no indication that maintenance of VVCSD infrastructure has affected Vandenberg monkeyflower or its habitat at either of these locations.

The VVCSD filed a request with the State Lands Commission in May 2010 to acquire 27 ac (11 ha) of land within the Reserve east of their existing water tanks for the construction of a replacement water well (VVCSD 2010). The 27–ac (11–ha) site is within the Burton Mesa Ecological Reserve and is currently leased to the CDFW. Approximately 180 Vandenberg monkeyflower individuals (see the Davis Creek occurrence discussion under the *Occurrences Located on Burton Mesa Ecological Reserve* section above) were observed in 2010 within the 27–ac (11–ha) parcel of land where the VVCSD proposes to construct wells in the future. Therefore, if development occurs at this parcel, habitat associated with approximately 25 percent of the known individuals of Vandenberg monkeyflower that were observed in 2010 within the Davis Creek occurrence could be impacted (Meyer *in litt.* 2010a) (see *Factor E—Utility and Pipeline Maintenance* section below). Additionally, removing vegetation would create open space for nonnative plants to invade this area.

In summary, there is no indication that ongoing maintenance activities of existing pipelines and utilities have directly impacted Vandenberg monkeyflower habitat. However, utility maintenance actions could result in ground disturbance that removes Burton Mesa chaparral, creating open areas in the vegetation that act as pathways for nonnative plants to invade.

Invasive, Nonnative Species

Invasive, nonnative plants occur throughout Burton Mesa and represent the greatest threat to the remaining individuals of, and suitable habitat for, Vandenberg monkeyflower. Invasive, nonnative plants occur across Vandenberg monkeyflower's range, including within and adjacent to occupied habitat at all nine extant locations, as well as at the potentially extirpated location (Lower Santa Lucia Canyon). The presence of invasive, nonnative plants can alter all components of an ecosystem, from directly altering habitat and displacing individuals (the latter of which is described under Factor E), to negatively affecting the abundance and diversity of small mammals and insects that disperse seeds or pollinate the native vegetation.

Disturbance is one of the primary factors that promote invasion of nonnative species (Rejmanek 1996; D'Antonio and Vitousek 1992; Hobbs and Huenneke 1992; Brooks *et al.* 2004; Keeley *et al.* 2005). Broad disturbances such as urban development, and disturbances along corridors, such as roadsides and trails, provide opportunities for nonnative plants to invade and gain a foothold in Burton Mesa (Keil and Holland 1998, p. 23). The primary fragmenting (disturbance) event can be the construction of a road, with or without associated housing development; later the habitat remnants are subdivided by additional development, or trails and smaller disturbances that occur within the habitat remnants (Soule *et al.* 1992, p. 43). It is well known that roadside edges tend to be highly invaded habitats (Gelbard and Belnap 2003, p. 422). Paved roads tend to have larger verges and more adjacent invasive plants present than unpaved roads because of the ongoing maintenance and improvements of paved roads (Gelbard and Belnap 2003, pp. 422–430). Additionally, wheeled vehicles effectively disperse seed and seed-bearing plant parts along travel routes and trails, helping to spread invasive, nonnative plants (Gelbard and Belnap 2003; Gevirtz *et al.* 2005, p. 225). Several native mammals also disperse seeds of nonnative plants (D'Antonio 1990, pp. 697–698), including deer (*Odocoileus* spp.) and rabbits (*Sylvilagus* spp.), which effectively disperse the seeds in feces (Odion *et al.* 1992, pp. 1, 27). Furthermore, the prevailing onshore winds contribute to the rapid spread of nonnative plants across Burton Mesa.

The expansion of nonnative plants represents a substantial problem as it displaces native vegetation on Burton Mesa. Keil and Holland (1998, p. 27) documented 220 nonnative plant species on Vandenberg AFB, the majority of which are native to the Mediterranean region and a smaller number native to Eurasia, South America, Australia, South Africa, or other regions. A total of 124 nonnative plant species were observed on the Reserve, 17 of which are recognized as high concern because of their severe ecological impacts on native ecosystems (Gevirtz *et al.* 2007, p. 181). Ferren *et al.* (1984, p. 75) documented 90 species of nonnative plants in La Purisima Mission SHP, comprising approximately 25 percent of the total flora at the park. The list of species observed by Ferren *et al.* (1984) is not comprehensive but includes nearly all species occurring on unplowed uplands of Burton Mesa where Vandenberg monkeyflower habitat occurs (Hickson 1987, p. 21).

Several invasive plant species that are present within Vandenberg monkeyflower habitat and of particular concern with regard to altering habitat of Vandenberg monkeyflower on Burton Mesa include veldt grass, pampas grass, bromes, Sahara mustard, *Centaurea solstitialis* (star thistle), iceplant, *Carduus pycnocephalus* (Italian thistle), and *Cirsium vulgare* (bull thistle). The first five of these species have a ranking of ''A'' by the California Invasive Plants

Council (Cal-IPC), denoting the highest level of impact on native habitats; iceplant, Italian thistle, and bull thistle have a ranking of ''B'', denoting a moderate level of impact on native habitats (Cal-IPC 2012).

The following paragraphs include a brief discussion of four prolific invasive, nonnative plants (veldt grass, iceplant, Sahara mustard, and pampas grass) that are having the greatest impact to Vandenberg monkeyflower occupied and suitable habitat across its range. We describe general biological impacts these four invasive plants have on native vegetation, including known impacts to Burton Mesa chaparral, and thus, suitable habitat for Vandenberg monkeyflower. We then discuss the specific presence and known impacts of these invasive plants on Burton Mesa chaparral at each of the nine extant Vandenberg monkeyflower locations and one potentially extirpated location. We describe the biological impacts using the best available information, which includes personal observations of many scientists who are local experts concerning Burton Mesa or Vandenberg monkeyflower and its habitat. Available conservation measures to minimize the threat of invasive, nonnative plants are discussed below under *Factor A—Conservation Measures Undertaken.*

(1) *Veldt Grass.* Veldt grass may be the most pervasive of the nonnative species in Vandenberg monkeyflower habitat because it can produce an abundance of seeds year-round, and grows under a wide variety of light, temperature, moisture, and substrate conditions (Keil and Holland 1998, p. 23; The Nature Conservancy (TNC) 2005, pp. 6–7). Additionally, it is extremely difficult to eradicate once established. Note that, while several species of veldt grass occur in this region, the most prevalent, and the one we are focusing on in this rule, is South African perennial veldt grass. As a sprawling perennial, veldt grass substantially changes the plant community composition in invaded habitats, altering fire potential by buildup of dense thatch during the summer months (see *Factor A—Anthropogenic Fire*), and increasing the rate of organic matter accumulation (TNC 2005, p. 6; Cal-IPC 2012). Veldt grass tends to crowd out native species and prevents the reestablishment of native herbs and shrubs; larger shrubs are not replaced after they die (Keil and Holland 1998, p. 23; Bossard *et al.* 2000 pp. 164–170; Earth Tech *et al.* 1996, p. 314). Veldt grass also readily spreads into roadsides and from there into openings between shrubs (Bossard *et al.* 2000, p. 168). In the absence of veldt grass, open areas that occur in native vegetative communities on the mesa tend to be occupied by a variety of native annual herbs and short-lived perennials (Earth Tech *et al.* 1996, p. 314). These open areas may provide habitat for Vandenberg monkeyflower.

Veldt grass is spreading rapidly across Vandenberg AFB and the Burton Mesa and represents a significant problem (Gevirtz *et at.* 2007, p. 181). It was established on Vandenberg AFB in the late 1950s to stabilize sand dunes in the Purisima Point area approximately 5 mi (8 km) south of San Antonio Terrace (Peters and Sciandrone 1964, pp. 98, 101); the San Antonio Terrace dune sheet overlies the western edges of Burton Mesa and is upwind of Burton Mesa (Hunt 1993, p. 8). In a study of the vegetation of San Antonio Terrace, photos from 1979 and the early 1990s were compared, noting that veldt grass had expanded from a few localized areas (generally around existing roads and buildings) to become a dominant component of the vegetation and had expanded to new areas (Earth Tech *et al.* 1996). Veldt grass initially invades roadway corridors or other disturbed areas, and then spreads into the more open herbaceous or unvegetated areas between shrubs (Earth Tech *et al.* 1996, p. 314). Grasses like veldt grass that are prolific seeders can build up a large seed bank in the soil, increasing their capacity to respond to disturbances; however, D'Antonio and Vitousek (1992, p. 66) noted that veldt grass is also a threat in the absence of habitat disturbance because it can invade undisturbed coastal habitats in California. Sandy habitats appear to be particularly susceptible to invasion in California (TNC 2005, p. 6). Human (1990, p. 34) identified veldt grass as the most devastating of the nonnative invaders on San Antonio Terrace (which is upwind of Burton Mesa and thus Vandenberg monkeyflower habitat) because it forms solid stands and excludes native plant species.

Currently, veldt grass occurs in more areas on Vandenberg AFB than where it was initially introduced. On Vandenberg AFB, veldt grass occurs both within and adjacent to occupied Vandenberg monkeyflower habitat and is expanding at Santa Lucia, Lake, and Pine Canyons, and has become the dominant vegetation cover in portions of lower Oak Canyon. Additionally, veldt grass is present and expanding at certain locations on the Reserve, including at the Volans Avenue, Clubhouse Estates, and Davis Creek occurrences. Veldt grass is also present at La Purisima Mission SHP. See section below entitled *Review of Invasive, Nonnative Species Present by Occurrence* regarding the presence and known impacts of veldt grass at each of the Vandenberg monkeyflower occurrences.

(2) *Iceplant.* Iceplant is a succulent, mat-forming perennial (D'Antonio 1990, p. 694). A single iceplant individual can form dense, circular mats up to 33 ft (10 m) in diameter and approximately 20 in (40 cm) thick (D'Antonio and Mahall 1991, p. 886). It overcrowds native plants and has an exceptional ability to spread to sandy soils along the coast (Jacks *et al.* 1984, p. 12; Zedler and Scheid 1988, p. 196).

The reproductive potential of iceplant is very high (Schmalzer and Hinkle 1987, p. 18). It propagates by seed and vegetatively; even small stem fragments can regenerate into a new plant (Cal-IPC 2012). Iceplant is a successful invader because seeds are dispersed before or during the time of year when they are most likely to germinate, which allows little time for post-dispersal predation to occur; and the seeds are dispersed by a diversity of mammals (D'Antonio 1990, p. 700). Additionally, Vivrette and Muller (1977, pp. 315–317) showed that the salt leached from iceplant individuals was the limiting factor in the growth and establishment of native grassland species. Salt retained in aerial parts of dried iceplant individuals is transported into the soil through leaching by fog in the summer and rain in the fall (Vivrette and Muller 1977, pp. 311, 316; Kloot 1983, pp. 304–305). On sandy soils, salt deposited in the summer is washed through the soil and replaced by the remaining lower levels of salt leaching out of the plant with the first rains in the fall (Vivrette and Muller 1977, p. 316).

Iceplant is an invasive species of great concern on Vandenberg AFB (Keil and Holland 1998, p. 22). It was originally planted on Base along roads and about buildings to prevent wind erosion (Human 1990, pp. 32, 42). By the mid-1990s, iceplant occupied hundreds of acres on the San Antonio Terrace, having spread into adjacent habitats from plantings along roadsides, the Southern Pacific Railroad tracks, and around missile testing facilities (Earth Tech 1996, p. 264). It is especially prevalent west of the main developed area on Vandenberg AFB because there is extensive iceplant in the adjacent dune habitat and former chaparral habitat, and because of extensive past mechanical disturbance (i.e., land disturbed by mechanical equipment) within the chaparral west of the primary developed area (Odion *et al.* 1992, p. 13).

Iceplant recruits abundantly within openings in the chaparral canopy such

as those created by burning or mechanical disturbance (Odion *et al.* 1992, p. 1), and there is no area of Burton Mesa chaparral on Base where iceplant will not invade (Odion *et al.* 1992, p. 13). In one instance after a prescribed burn, iceplant was discovered in the burned plot after the fire, which was unexpected because succulent plants (such as iceplant) are not known to have the capacity to recover rapidly from fire (Jacks *et al.* 1984, pp. 11–12). Iceplant was not known to occur in the burn plot prior to fire; however, within 3 years of the prescribed burn, iceplant was the second most prevalent post-fire perennial plant observed (Zedler and Schied 1988, p. 198). Because iceplant distribution is extensive on Vandenberg AFB (Air Force 2011a) and is common within most chaparral on the Base (Odion *et al.* 1992, p. 13), little effort has been made to map individuals of iceplant that are mixed within many habitats on the Base, including Burton Mesa chaparral.

Iceplant has also been observed in the Reserve (Junak 2011; Meyer 2012, pers. comm.) and at La Purisima Mission SHP (Gevirtz *et al.* 2005, Appendix 5), although it is not as common as it is on Vandenberg AFB. Please see the *Review of Invasive, Nonnative Species Present by Occurrence* section below regarding the presence and known impacts of iceplant at each of the Vandenberg monkeyflower occurrences.

(3) *Sahara Mustard.* Dense stands of Sahara mustard have the potential to dominate native ecosystems, especially in dry sandy soils (County of Santa Barbara Agricultural Commissioner's Office (Santa Barbara Ag. Comm.) 2012). Sahara mustard is especially common in areas with wind-blown sand deposits and in disturbed sites, such as roadsides. Additionally, it is invading nonnative annual grassland and coastal sage scrub on the coastal slope of southern California and is well-established in all counties of southern California (Cal-IPC 2012). In coastal southern California, it locally dominates nonnative grasslands in dry, open sites, especially disturbed areas, and can expand over larger areas replacing other nonnative annuals during drought conditions (Cal-IPC 2012). Its early-season growth and large size allow it to monopolize early-season moisture, expand its canopy, and set seed before other plants have emerged (Cal-IPC 2012; Santa Barbara Ag. Comm. 2012; Barrows *et al.* 2009).

Barrows *et al.* (2009, pp. 677–683) conducted a study in the Coachella Valley (Imperial County, California) from 2002 to 2008, to determine whether native annual plants were negatively affected by the presence of Sahara mustard by comparing plots with Sahara mustard to plots where Sahara mustard had been manually removed. Sahara mustard formed a canopy 1 to 3 ft (0.3 to 1.0 m) from the ground and native annuals under the canopy were often weakened by loss of sunlight, resulting in natives that grew taller; however, the increased plant height was at the expense of producing branches, flowers, and fruits (Barrows *et al.* 2009, p. 683). Flower and seed production of annuals growing under the Sahara mustard canopy decreased 80 to 90 percent compared to annuals free from mustard competition (Barrows *et al.* 2009, p. 683). Additionally, species richness, density, and total percent cover of natives were higher in the plots where Sahara mustard was removed (Barrows *et al.* 2009, p. 679). The strongest effect was on the percent cover of natives, with nearly double the native annual plant cover on plots where Sahara mustard had been manually removed.

Sahara mustard was collected at three locations on Vandenberg AFB in the late 1990s and is likely to be more common (Keil *in litt.* 2013). One of these collections was from Lake Canyon (which is the location for one of the nine extant Vandenberg monkeyflower occurrences). A second collection of Sahara mustard was located on North Base, upwind of Burton Mesa and thus Vandenberg monkeyflower habitat. The third collection was from near Point Arguello on South Base and not near or upwind of Burton Mesa.

More recently, Sahara mustard has been observed on Department of Justice lands at the Lompoc Penitentiary that is near the southern terminus of Santa Lucia Canyon Road and Oak Canyon, and borders the southwestern corner of the Vandenberg Management Unit of the Reserve (Meyer *in litt.* 2012a; Lum *in litt.* 2012c). It is spreading rapidly across the Reserve, notably in the La Purisima, Santa Lucia, Vandenberg, and Encina Management Units (Gevirtz *et al.* 2007, p. 241, Junak 2011; Meyer *in litt.* 2012a). Specifically, Sahara mustard is known to occur adjacent to the Clubhouse Estates occurrence of Vandenberg monkeyflower (Meyer *in litt.* 2012a). Additionally, a small-scale infestation occurs by the eastern edge of La Purisima Mission SHP (California State Parks 2011, p. 4; Santa Barbara Ag. Comm. 2012). See the section below titled *Review of Invasive, Nonnative Species Present by Occurrence* regarding the presence and known impacts of Sahara mustard at each of the Vandenberg monkeyflower occurrences.

(4) *Pampas Grass.* The invasion of pampas grass has altered the landscape of Burton Mesa because it has the ability to convert shrubland into nonnative perennial grassland and prevent native plants from reestablishing (Permberton 1985, p. 4; Lambrinos 2000, pp. 224–225). Once pampas grass is established, it is extremely difficult to eradicate (McClintock 1985, p. 5). Individual plants already present in the landscape may greatly accelerate the conversion of native vegetation into pampas grass-dominated grasslands (Lambrinos 2002, p. 527). Therefore, the ability of pampas grass to persist for long periods of time poses a serious threat to the native diversity of this ecosystem (Lambrinos 2000, p. 217). Large individuals can produce billions of seeds over the course of their reproductive lives (Lambrinos 2000, p. 225), and because the grass seeds are wind-dispersed (Keil and Holland 1998, p. 23), pampas grass is able to spread into adjacent vegetation, particularly chaparral, in which there are openings and bare soil (Schmalzer and Hinkle 1987, pp. 30–31). Additionally, it creates a fire hazard with excessive buildup of dry leaves, leaf bases, and flowering stalks (Cal-IPC 2012) (see *Factor A—Anthropogenic Fire*).

Lambrinos (2000, p. 225) studied the effects of pampas grass invasion at Vandenberg AFB. Plots with pampas grass were compared to adjacent plots of pristine maritime chaparral. The pampas grass-invaded portions of the plots were associated with adjacent, relatively small-scale disturbances, such as dirt roads, water runoff channels, and a paved road. The only disturbance within the plots was narrow trails used by mule deer (*Odocoileus hemionus*) that crossed both invaded and noninvaded plots (Lambrinos 2000, pp. 219, 225). The cover of dead shrubs was significantly greater in invaded plots, indicating shrub cover was higher in the invaded plots at the time of invasion. Additionally, shrub recruitment into stands of pampas grass was low, and pampas grass individuals exhibited high recruitment rates in both invaded and pristine maritime chaparral stands (Lambrinos 2000, p. 225).

Populations of pampas grass have been well-established on Vandenberg AFB since 1975 (Coulombe and Cooper 1976, pp. 93–94). It was introduced along the railroad tracks (Odion *et al.* 1992, p. 14), and major populations occur around the airfield extending from the railroad tracks south along both sides of the runway and in adjacent areas (Schmalzer and Hinkle 1987, p. 30; Keil and Holland 1998, p. 23). Nearly all mechanically disturbed areas

on Base downwind of established pampas grass are now invaded (Odion *et al.* 1992, p. 14). From the ruderal populations, pampas grass has also expanded into the surrounding, relatively undisturbed chaparral where there are openings and bare soil (Lambrinos 2000, p. 218; Schmalzer and Hinkle 1987, pp. 30–31). Therefore, over extended periods of time pampas grass can reduce native plant diversity, even in the absence of large-scale disturbances (Lambrinos 2000, p. 227). The most affected habitat is Burton Mesa chaparral because the natural integrity of the community was lost due to previous disturbances (Keil and Holland 1998, p. 23; Lambrinos 2002, p. 519). Thus, any activities that remove native vegetation and leave bare soil create an opportunity for pampas grass invasion (Schmalzer and Hinkle 1987, pp. 30–31).

Pampas grass has also been observed in the Reserve (Junak 2011) and at La Purisima Mission SHP (Gevirtz *et al.* 2005, Appendix 5), although it is not as widespread as it is on Vandenberg AFB. See the section below titled *Review of Invasive, Nonnative Species Present by Occurrence* regarding the presence and known impacts of pampas grass at each of the Vandenberg monkeyflower occurrences.

Review of Invasive, Nonnative Species Present by Occurrence

In the paragraphs below we discuss the presence of invasive plants that occur within or adjacent to Vandenberg monkeyflower and its habitat at each of the nine extant locations and one potentially extirpated location. The Pine, Lake, and Santa Lucia Canyon locations are grouped based on the information available.

(1) *Vandenberg AFB—Oak Canyon.* Oak Canyon is a location where Vandenberg monkeyflower was reported as common in the 1980s (see *Current Locations—Occurrences Located on Vandenberg AFB* section for additional site-specific information). In 2004, a 12-ac (4.86-ha) fire burned the northeast-facing slope of lower Oak Canyon (Lum *in litt.* 2012e); a detailed description of the vegetation at this site prior to the fire is not available. Since then, however, veldt grass has filled almost every opening in the scrub in Oak Canyon and in 2012, it was the dominant species in this area (Rutherford *in litt.* 2012). Four individuals of Vandenberg monkeyflower were found in 2006 (VFWO 2013), and none were observed in 2010 or 2012 (Air Force 2012, p. 1; Lum *in litt.* 2012b; Rutherford *in litt.* 2012).

(2), (3), and (4) *Vandenberg AFB—Pine, Lake, and Santa Lucia Canyons.* Veldt grass occurs within and near each of the occurrences of Vandenberg monkeyflower at Pine, Lake, and Santa Lucia Canyons, and the area occupied by veldt grass is expanding at each site (SAIC 2012, p. 5; Air Force 2012). Additionally, the Highway Incident wildfire in 2009 (see *Factor A—Anthropogenic Fire*) that burned in upper Lake Canyon fostered expansion of invasive, nonnative plants already present in the area, such as veldt grass, pampas grass, iceplant, and bull thistle (Air Force 2009b, Appendix E).

(5) *Burton Mesa Ecological Reserve—Volans Avenue.* Veldt grass and iceplant occur within Vandenberg monkeyflower suitable habitat and near the known occurrences at this location, and both species are likely directly affecting the availability of sandy openings at this location (Meyer *in litt.* 2013). The last time Vandenberg monkeyflower was observed at this location was in 2007 (Meyer *in litt.* 2007), although we still consider this occurrence extant.

(6) *Burton Mesa Ecological Reserve—Clubhouse Estates.* As of the most recent survey in 2009, the Clubhouse Estates occurrence supported 350–400 Vandenberg monkeyflower individuals (McGowen *in litt.* 2009). Since a portion of the vegetation was cleared from this project site in 2006 and later graded in 2007, veldt grass and Sahara mustard have expanded within Vandenberg monkeyflower suitable habitat and near individual plants (Meyer *in litt.* 2010b) (see also *Current Locations—Occurrences Located on Burton Mesa Ecological Reserve;* and *Factor A—Development* sections above). In particular, veldt grass has moved into the Clubhouse Estates location and is expanding into undisturbed areas where veldt grass did not previously occur (Meyer *in litt.* 2010b). Prior to the 2006 ground disturbance, iceplant and pampas grass were present on the project site (SAIC 2005b, pp. 13–14). Iceplant typically occurred in scattered patches adjacent to areas disturbed by roadways and existing infrastructure (SAIC 2005b, pp. 13–14; LFR, Inc. 2006, p. 23), and pampas grass occurred throughout the project site, especially in moister places adjacent to wetlands, along both branches of Davis Creek that run through the site, and along roadways (SAIC 2005b, pp. 13–14; LFR, Inc. 2006, p. 23). Following the ground disturbance, veldt grass, pampas grass, and iceplant continue to expand in the undisturbed parcel that is designated as open space as part of the development project. It was previously controlled around 2008, but the required 3 years of weeding (LFR, Inc 2006, pp. 48–50, 75 (Table 10)) have not occurred (Meyer *in litt.* 2013).

(7) *Burton Mesa Ecological Reserve—Davis Creek.* Veldt grass and iceplant have been observed within sandy openings at the Davis Creek occurrence of Vandenberg monkeyflower. The CDFW observed veldt grass within the southern portion of the area occupied by Vandenberg monkeyflower in addition to the area approximately 100 ft (30 m) to the north of the plants (Meyer 2012, pers. comm.). Additionally, patches of iceplant were observed at the northern portion of the Davis Creek occurrence (Meyer 2012, pers. comm.).

Burton Mesa Ecological Reserve—Potentially Extirpated Occurrence at Lower Santa Lucia Canyon. An historical observation of Vandenberg monkeyflower was made in 1985 (Hickson *in litt.* 2007). However, this species has not been recently observed at this location and is considered potentially extirpated (see Figure 2 and Table 1) because it has been approximately 30 years since individuals were observed (with little survey effort between 1985 and 2011); suitable habitat remains but it is overcrowded with invasive, nonnative plants. Currently, veldt grass is dominant within the sandy openings in the Burton Mesa chaparral, and herbs commonly associated with Vandenberg monkeyflower are absent (Meyer *in litt.* 2012c). Sahara mustard is expanding into the Vandenberg Management Unit at the southwestern corner of the Reserve from the adjacent Lompoc Penitentiary (Meyer *in litt.* 2012a).

(8) and (9) *La Purisima Mission State Historic Park—La Purisima Mission SHP East and West.* Veldt grass occurs at both the western and eastern occurrences of Vandenberg monkeyflower in the park. Specifically, veldt grass is encroaching into intact Burton Mesa chaparral and into open sandy areas where Vandenberg monkeyflower grows (Ballard 2006; California State Parks 2011, p. 4).

Summary—Invasive, Nonnative Species

Invasive, nonnative plants occur and are expanding throughout the Burton Mesa. More specifically, at least one of the four most problematic invasive plants occurs within or adjacent to suitable habitat at each of the nine extant occurrences of Vandenberg monkeyflower and at one potentially extirpated location. Invasive plants have demonstrated the ability to reduce the diversity of native vegetation and convert the native shrublands into nonnative-dominated vegetation. In some areas, particularly on Vandenberg

AFB, veldt grass, iceplant, and pampas grass when first introduced were only minor components of the vegetation; today, these nonnatives are dominant components of the vegetation at the locations where they were introduced, and they have expanded to new areas. The expansion of invasive, nonnative plants is also prevalent on the Reserve and at La Purisima Mission SHP. Native shrub recruitment and growth of native annuals into open areas is substantially decreased where these invasive, nonnative plants become established. Thus, it is likely that invasive, nonnative plants will become more dominant where they already occur and will continue to expand to new areas due to the human activities on Burton Mesa, the competitive fitness of these invasive plants, the direction of the prevailing wind, and the potential for small- and large-scale disturbances (see *Factor A—Development and Anthropogenic Fire*), all of which could create open areas that promote invasive, nonnative species invasion and expansion.

With regard to site-specific impacts to Vandenberg monkeyflower habitat, veldt grass has been observed occurring within suitable habitat at each of the nine extant occurrences and at one potentially extirpated location. Recent observations of the habitat at all nine extant occurrences indicate that veldt grass is expanding and becoming dominant in the sandy openings where Vandenberg monkeyflower grows. Because veldt grass will outcompete native vegetation (including overcrowding the sandy openings where Vandenberg monkeyflower grows) and is very difficult to eradicate once it is established, the presence and expansion of veldt grass within known occurrences of Vandenberg monkeyflower is a continuous threat because it reduces the amount and quality of this species' habitat. We also discussed above three other invasive, nonnative species (iceplant, Sahara mustard, and pampas grass) that have substantial impacts to Vandenberg monkeyflower and its habitat. These species, along with numerous other nonnative plant species, are present throughout Burton Mesa and at all extant occurrences of Vandenberg monkeyflower. Similar to veldt grass, the other invasive, nonnative plants reduce the amount and quality of habitat for Vandenberg monkeyflower by outcompeting Burton Mesa chaparral vegetation and decreasing the amount and availability of the sandy openings where Vandenberg monkeyflower grows. Nevertheless, no invasive plant is as prevalent and represents as much of a threat to Vandenberg monkeyflower habitat as veldt grass.

Anthropogenic Fire

The disturbance to maritime chaparral that anthropogenic fires cause may exceed the tolerance thresholds (ability to tolerate naturally occurring fire regimes and regenerate post-fire) of many shrub species, resulting in an open canopy, the demise of shrublands, and persistence of nonnative plants (Haidinger and Keeley 1993, pp. 143–147). The common pattern after chaparral fires is for native and nonnative annual herbs to dominate for the first year and then gradually decline as the cover of shrub and subshrubs increases (Zedler *et al.* 1983, p. 816). A high cover of annual and perennial herbs the first few years following the fire decreases as the shrub canopy closes, and there is little herbaceous cover once the canopy closes, although senescence (aging) in some shrubs may allow the recruitment of opportunistic herb or shrub species into gaps in the chaparral (Hickson 1987, p. 5). Patterns of post-fire vegetation vary depending on chaparral habitat composition, fire timing and intensity, and the physical attributes and disturbance history of the site (Davis *et al.* 1988, p. 169).

At historical fire frequencies, chaparral species are generally resilient to fire because they are well known to regenerate from either resprouting of perennial root crowns or germination of seeds in the soil when heated or exposed to smoke (obligate and sprouter seeders) (Lambert *et al.* 2010, p. 31). However, increased fire frequencies in chaparral have led to the loss of native species that rely on seed regeneration because there is insufficient time between fires for shrub species to reach reproductive age and replenish the soil seed bank (Lambert *et al.* 2010, p. 31). Zedler *et al.* (1983, pp. 815–816) noted that high fire frequency has devastating impacts on shrub species that require a period of recovery before being resilient to further disturbance. On the other hand, long-term absence of fire may lead to a gradual transition from chaparral to oak woodland (Van Dyke *et al.* 2001, p. 2), although this transition is also dependent upon soil differences (Davis *et al.* 1988, pp.187–188). Given sufficient time without fire, successional changes in shrublands may result in a closed canopy that is capable of excluding most nonnative species (Keeley *et al.* 2005, p. 2110).

The long-term fire history for Santa Barbara County indicates that large fires (more than 49,400 ac (20,000 ha) and typically driven by Santa Ana wind conditions) are part of the historical fire regime in this region. The average time between these large fires has remained relatively consistent over the last 500 years, regardless of changes in land use, from the Chumash who purposely set fires along the coast (1425–1770), to Spanish and American settlers (1770–1900) who practiced fire suppression but with little enforcement, to the more recent period (1900–1985) of active fire suppression (Mensing *et al.* 1999, pp. 301–304). The average interval between these large fires ranges between 20 and 30 years and is strongly controlled by precipitation patterns, with fires generally occurring at the end of wet phases and the beginning of droughts (Mensing *et al.* 1999, p. 304). The range between large fire events is 5 to 75 years (Mensing *et al.* 1999, p. 304).

The historical fire regime on Burton Mesa is unknown (Hickson 1987, p. 25), but it is likely that naturally occurring fires were less frequent as compared to inland areas because the mesa is at low elevation and the few lightning strikes recorded in the region have been in the distant mountains farther inland (Hickson 1988, p. 20). Additionally, because fog, cool temperatures, and cool winds blowing off the ocean are typical, the weather conditions conducive to naturally occurring fires are rare on Burton Mesa (Hickson 1988, p. 22; Gevirtz *et al.* 2007, p. 58). Therefore, the natural fire interval for Burton Mesa, similar to coastal chaparral environments north of the Transverse Ranges of southern California, may be on the order of 100 years (Greenlee and Langenheim 1990, pp. 242–250; Odion and Tyler 2002, p. 9; Moritz *et al.* 1997, p. 1258).

The present fire regime on Burton Mesa is likely anthropogenic (Davis *et al.* 1988, p. 185; Davis and Borchert 2006, p. 338), especially given the historical densities of Native American and European settlers in coastal areas supporting maritime chaparral (Davis and Borchert 2006, p. 328; Mensing *et al.* 1999, p. 301) along with the related infrastructure that currently exists. Today, human-caused ignitions are more frequent in maritime chaparral, but wildfires are quickly suppressed or extinguished at roads and fuel breaks (Davis *et al.* 1988, p. 177; Davis and Borchert 2006, p. 338). Additionally, modern land use has fragmented the Burton Mesa chaparral into isolated patches (see *Habitat* section above), so that while fires may be more frequent now than in the past, fire size is probably reduced and the average time between fires on certain sites increased (Hickson 1987, p. 20).

Approximately 34 fires have occurred within or adjacent to Burton Mesa chaparral since 1940 on Vandenberg AFB, east of the main developed area, and from San Antonio Creek south to the Santa Ynez River (Lum *in litt.* 2012f). Odion *et al.* 1992 (pp. 12–14) stated that 44 fires have occurred within or adjacent to chaparral on Burton Mesa; however, this calculation also included fires that occurred west of the main developed area on Vandenberg AFB, and, therefore, a larger area than what the Air Force used. Some of the areas burned more than once because the perimeter of different fires overlapped (Odion *et al.* 1992, p. 12; Lum *in litt.* 2012f). A portion of the fires were prescribed burns (Lum *in litt.* 2012f; Odion *et al.* 1992, pp. 12–14). In total, at least 2,500 ac (1,012 ha) have burned on Vandenberg AFB since 1957 (Odion *et al.* 1992, p. 13). In recent years fires have accidentally ignited on Vandenberg AFB (see discussion of *Highway Incident* in paragraph below).

Twenty-eight wildfires occurred on the Reserve and adjacent La Purisima Mission SHP in the period 1950–2003; the most recent wildfire (Harris Grade Fire) occurred in 2000 and was caused by a power line that may have sparked in high winds (Gevirtz *et al.* 2007, p. 60). This fire consumed 11,000 ac (4,451 ha) and was the largest fire in the area since 1977 (Gevirtz *et al.* 2007, p. 60). All of the fires on the Reserve and at La Purisima Mission SHP since 1950 have been a result of human activity (Gevirtz *et al.* 2007, p. 60). Based on an analysis of the fire history, approximately 3,440 ac (1,392 ha) of the 5,186-ac (2,099-ha) Reserve has not burned since 1938 (Gevirtz *et al.* 2007, p. 60), indicating an absence of fire for at least 70 years on 66 percent of the Reserve's property. Similarly, the majority of vegetation at La Purisima Mission SHP has not been burned since before 1938, and most of the native habitat in the park is also more than 70 years old (Gevirtz *et al.* 2005, p. 77).

Although the fire interval in maritime chaparral is an important factor in determining species composition, on Burton Mesa, and for Vandenberg monkeyflower habitat specifically, the frequency of fire is secondary to the primary threat, which is the post-fire expansion of invasive, nonnative plants. California's chaparral habitats, like Burton Mesa, are most vulnerable to invasion by nonnative plants in the first few years after fire because fires open large areas of bare, nutrient-rich ground and remove toxins from the soil, chaparral recolonizes much more slowly because of limited seed dispersal, and some seedlings are poor competitors against nonnative annual species (Keeley *et al.* 2003, pp. 1362–1363; Alberts *et al.* 1993, p. 107; Davis and Mooney 1985, p. 528).

Because sites favorable for invasion by nonnative plants tend to be relatively open areas where existing plant cover is minimal (see *Factor A—Invasive, Nonnative Plants*), and wildfires occurring on Burton Mesa create such open areas, fires within Vandenberg monkeyflower habitat tend to increase the expansion of invasive plants that are already established. For example, an accidental wildfire (Highway Incident) occurred in September 2009 on Vandenberg AFB when sparks from a power line started a wildfire that burned approximately 617 ac (250 ha) (Air Force 2009b, p. 1) in upper Lake Canyon. The southern boundary of this wildfire burned to within 0.25 mi (0.4 km) of the known Vandenberg monkeyflower occurrence down-slope in Lake Canyon. The Burned Area Emergency Response (BAER) Plan noted that invasive, nonnative species already present in the area, including veldt grass, pampas grass, iceplant, and bull thistle, were confirmed or discovered in the burn area within 2 weeks of the fire (Air Force 2009b, Appendix E). Veldt grass initially colonizes disturbed areas, such as open areas created by wildfires, and can become a dominant component of the vegetation and expand to new areas (see *Factor A—Invasive, Nonnative Plants*). Another example in Vandenberg monkeyflower habitat includes a 12–ac (5–ha) fire that occurred in Oak Canyon on Vandenberg AFB in 2004; as a result, veldt grass is the dominant vegetation on a hillside sloping toward the canyon (Google Earth 2012).

In addition to displacing native vegetation, the presence of nonnative plants (in particular nonnative grasses) has increased the supply of readily ignitable fuel and increased the seasonal duration when fuels are susceptible to ignition, both because of their earlier seasonal drying compared to shrubs and their high surface-to-volume ratio (Lambert *et al.* 2010, p. 31). Mediterranean grasses such as bromes and *Avena barbata* (slender wild oat) are particularly implicated since they act as wicks, spreading fast-moving fire into the canopies of larger shrub vegetation (Lambert *et al.* 2010, p. 31). Thus, the abundance of nonnative vegetation initiates a positive feedback cycle based on increased biomass, changes in the distribution of flammable biomass, and increased flammability (Lambert *et al.* 2010, p. 29). *Bromus rubens* (red brome) occurs on Burton Mesa and is known to rapidly colonize disturbed sites with open canopies and exposed bare ground (Brown and Minnich 1986, pp. 414, 418; Bossard *et al.* 2000, pp. 72–80). The prevalence of veldt grass and pampas grass also increases the fire potential on Burton Mesa (see *Factor A—Invasive, Nonnative Plants* section).

Fire Prevention and Suppression Activities

The Air Force, CDFW, and California State Parks have developed wildfire prevention and suppression practices not only to minimize the potential for wildfire, but also to minimize the impacts to the biological resources during suppression activities. As part of wildfire management practices, landowners and agencies may create fuel breaks (a permanent area of low volume fuel) to limit the spread of wildfire and to provide access for fire suppression activities (Gevirtz *et al.* 2007, p. 261). Merriam *et al.* (2006, pp. 525–526) observed that nonnative species represented an increasing proportion of total plant cover on fuel breaks with fuel-break age, suggesting that nonnative species can displace native species on fuel breaks, and become increasingly dominant over time (for example, bromes were four of the five most observed nonnative plants on fuel breaks (Merriam *et al.* 2006, p. 519)). Additionally, wildland areas adjacent to fuel breaks were more likely to be invaded by nonnative species when these areas had been subject to recurrent fires (Merriam *et al.* 2006, p. 526).

Fire suppression activities that impact suitable Vandenberg monkeyflower habitat include bulldozed and hand-cut fire lines and the application of fire retardants. During the Highway Incident wildfire, the Air Force cut fire lines that resulted in a loss of Burton Mesa chaparral (Air Force 2009b, p. 28). Additionally, approximately 65,000 gallons (246,052 liters) of fire retardant (which is known to act as a fertilizer enhancing the growth of nonnative grasses (Avery 2001, pp. 17–18)) were spread over this site (Air Force 2009b, p. 28). Therefore, by burning the existing vegetation, fire creates open areas where invasive, nonnative plants can expand. Additionally, fire prevention and suppression activities (e.g., fire breaks and application of fire retardant) can exacerbate the resulting post-fire expansion of nonnative plants by creating open fire lines and if fire retardants add chemicals to the soil that stimulate growth of nonnative vegetation.

The Air Force, CDFW, and California State Parks are studying the feasibility

of a prescribed burning program to restore fire to its natural role in the environment and help restore the native vegetation of Burton Mesa (California State Parks 1991, p. 110; Gevirtz *et al.* 2007, p. 258; California State Parks 2010, p. 3; Air Force 2012, p. 2). However, many local communities are concerned about the safety of conducting prescribed burns on wildlands when they occur within or near urban areas, thus complicating the ability of agencies to carry out such burns.

In summary, because of the human presence and infrastructure on the mesa, the frequency of human-caused wildfires is likely greater than the frequency of the historical fires in the past on Burton Mesa. An increased fire frequency in Burton Mesa chaparral would tend to favor the establishment of nonnative vegetation in open areas at the expense of native vegetation. However, the primary threat to Vandenberg monkeyflower and its habitat from fire is the post-fire expansion of invasive, nonnative plants, regardless of the fire frequency. Because an abundance of nonnative plants already occurs on the mesa and invasive plants rapidly invade open areas, any fire that occurs within or adjacent to Vandenberg monkeyflower habitat is likely to result in an increase of invasive, nonnative vegetation. Likewise, fire suppression activities that include clearing vegetation in fuel breaks or spreading retardant would increase the likelihood of nonnative species invading suitable Vandenberg monkeyflower habitat, as well as enhance the habitat conditions for invasive species expansion. Additionally, because the presence of invasive, nonnative plants creates a positive feedback mechanism, the greater the percent cover of nonnative vegetation, the more likely fires will occur on Burton Mesa. Based on the information presented in this section, the current threat from anthropogenic fire and associated fire suppression activities to Vandenberg monkeyflower habitat described above is expected to continue into the future. Available conservation measures to minimize the threat of anthropogenic wildfire are discussed below (see *Factor A—Conservation Measures Undertaken*).

Recreation and Other Human Activities

Recreational activities that occur throughout Burton Mesa include authorized uses such as hunting, hiking, biking, wildlife observation, and leashed-dog walking. Additionally, off-road vehicle (ORV) use is authorized on Vandenberg AFB (Air Force 2011b, p. 6), but it is not permitted on the Reserve (Gevirtz *et al.* 2007, p. 70) or La Purisima Mission SHP (California State Parks 1991, p. 109).

Vandenberg Air Force Base (AFB)

On the west end of Burton Mesa on Vandenberg AFB, recreational activities include OHV use and other casual-use activities, such as hunting, picnicking, and horseback riding. There is also an existing 237–ac (96–ha) golf course.

Prior to 1974, Vandenberg AFB was subject to uncontrolled use by ORVs. In April 1974, efforts to establish a program to control ORV use was prompted by dune damage and the complaints of recreational users, along with consideration of soil, water, air, noise, aesthetics, recreational users, wildlife, vegetation, suitability of other public lands, archaeological sites, threatened and endangered species, and the accessibility for users (Air Force 2011b, p. 6). Thus, Vandenberg AFB environmental staff and the Base's motorcycle club designated an ORV area (Air Force 2011b, p. 6). Currently, ORV use occurs within a 600–ac (243–ha) site that is west of the primary developed area on Base and an additional site referred to as Northstar that is located in the northeast portion of the Base (Air Force 2011b, p. 6), both of which are not within Vandenberg monkeyflower habitat. The ORVs use existing trails and roads, and are managed to prevent damage to sensitive areas such as wetlands and highly erodible soils (Air Force 2011b, p. 6). Therefore, ORV use on Vandenberg AFB is not within the vicinity of Vandenberg monkeyflower occurrences on the Base and is not a direct threat to this species and its habitat.

The west end of Burton Mesa on Vandenberg AFB (west of the primary developed area) is heavily disturbed by existing trails and service roads, which may be used by recreationists. Although vehicles using these roads and trails (including wheeled vehicles for recreational activities) likely contribute to the spread of invasive, nonnative plant species on Burton Mesa (see *Invasive, Nonnative Species* section above), no information is available to assess the extent and degree to which this may be occurring on Vandenberg AFB. Moreover, the best available information does not indicate that these recreational activities on the west end of Burton Mesa on Base are a direct threat to Vandenberg monkeyflower and its habitat.

To the east of the developed area where higher-quality Burton Mesa chaparral still remains and where Vandenberg monkeyflower occurs on Base, recreational activities that may impact the habitat of this species include hunting and picnicking. Hunting occurs over much of the Base and is subject to restrictions at any time based on human safety and security concerns, as well as wildlife management goals (Air Force 2011b, p. 7). Lake Canyon Lakes picnic area is within a few hundred feet of Vandenberg monkeyflower plants that are located in lower Lake Canyon, but the picnic facilities are located on concrete or asphalt and thus not in Vandenberg monkeyflower habitat. Overall, the best available information does not indicate that recreational activities on Base, including hunting and picnicking, are directly impacting Vandenberg monkeyflower or its habitat. However, these activities pose an indirect threat to the habitat quality because they contribute to the spread of nonnative plants within suitable habitat.

Burton Mesa Ecological Reserve

There are no formal recreational or public facilities currently within the Reserve, including no designated parking or restroom facilities (Gevirtz *et al.* 2007, p. 69). Authorized uses include hiking, wildlife observation, and leashed-dog walking. Wheeled recreational activities such as OHV use and bicycles are not allowed in the Reserve (Gevirtz *et al.* 2007, p. 70). The management plan for the Reserve identifies approximately 28 mi (45 km) of trails (Gevirtz *et al.* 2007, p. 71). The existing trails are a combination of oil and utility service roads and an informal network of pathways from the surrounding residential areas (Gevirtz *et al.* 2007, p. 69). Impacts to Vandenberg monkeyflower habitat from authorized recreational uses are likely negligible because visitors walk into the Reserve and the CDFW has posted signs at the most highly used access points to direct recreational users to low-impact trails so as to reduce disturbances to the native vegetation.

The Volans Avenue occurrence of Vandenberg monkeyflower is located adjacent to Vandenberg Village and a VVCSD pipeline easement that is used by local residents for hiking, jogging, dog walking, and other casual recreational activities. Running events have previously occurred in this area of the Reserve, and the running route was likely in close vicinity to the Volans Avenue occurrence of Vandenberg monkeyflower (Ballard *in litt.* 2012). Vandenberg monkeyflower was last observed in 2007 at this location (Meyer *in litt.* 2007; Ballard *in litt.* 2007), although habitat is still present. In the other years from 2004 to 2006, and in

2009, no plants were found (Meyer *in litt.* 2007; Ballard *in litt.* 2007; Meyer *in litt.* 2009a).

It is unknown whether disturbance created by casual human use has played a role in the absence of Vandenberg monkeyflower's aboveground expression at this location since 2007. The best available information indicates that recreational activities involving casual human use on the Reserve are having minimal to no direct effect on Vandenberg monkeyflower habitat on Burton Mesa. However, veldt grass, which produces an abundance of seeds and tends to crowd out native species and prevent their reestablishment, is likely reducing the amount of available Vandenberg monkeyflower habitat at this location (see the specific Volans Avenue discussion above under the Review of Invasive, Nonnative Species Present by Occurrence section). Additionally, because Vandenberg monkeyflower habitat is fragmented by recreational trails, the introduction of additional invasive, nonnative plants into this area is likely because spreading of nonnative vegetation is known to occur through visitors' shoes (Gevirtz *et al.* 2005, p. 225). Therefore, recreational activities may indirectly affect this species by spreading invasive, nonnative plants into the habitat (i.e., sandy openings) where Vandenberg monkeyflower grows.

Unauthorized ORV use has been reported on the western portions of the Reserve (Santa Lucia Management Unit) from adjacent lands on Vandenberg AFB. It is likely that the trespass is originating from the general public (nonmilitary) because public roadways (such as Santa Lucia Canyon Road) cross Vandenberg AFB lands on this portion of the Base and the Air Force controls the use of ORVs by military staff on the Base. As a result of unauthorized use on the Reserve, CDFW installed a gate in 2009 to control access along Santa Lucia Canyon Road (Meyer *in litt* 2009b). Unauthorized ORV activity has also been reported at another location of the Reserve that supports Vandenberg monkeyflower occurrences and suitable habitat (i.e., east of, and adjacent to, the Clubhouse Estates project site) (Meyer *in litt* 2010c). Additionally, bicycles are prohibited in Burton Mesa (14 California Code of Regulations (CCR) 630 (b)(22)(B)). However, unauthorized mountain biking has been observed in the Reserve within Vandenberg monkeyflower habitat (Meyer *in litt.* 2013). The available information does not indicate the extent and degree to which ORV and mountain biking may be directly impacting Vandenberg monkeyflower habitat on the Reserve. However, wheeled recreational activities likely contribute to the spread of invasive, nonnative plant species within the Reserve along the travel routes, some of which occur within Vandenberg monkeyflower habitat.

The Santa Barbara County Sheriff and Fire Departments maintain facilities on a county-owned inholding within the Reserve. They have been leasing an adjacent 3–ac (1.2–ha) parcel from the State Lands Commission (SLC) for the last 15 years to maintain their equestrian training facility, and the use of horses has expanded onto the Reserve. The lease has since expired, and the SLC is evaluating whether to renew the lease or modify its terms (Meyer *in litt.* 2012b). The Santa Barbara County Sheriff Department desires to keep horses in the stalls behind the facility; however, horse use is not allowed on Burton Mesa Ecological Reserve (14 CCR Section 630(b)(22(B)), and CDFW wants to keep the area of impact to a few acres near the stalls (Meyer *in litt.* 2012b). Vandenberg monkeyflower occurrences and suitable habitat do not occur near this facility and, therefore, no direct impacts to the habitat would occur.

The Lompoc Valley Flyers Club (Flyers Club) operated a dirt take-off and landing strip for model airplanes, a race track for model cars, and several picnic tables in the Vandenberg Management Unit of the Reserve (just south of California State Highway 1) from 1988 to 2000 (Gevirtz *et al.* 2007, p. 63). The Flyers Club routinely graded the landing strip and access road; this surface scar is still evident in aerial photographs and erosion is a continuing problem at this site (Gevirtz *et al.* 2007, p. 63). The activities occurred in Burton Mesa chaparral but not near known occurrences of Vandenberg monkeyflower. However, these activities have reduced suitable habitat for Vandenberg monkeyflower through removal and degradation of Burton Mesa chaparral and creation of open areas that allow nonnative plants to establish.

La Purisima Mission State Historic Park

La Purisima Mission SHP contains roads and trails authorized for use by local residents for hiking, dog walking, and horseback riding, and employs park rangers and staff to maintain the grounds and conduct patrols. Twelve miles (19 km) of riding and hiking trails wind through the park, including 3.7 mi (6 km) of historical trails near the mission and 8.8 mi (14 km) in the surrounding hills (California State Parks 1991, pp. 9, 107). Bicycles are permitted on approximately 5 mi (8 km) of these trails (which are also designated fire roads), and the remainder, with a few exceptions, are open to horses (California State Parks 1991, pp. 9, 107). Vehicle movement and pedestrian and equestrian use do not directly impact Vandenberg monkeyflower habitat at La Purisima Mission SHP because the roads and trails do not overlap where Vandenberg monkeyflower occurs. However, indirect impacts to Vandenberg monkeyflower habitat may occur due to nonnative plant invasions introduced through visitors' shoes, horse hoofs, vehicle tires, and tractor treads (Gevirtz *et al.* 2005, p. 225). The best available information indicates that recreational activities involving casual human use at La Purisima Mission SHP are having minimal to no direct effect on Vandenberg monkeyflower habitat on Burton Mesa.

Summary—Recreation and Other Human Activities

Off-road vehicle use and other casual recreational activities may contribute to soil disturbance and increase the potential for invasive, nonnative plants to be introduced and further spread across Burton Mesa, including into locations where Vandenberg monkeyflower and its suitable habitat occurs. At this time, the best available information does not indicate that recreational activities pose a substantial direct threat to Vandenberg monkeyflower habitat, although these activities would indirectly affect the habitat by contributing to the spread of invasive, nonnative plants within the habitat and reducing the habitat quality. Available conservation measures to minimize the threat of recreation are discussed below under *Factor A—Conservation Measures Undertaken.*

Climate Change

Our analyses under the Act include consideration of ongoing and projected changes in climate. The terms ''climate'' and ''climate change'' are defined by the Intergovernmental Panel on Climate Change (IPCC). The term ''climate'' refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2007a, p. 78). The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (for example, temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability,

human activity, or both (IPCC 2007a, p. 78).

Scientific measurements spanning several decades demonstrate that changes in climate are occurring, and that the rate of change has increased since the 1950s. Examples include warming of the global climate system, and substantial increases in precipitation in some regions of the world and decreases in others (For these and other examples, see IPCC 2007a, p. 30; and Solomon *et al.* 2007, pp. 35–54, 82–85). Results of scientific analyses presented by the IPCC show that most of the observed increase in global average temperature since the mid-20th century cannot be explained by natural variability in climate, and is ''very likely'' (defined by the IPCC as 90 percent or higher probability) due to the observed increase in greenhouse gas (GHG) concentrations in the atmosphere as a result of human activities, particularly carbon dioxide emissions from use of fossil fuels (IPCC 2007a, pp. 5–6 and figures SPM.3 and SPM.4; Solomon *et al.* 2007, pp. 21–35). Further confirmation of the role of GHGs comes from analyses by Huber and Knutti (2011, p. 4), who concluded that it is extremely likely that approximately 75 percent of global warming since 1950 has been caused by human activities.

Scientists use a variety of climate models, which include consideration of natural processes and variability, as well as various scenarios of potential levels and timing of GHG emissions, to evaluate the causes of changes already observed and to project future changes in temperature and other climate conditions (for example, Meehl *et al.* 2007, entire; Ganguly *et al.* 2009, pp. 11555, 15558; Prinn *et al.* 2011, pp. 527, 529). All combinations of models and emissions scenarios yield very similar projections of increases in the most common measure of climate change, average global surface temperature (commonly known as global warming), until about 2030. Although projections of the magnitude and rate of warming differ after about 2030, the overall trajectory of all the projections is one of increased global warming through the end of this century, even for the projections based on scenarios that assume that GHG emissions will stabilize or decline. Thus, there is strong scientific support for projections that warming will continue through the 21st century, and that the magnitude and rate of change will be influenced substantially by the extent of GHG emissions (IPCC 2007a, pp. 44–45; Meehl *et al.* 2007, pp. 760–764, 797–811; Ganguly *et al.* 2009, pp. 15555–15558; Prinn *et al.* 2011, pp. 527, 529). (See IPCC 2007b, p. 8, for a summary of other global projections of climate-related changes, such as frequency of heat waves and changes in precipitation. Also see IPCC 2011 (entire) for a summary of observations and projections of extreme climate events.)

Various changes in climate may have direct or indirect effects on species. These effects may be positive, neutral, or negative, and they may change over time, depending on the species and other relevant considerations, such as interactions of climate with other variables (for example, habitat fragmentation) (IPCC 2007, pp. 8–14, 18–19). Identifying likely effects often involves aspects of climate change vulnerability analysis. Vulnerability refers to the degree to which a species (or system) is susceptible to, and unable to cope with, adverse effects of climate change, including climate variability and extremes. Vulnerability is a function of the type, magnitude, and rate of climate change and variation to which a species is exposed, its sensitivity, and its adaptive capacity (IPCC 2007a, p. 89; see also Glick *et al.* 2011, pp. 19–22). No single method for conducting such analyses applies to all situations (Glick *et al.* 2011, p. 3). We use our expert judgment and appropriate analytical approaches to weigh relevant information, including uncertainty, in our consideration of various aspects of climate change.

As is the case with all stressors that we assess, even if we conclude that a species is currently affected or is likely to be affected in a negative way by one or more climate-related impacts, it does not necessarily follow that the species meets the definition of an ''endangered species'' or a ''threatened species'' under the Act. If a species is listed as endangered or threatened, knowledge regarding the vulnerability of the species to, and known or anticipated impacts from, climate-associated changes in environmental conditions can be used to help devise appropriate strategies for its recovery.

Global climate projections are informative and, in some cases, the only or the best scientific information available for us to use. However, projected changes in climate and related impacts can vary substantially across and within different regions of the world (for example, IPCC 2007a, pp. 8–12). Therefore, we use ''downscaled'' climate projections when they are available and have been developed through appropriate scientific procedures, because such projections provide higher resolution information that is more relevant to spatial scales used for analyses of a given species (see Glick *et al.* 2011, pp. 58–61, for a discussion of downscaling). With regard to our analysis for Vandenberg monkeyflower, downscaled climate projections are available.

Within central-western California (i.e., counties along the California coast from the San Francisco Bay area south to Santa Barbara County), regional climate models project a mean annual temperature increase of 1.6 to 1.9 degrees Celsius (°C) (2.9–3.4 degrees Fahrenheit (°F)) and a mean diurnal temperature range increase of 0.1 to 0.2 °C (0.2–0.4 °F) by 2070 (Point Reyes Bird Observatory (PRBO) Conservation Science 2011, p. 35). The projected impacts of climate change are warmer winter temperatures, earlier warming in the spring, and increased summer temperatures (PRBO Conservation Science 2011, p. 35). Additionally, regional climate models project a decrease in mean annual rainfall of 2.4 to 7.4 in (6.1 to 18.8 cm) (PRBO Conservation Science 2011, p. 35). The large range of possible precipitation change (−11 percent to −32 percent) is due to different model projections and sensitivity. This sensitivity indicates substantial uncertainty in precipitation projections (PRBO Conservation Science 2011, p. 35). Other scientific sources (Snyder *et al.* 2004, pp. 594–595) project similar temperature increases and precipitation decreases along the central California coast.

Of the three major vegetation types within central-western California, decreases in cover are projected for chaparral-coastal scrub habitat (−19 to −43 percent) and blue oak woodland-foothill pine habitat (−44 to −55 percent), and an increase in cover projected for grassland habitat (85 to 140 percent) to 2070 (PRBO Conservation Science 2011, p. 38). Lenihan *et al.* (2008) also projects decreases in cover for conifer forests and shrublands, and increases in cover for grasslands in central-western California by the 2070–2099 period. Additionally, changes in vegetation communities could also be hastened by more and larger wildfires, as well as effective wildfire suppression (PRBO Conservation Science 2011, pp. 37–38) (see *Factor A—Anthropogenic Fire* section).

To estimate what changes in rainfall and temperature, if any, would occur in the Burton Mesa area over the next 50 years, we used both local weather data and an available projection tool called ClimateWizard (2012). Temperature and precipitation data have been recorded in the City of Lompoc, approximately 4 mi (6.4 km) to the south of Burton Mesa

Ecological Reserve. Between 1950 and 2006, the average annual temperature was approximately 58 °F (14 °C); the average annual precipitation was approximately 15 in (38 cm) (Western Regional Climate Center 2012). We then used ClimateWizard (2012) to project future climate conditions and compare to baseline values (the latter of which is defined as the average temperature or precipitation between 1961 and 1990 (ClimateWizard 2012)). ClimateWizard (2012) projects that rainfall would decrease an average of 8 to 12 percent from baseline and temperature would rise approximately 2.5 °F (1.4 °C) by the 2050s. A comparison between the Burton Mesa area and the eastern portion of Santa Barbara County (for example, 30 mi (48 km) east of the Burton Mesa area, which is projected to rise approximately 5 °F (2.8 °C)), indicates that the change in temperature is expected to be less in the Burton Mesa area. This is likely due to the moderating influence of ocean temperatures in coastal areas.

In a changing climate, conditions could change in a way that would allow both native and nonnative plants to invade the habitat where Vandenberg monkeyflower occurs. A growing body of literature discusses the specific mechanisms by which climate change could affect the abundance, distribution, and long-term viability of plant species, as well as current habitat configuration over time, including (but not limited to): Root *et al.* (2003), Parmesan and Yohe (2003), and Visser and Both (2005). While studies on response to climate change have not been conducted for Vandenberg monkeyflower, responses may be similar to other plant species with a similar life history. Some of the responses by plants to climate change presented by Root *et al.* (2003), Parmesan and Yohe (2003), Visser and Both (2005), and others include the following:

(1) Drier conditions may result in less suitable habitat, or a lower germination success and smaller population sizes.

(2) Higher temperatures may inhibit germination, dry out soil, or affect pollinator services.

(3) The timing of pollinator life cycles may become out-of-sync with timing of flowering.

(4) A shift in the timing and nature of annual precipitation may favor expansion in abundance and distribution of nonnative species.

(5) Drier conditions may result in increased fire frequency, making the ecosystems in which a species currently grows more vulnerable to threats of nonnative plant invasion.

We recognize that climate change is an important issue with potential impacts to species and their habitats, including Vandenberg monkeyflower. Regional climate projections indicate that a warming and drying trend is likely in central-western California, which would likely make habitat less favorable for Vandenberg monkeyflower. However, as stated above, these warming and drying effects may be moderated by the marine influence. Therefore, climate change may not affect Vandenberg monkeyflower or its habitat as quickly or as extensively as may be projected. We will continue to seek additional information concerning how climate change may affect the Burton Mesa area (see Information Received section above).

Conservation Measures Undertaken

The Air Force has an approved Integrated Natural Resources Management Plan (INRMP) on Vandenberg AFB, and the CDFW and California State Parks have established natural resources management plans for the Reserve and La Purisima Mission SHP, respectively. Herein, we discuss specific conservation measures as they apply to each threat described above (see *Factor A—Development, Utility Maintenance and Miscellaneous Activities, Invasive, Nonnative Plants, Anthropogenic Fire, and Recreation* sections above); however, not all landowners implement conservation measures that address each threat.

Vandenberg Air Force Base (AFB)

The Air Force developed an INRMP in 2011 (Air Force 2011c) pursuant to the Sikes Act Improvement Act of 1997 (Sikes Act). The Sikes Act requires the Department of Defense to develop and implement INRMPs for military installations in the United States. INRMPs direct the management and use of the lands on a military installation and are prepared in cooperation with the Service and State fish and wildlife agencies to ensure proper consideration of fish, wildlife, and habitat needs. This Vandenberg AFB INRMP was prepared to provide strategic direction to ecosystem and natural resources management on Base. The long-term goal of the INRMP is to integrate all management activities in a manner that sustains, promotes, and restores the health and integrity of ecosystems using an adaptive management approach. The INRMP was designed to: (1) Summarize existing management plans and natural resources literature pertaining to Vandenberg AFB; (2) identify and analyze management goals in existing plans; (3) integrate the management goals and objectives of individual plans; (4) support Base compliance with applicable regulatory requirements; (5) support the integration of natural resource stewardship with the Air Force mission; and (6) provide direction for monitoring strategies. The INRMP includes a chapter that identifies step-down goals for the management of threatened and endangered species on Base; however, since Vandenberg monkeyflower was not a listed species at that time, specific goals for it were not included. In 2012, the Air Force approved an addendum that addresses specific goals for Vandenberg monkeyflower (Air Force 2012). The INRMP and addendum provide for measures that would conserve Vandenberg monkeyflower, as follows:

(1) *Development.* The Air Force is not likely to construct new launch facilities within suitable habitat near human-populated areas, and the future siting of community facilities is expected to occur in a manner that capitalizes on existing infrastructure and circulation systems (Air Force 2009a, p. 32). Thus, no specific conservation measures have been proposed to minimize the threat of development to Vandenberg monkeyflower or its habitat on Base.

(2) *Utility Maintenance and Miscellaneous Activities.* Construction of new facilities is not likely to occur within Vandenberg monkeyflower habitat; however, existing utilities will require periodic maintenance. No specific conservation measures were proposed in the addendum to the INRMP (Air Force 2012). The main objective is to avoid any impacts to habitat, when possible, by either confining the work to existing disturbed areas or rerouting the work to avoid suitable habitat completely, and minimize the impact as much as possible (Air Force 2012, p. 2). For Vandenberg monkeyflower, the Air Force would avoid impacting Burton Mesa chaparral as much as possible if utility maintenance is required in suitable habitat.

(3) *Invasive, Nonnative Plants.* The INRMP (Air Force 2011a) includes an Invasive Plant Species Management Plan that identifies the threat of invasive, nonnative plants on Base, and proposes removal methods to limit further spread and assist in restoration of habitat degraded by invasive species. In most cases, the Air Force would utilize chemical application to manage for invasive plants (Air Force 2011a, p. 43). Although the INRMP identified invasive, nonnative plants as a threat and calls for their removal, it did not identify which nonnative species, and

which areas on Base, were a priority for treatment.

In the 2012 addendum to their INRMP, the Air Force identifies veldt grass as the most problematic invasive, nonnative plant on Base for Vandenberg monkeyflower. As part of this addendum, the Air Force also identified their 10-year funding program, which included more than $500,000 to treat veldt grass, starting in 2009 and continuing through 2019 (Air Force 2012). While the Air Force does not specify precisely where, when, or how much veldt grass will be treated or removed in specific years, they state that a substantial portion of this effort will focus on areas within the range of Vandenberg monkeyflower (Air Force 2012, p. 1). Through 2012, the Air Force has chemically treated approximately 141 acres (57 ha) of invasive, nonnative plants, mostly treating pampas grass within Burton Mesa chaparral but not near extant Vandenberg monkeyflower occurrences (treatment was to benefit *Eriodictyon capitatum* (Lompoc yerba santa)). Other invasive, nonnative plants treated included veldt grass, iceplant, *Eucalyptus* spp. (Eucalyptus), and *Pinus* spp. (Pine)). Only a small proportion of this chemical removal occurred within Burton Mesa chaparral at two locations where Vandenberg monkeyflower occurs (Lake and Pine Canyons) (Lum *in litt.* 2013).

(4) *Fire.* For fires that would affect Vandenberg monkeyflower and its habitat, the Air Force developed a GIS layer incorporating all potential suitable habitat areas, which has been made available to fire response crews for use during actual fire events. Multiple conservation measures that address the potential threat of fire are included in the addendum (Air Force 2012, p. 2), including the following:

(a) Established roads, both paved and unpaved, would be used to the greatest extent possible as fire lines unless an emergency dictates otherwise.

(b) Burned areas would be assessed after a fire for rehabilitation options within 10 days of the area being declared safe for entry.

(c) Vandenberg monkeyflower habitat affected by wildfire and rehabilitation projects will be monitored, which would include recommendations for nonnative species control.

(d) Following any significant wildfire event within the range of Vandenberg monkeyflower on Base, a Burn Area Emergency Response (BAER) project will be initiated. This generally includes implementation of erosion control, native vegetation restoration, firebreak rehabilitation, and invasive species management.

Additionally, the addendum proposes to incorporate portions of Vandenberg monkeyflower habitat in a controlled burn program (Air Force 2012, p. 2).

(5) *Recreation.* No conservation measures have been proposed to address the threat of recreation to Vandenberg monkeyflower.

Burton Mesa Ecological Reserve (Reserve)

Ecological Reserves are established under California State law to provide protection for rare, threatened, or endangered native plants, wildlife, aquatic organisms, and specialized terrestrial or aquatic habitat types. According to the California Code of Regulations (14 CCR Section 630), public entry and use of ecological reserves shall be compatible with the primary purposes of such reserves, and subject to general rules and regulations. The State Lands Commission signed a 49-year lease of the Burton Mesa Ecological Reserve on January 20, 2000. The purpose of the lease is to manage, operate, and maintain these sovereign lands for the sensitive species and habitats they support (Gevirtz *et al.* 2007, p. 3). The CDFW developed a management plan for the Reserve that guides management of habitats, species, and programs to achieve the mission of CDFW to protect and enhance wildlife values (Gevirtz *et al.* 2007, p. 1).

Conservation measures are proposed in the management plan, as outlined below. However, implementation of the management goals is contingent upon available funding and staffing. Currently, no funding is dedicated for the management of the Reserve and it is staffed by 10 percent of one biologist position. Some grant funding has been used for specific management needs.

(1) *Development.* Because new development would not occur on the Reserve, there are no conservation measures to implement that would minimize this threat to Vandenberg monkeyflower.

(2) *Utility Maintenance and Miscellaneous Activities.* Several public utilities and local governmental agencies provide services to the local community and use the Reserve to accomplish their roles. Within the Reserve, agencies responsible for conducting maintenance activities submit maintenance plans for all scheduled activities to CDFW, who in turn may request conservation measures (such as modifying the size and frequency of actions) to minimize impacts on natural resources (Gevirtz *et al.* 2007, pp. 230–236). We are not aware of specific projects in which the CDFW has requested conservation measures to minimize the impacts to Vandenberg monkeyflower and its habitat. However, the goal is to minimize damage to sensitive biological and cultural resources (Gevirtz *et al.* 2007, p. 230), which would include minimizing impacts to Burton Mesa chaparral.

(3) *Invasive, Nonnative Species.* The Reserve's management plan encourages minimizing the impact and presence of invasive, nonnative plants, including monitoring and removing nonnative plants; preventing new introductions by working with public utilities, local governmental agencies, and recreationists that use the Reserve; and restoring disturbed and degraded areas with native species (Gevirtz *et al.* 2007, pp. 241–242, 249–253). Additionally, during spring of 2011, the Santa Barbara Botanic Garden conducted a 2-day educational workshop at the Reserve to discuss Burton Mesa chaparral and identify the local plants, learn more about the distribution and habitat requirements of some of the County's rare plants, and document populations of rapidly spreading weeds, such as Sahara mustard, that are threatening rare species (Junak 2011). Furthermore, volunteers, CDFW, and our staff have occasionally mapped, removed, or chemically treated a few populations of invasive, nonnative plants on the Reserve, including Sahara mustard, veldt grass, iceplant, and pampas grass (Junak 2011; Meyer 2012, pers. comm.). We recently provided funding ($60,000) to CDFW to compare various removal methods for invasive species, in which part of the funding would be used to enhance suitable Vandenberg monkeyflower habitat on the Reserve and monitor the results; work will commence in 2013 (CDFG 2011, entire).

(4) *Fire.* The CDFW management plan for the Reserve calls for coordination among the Santa Barbara County Fire Department, enforcement agencies, local governmental agencies, and adjacent small and large landowners to ensure that fire risk is reduced, that new development projects adjacent to the Reserve are reviewed by CDFW staff and address fuel reduction needs and requirements, and that appropriate and efficient post-fire remediation takes place, where needed (Gevirtz *et al.* 2007, pp. 255–262). Reducing the risk of fire would limit the potential for wildfire to occur within Vandenberg monkeyflower habitat, and thus reduce the impact of fire suppression activities and the impact of invasive, nonnative plants invading the habitat post-fire (see *Factor A—Invasive, Nonnative Plants and Anthropogenic Fire* sections above). Additionally, the plan suggests

prohibiting the use of prescribed fire for the purposes of reducing fuel load, but allowing use of controlled burns for small-scale restoration projects (such as suppression of annual grasses or stimulation of chaparral seed bank for restoration projects) (Gevirtz *et al.* 2007, p. 258). No controlled burns within Vandenberg monkeyflower habitat have occurred to date.

(5) *Recreation.* CDFW developed a trails plan that shows existing trails within the Reserve as well as proposed new trail construction; seasonal trail closures or restrictions may occur to protect sensitive resources such as wildlife breeding locations or rare plant assemblages that vary from year to year (Gevirtz *et al.* 2007, p. 70). This system of trails would reduce the risk of authorized recreational uses directly impacting suitable Vandenberg monkeyflower habitat. The management plan calls for maintaining public access to the Reserve through pedestrian hiking trails by providing a network of trails, including loop trails, linking interesting areas while protecting resources, and preventing unauthorized uses (Gevirtz *et al.* 2007, p. 231).

La Purisima Mission State Historic Park

General plans for State Parks are prepared to guide future management and development of State Park System units. The goal of the State Parks natural resource management program is to protect, restore, and maintain the natural resources in the State Park System. A general plan is the primary management document for each unit of the California State Park System, defining a park's primary purpose, and establishing a management direction for its future. The General Plan must satisfy certain requirements of the Public Resources Code and be approved by the California State Park and Recreation Commission before the Department undertakes any development in the park that would constitute a permanent commitment of natural or cultural resources. Further, broad resource management policies concerning State Historic Parks are stated in the Public Resources Code, the California Code of Regulations, and the Department's Resource Management Directives (California State Parks 1991, p. 54). A general management plan for La Purisima Mission SHP was completed in 1991 (California State Parks 1991, entire), and an ecosystem characterization of La Purisima Mission SHP was completed in 2005 (Gevirtz *et al.* 2005, entire). Directives specific to La Purisima Mission SHP that concern the habitat where Vandenberg monkeyflower occurs include preserving Burton Mesa chaparral, protecting and managing rare and endangered plants in perpetuity, controlling nonnative plants that have become established, and developing a prescribed-burn plan (California State Parks 1991, p. 54).

Conservation measures are proposed in the general management plan, as outlined below. However, implementation of the management goals is contingent upon available funding and staffing. State Parks often rely upon the dedicated work of volunteers. Additionally, while the management plan contains biological resource conservation measures, the primary goal of the plan for La Purisima Mission SHP is to preserve the historical setting and maintain the historical ''sense of place''—visitors' sense of stepping back in history (California State Parks 1991, p. 3).

(1) *Development.* The significance of the historical setting at La Purisima Mission SHP has always been given a high priority, as has management of the existing facilities (California State Parks 1991, p. 120). There are multiple existing structures within the park, and any new structures must provide for visitors' needs without competing for attention with historical buildings or the natural setting. All new development must be sensitive to that purpose of providing appropriate visitor facilities without detracting from the historical and natural setting of La Purisima Mission (California State Parks 1991, p. 121). Additionally, Burton Mesa chaparral habitat areas are designated as low-intensity use areas (California State Parks 1991, p. 66). Therefore, any new development is unlikely to impact Vandenberg monkeyflower or its habitat in the park.

(2) *Utility Maintenance and Miscellaneous Activities.* No conservation measures are proposed for the threat of utility maintenance actions within the park; however, there is no indication that the maintenance activities for existing utilities have affected Vandenberg monkeyflower or its habitat.

(3) *Invasive, Nonnative Species.* California State Parks' resource management programs try to remove or control invasive, nonnative species and reestablish indigenous native species (California State Parks 2013). Stands of veldt grass and pampas grass within Burton Mesa chaparral were chemically treated in 2009 and 2010 (California State Parks 2010, p. 3). Veldt grass removal efforts have focused on hand removal in areas where it is encroaching into intact native habitat and into sparsely vegetated areas where native annual herbs grow, including Vandenberg monkeyflower. California State Parks received funding from the Service's Coastal Program in August 2012 and anticipates commencing veldt grass eradication efforts in 2013 to enhance Vandenberg monkeyflower habitat (Service 2012c, pp. 5–6). Specifically, California State Parks will enhance 91 ac (37 ha) of upland habitat surrounding extant occurrences of Vandenberg monkeyflower by removing veldt grass (Service 2012c, entire).

(4) *Fire.* California State Parks requires that a wildfire management plan be developed for every State Park. They developed a general management plan in 1991 and stated their intent to continue to work with the Santa Barbara County Fire Department, the California Department of Forestry and Fire Protection, local fire districts, and other appropriate agencies to implement and keep this plan current (California State Parks 1991, p. 57). In 2007, California State Parks initiated development of a wildfire management plan that would include management strategies to protect the existing infrastructure (buildings) and protect cultural resources and biological resources of the park (which would include Vandenberg monkeyflower habitat), as well as informing fire suppression agencies of the areas with high-value resources and the limits of fire suppression activities in those areas. No prescribed burns currently occur within the park (Cox 2013, pers. comm).

(5) *Recreation.* As part of the general management plan, California State Parks developed a trail management plan to reduce conflicts between recreational use and historical values of the park (California State Parks 1991, pp. 5, 109). Consideration will be given to designating trails for specific types of uses and constructing new trail segments to avoid conflicts (California State Parks 1991, p. 65). The trail system requires continual brush and erosion control, in which California State Parks often relies on numerous volunteers such as scouts and environmental groups to assist the park each year in various projects, from litter pickup to trail construction (California State Parks 1991, p. 109). A designated trail system would reduce the risk of authorized recreational uses directly impacting Vandenberg monkeyflower habitat. However, as described above in the *Recreation and Other Human Impacts* section, the best available information indicates that recreational activities are currently having minimal to no effect on Vandenberg monkeyflower habitat at La Purisima Mission SHP.

Summary of Conservation Measures Undertaken for Vandenberg AFB, the Reserve, and La Purisima Mission SHP

Management goals for the Air Force, CDFW, and California State Parks in these plans include, but are not limited to, minimizing the spread and impact of invasive, nonnative species; working with local agencies to recognize the importance of, and resource protections afforded to, sensitive species like Vandenberg monkeyflower and its habitat; and maintaining the natural resources of Burton Mesa, especially Burton Mesa chaparral habitat. The Air Force, CDFW, and California State Parks have attempted to address the greatest threat to Vandenberg monkeyflower by removing or chemically treating invasive, nonnative plants on their lands, respectively. Working collaboratively in some instances, the Service has funded and volunteered manpower to help reduce the spread and impact of invasive, nonnative plants. Overall, because implementation of the management plans is dependent upon available funding and staffing, because of the quantity of invasive, nonnative species that threaten Vandenberg monkeyflower habitat (Burton Mesa chaparral), and because of the difficulty eradicating invasive, nonnative species once they become established on Burton Mesa, the implementation of the management plans as currently constituted would not eliminate the threats described in Factor A.

Summary of Factor A

Most of the historical loss of Burton Mesa chaparral is due to military, residential, and commercial development that occurred in the past and resulted in many developed areas that have existed for decades, although historical loss of chaparral is also due to the presence and expansion of invasive, nonnative plants. Prior to 1938, there were approximately 23,550 ac (9,350 ha) of Burton Mesa chaparral (Hickson 1987, p. 34). In 2012, approximately 10,057 ac (4,070 ha) of Burton Mesa chaparral remained, which represents a loss of 53 percent of the original upland habitat (Service 2012a, unpublished data). Based on the habitat characteristics of Burton Mesa chaparral, it is probable that an equivalent percent loss of sandy openings that occur in-between shrubs may have occurred over this timeframe (see *Background—Habitat* section above).

The majority of remaining Burton Mesa chaparral where Vandenberg monkeyflower occurs is within Federal or State-owned lands and is protected from development. Therefore, large-scale future development of remaining Burton Mesa chaparral is not likely to occur and thus is not a significant threat to Vandenberg monkeyflower. However, smaller scale private property development; access to easements; maintenance of utility, oil, and gas pipelines; fire and fire suppression; and authorized and unauthorized recreational activities may continue to take place throughout Burton Mesa. Some of these activities may occur within Burton Mesa chaparral or adjacent to occurrences of Vandenberg monkeyflower, resulting in the destruction and possible removal of Vandenberg monkeyflower habitat and creating open areas for nonnative plants to invade. Therefore, the direct destruction and alteration of chaparral habitat could continue to occur on a relatively small scale and is thus considered a threat to Vandenberg monkeyflower both currently and in the future.

The presence and proliferation of invasive, nonnative plants is a threat to Vandenberg monkeyflower habitat that has the most significant impact to the species because nonnatives are spreading rapidly across Burton Mesa. The Air Force, CDFW, and California State Parks are implementing conservation measures to address the threat of nonnative plants within Vandenberg monkeyflower habitat. Nevertheless, invasive, nonnative plants are present at all locations where Vandenberg monkeyflower occurs, are known to alter native habitat, including that of Vandenberg monkeyflower, and are reducing the abundance and diversity of native plant species. Many of the nonnative species that occur on Burton Mesa are species deemed to pose significant ecological concerns because they displace native vegetation and occupy sandy openings where Vandenberg monkeyflower grows. Additionally, development that has fragmented the mesa, ground disturbances along easements, and authorized and unauthorized recreational activities increase the pathways for nonnative plants to establish and spread. Moreover, fire increases the potential for the invasion of nonnative plants by creating bare ground that facilitates the spread of nonnative vegetation. Therefore, with the prevailing onshore wind, an abundant upwind source of nonnative plants and seed, and continued ground disturbances, we conclude that the presence and expansion of invasive, nonnative plants is a threat to Vandenberg monkeyflower habitat both currently and in the future.

Climate change may have potential impacts on Vandenberg monkeyflower and its habitat, such as increased temperatures and decreased precipitation that would likely reduce suitable habitat. However, because of the moderating influence of the ocean, the effect of climate change on Burton Mesa flora may be moderated.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

No available information indicates any impacts to Vandenberg monkeyflower related to overutilization for commercial, recreational, scientific, or educational purposes or that these activities would increase in the future. Therefore, we do not consider this factor to be a threat to Vandenberg monkeyflower, nor do we expect it to be in the future.

Factor C. Disease or Predation

There is no available information indicating any impacts to Vandenberg monkeyflower related to disease or predation, or that disease or predation may become a concern in the future. Therefore, we do not consider disease or predation to be threats to Vandenberg monkeyflower, nor do we expect them to become threats in the future.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Under this factor, we examine whether existing regulatory mechanisms are inadequate to address the threats to Vandenberg monkeyflower discussed under other factors. We give strongest weight to statutes and their implementing regulations, and management direction that stems from those laws and regulations. They are nondiscretionary and enforceable, and are considered a regulatory mechanism under this analysis. Examples include State governmental actions enforced under a State statute or constitution, or Federal action under statute.

Some other programs are more voluntary in nature or dependent on available funding (see *Conservation Measures Undertaken* section above); in those cases, we analyze the specific facts for that effort to ascertain its effectiveness at mitigating the threat and the extent to which it can be relied on in the future. Having evaluated the significance of the threat as mitigated by any such conservation efforts, we analyze under Factor D the extent to which existing regulatory mechanisms adequately address the specific threats to the species. Regulatory mechanisms,

if they exist, may preclude the need for listing if we determine that such mechanisms adequately address the threats to the species such that listing is not warranted.

Vandenberg monkeyflower is not federally or State-listed as endangered or threatened. The Service added this species to the Federal list of candidate species on November 10, 2010 (75 FR 69222; see Previous Federal Actions section above); however, candidate species are afforded no protections under the Act. The California Native Plant Society (CNPS) classifies this species as 1B.1, which denotes that a taxon is seriously endangered in California (CNPS 2012).

State Regulations

The California Endangered Species Act (CESA) allows the Fish and Game Commission to designate species, including plants, as threatened or endangered. The CESA makes it illegal to import, export, ''take,'' possess, purchase, sell, or attempt to do any of those actions to species that are designated as threatened, endangered, or candidates for listing, unless permitted by CDFW. Vandenberg monkeyflower is not listed as threatened or endangered under the CESA (CDFW 2012).

The Native Plant Protection Act (NPPA) was enacted in 1977 and allows the Fish and Game Commission to designate plants as rare or endangered. The NPPA prohibits take of endangered or rare native plants, but includes some exceptions for agricultural and nursery operations, emergencies, and (after properly notifying CDFW) vegetation removal from canals, roads, and other sites, changes in land use, and certain other situations. Vandenberg monkeyflower is not designated as rare or endangered under the NPPA (CDFW 2012).

Ecological Reserves are established under California State law to provide protection for rare, threatened, or endangered native plants, wildlife, aquatic organisms, and specialized terrestrial or aquatic habitat types. Likewise, the goal of the State Parks resource management program is to protect, restore and maintain the natural resources in the State Park System (see *Conservation Measures Undertaken* section above).

The California Environmental Quality Act (CEQA) requires a full disclosure of the potential impacts that proposed projects on non-Federal lands will have on the environment, including sensitive resources. CEQA does not confer any protection to sensitive species, but merely requires disclosure of potential impacts. Lead CEQA agencies are also required to disclose potential impacts to CNPS list 1B.1 species, including Vandenberg monkeyflower. The lead agency for CEQA analysis is the public agency with primary authority or jurisdiction over the project, and is responsible for conducting a review of the project and consulting with other agencies responsible for resources affected by the project; this agency is typically a county, city, or special district agency. Three proposed projects have undergone CEQA analysis on Burton Mesa in recent years, and the CEQA process adequately disclosed impacts of these projects (see *County or Local Regulations* below for a discussion of the CEQA process for these three proposed projects).

County and Local Regulations

(1) The County of Santa Barbara, which is the lead agency responsible for CEQA review for projects on non-Federal lands where Vandenberg monkeyflower occurs, approved the Clubhouse Estates residential development in August 2005 (County of Santa Barbara Planning Commission 2005) (see *Factor A—Development* for a description of the project).

While the CEQA review disclosed impacts to Vandenberg monkeyflower and its habitat at the Clubhouse Estates project site, the CEQA review does not afford protection to this species or its habitat. Therefore, the County of Santa Barbara included conditions to their approval of the Clubhouse Estates development project. County stipulations to the Clubhouse Estates approval that would benefit Vandenberg monkeyflower and its habitat included: onsite habitat restoration and preservation plan, an open space management plan, onsite habitat restoration, and native plant propagation. Thus, the project proponent (LFR, Inc.) developed a restoration, construction monitoring, and resource protection plan to address the mitigation of native ecological resources impacted by the development project, to provide for restoration of disturbed habitat within the designated open space (Lot 54), and to describe ecological resource protection measures that would be implemented during construction (LFR, Inc. 2006, p. 1, pp. 34–60). The restoration plan was developed (LFR, Inc. 2006) but has not been fully implemented, possibly due to the development project falling into foreclosure in December 2009 (VVCSD 2011). Additionally, LFR, Inc. conducted actions to further preserve Vandenberg monkeyflower by collecting seeds and storing them at the Santa Barbara Botanic Garden, salvaging topsoil from where Vandenberg monkeyflower previously occurred on the project site (which likely contained a seed bank), and depositing the topsoil outside of the project site and within suitable habitat, and transplanting three individual plants (McGowan *in litt.* 2007).

The County is also responsible for permitting other activities, such as grading, according to Santa Barbara County Grading Code, Chapter 14. A grading permit would have associated erosion and sediment controls, including best management practices and other conditions of approval that would minimize impacts to sensitive biological resources (County of Santa Barbara Planning and Development 2013; LFR, Inc. 2006, entire). Our records indicate that the Clubhouse Estates project site was cleared prior to the developer's acquisition of a grading permit from the County (Mooney *in litt* 2006; Meyer *in litt.* 2006). Thus, in this case, County regulations concerning grading were inadequate to ensure proper implementation of the permitting process, which would have included implementing the conditions of approval that serve to minimize impacts to sensitive biological resources. As a result, clearing the Clubhouse Estates project site destroyed Burton Mesa chaparral that was occupied by Vandenberg monkeyflower individuals and removed adjacent habitat that likely harbored a seed bank (Meyer *in litt.* 2010b; see *Development—Private Lands* under Factor A). Additionally, this unpermitted ground disturbance created open areas where veldt grass and Sahara mustard have expanded to areas where they did not occur prior to the vegetation being cleared from the project site (Meyer *in litt.* 2010b; see *Invasive, Nonnative Species* section above).

(2) The City of Lompoc conducted a CEQA review for the Burton Ranch (see *Factor A—Development* for a description of the project). Approximately 141 of 149 ac (57 of 60 ha) of the project site would be developed, including removal of 83 ac (34 ha) of chaparral habitat on Burton Mesa. No Vandenberg monkeyflower has been observed within this project site. A 100-ft (30-ha) buffer between the development and the Reserve boundary to the north of the project site and 10 ac (4 ha) of onsite open space were proposed as part of the project (SAIC 2005a). Additionally, to mitigate for the removal of native vegetation at the Burton Ranch project site, the project proponent completed a conservation easement with the Land Trust for Santa

Barbara County (Land Trust) that will protect 95 ac (38 ha) of land featuring unique Burton Mesa chaparral, coastal scrub and oak savannah habitat near Vandenberg Village, an area that is known as the Burton Ranch Chaparral Preserve (Feeney *in litt.* 2012). The Land Trust received this 95 ac (38 ha) and will monitor the property and work with CDFW to protect and enhance the ecological resources of the site (Land Trust 2013). This area straddles adjacent portions of the Burton Mesa Ecological Reserve and is connected to the Reserve via walking trails (Land Trust *in litt.* 2011).

(3) The Allan Hancock College District conducted the CEQA analysis for a proposal to construct a public safety complex at Allan Hancock College (see *Factor A—Development* section for a description of the project). The proposal includes removal of at least 40 ac (16 ha) of chaparral habitat on Burton Mesa along the northern project boundary that is contiguous with the Davis Creek drainage. Vandenberg monkeyflower has not been observed within this project site. Approximately 105 of the 200 ac (42 of 81 ha) of the site is covered with chaparral habitat and, minus the 40 ac (16 ha) of chaparral within the project footprint, approximately 65 ac (26 ha) of chaparral habitat that is contiguous would be preserved (Allan Hancock College 2009, pp. 9, 135). Preserving chaparral in this area may reduce the potential for nonnative plants to invade the intact Burton Mesa chaparral that is contiguous with the Reserve to the north of this project site.

Despite implementation of the CEQA process and disclosure of the impacts to this species or its habitat, these projects illustrate that development can constitute a direct threat (removal of Vandenberg monkeyflower individuals) to Vandenberg monkeyflower and/or suitable habitat, and this threat is present and is expected to continue into the future (see *Development—Private Lands* section under Factor A above) within Burton Mesa chaparral (Vandenberg monkeyflower habitat) on non-Federal lands. Threats to the habitat are exacerbated because ground-disturbing projects further fragment chaparral habitat and create open areas (i.e., vectors) for invasive, nonnative plants to establish and further expand into Burton Mesa (see the *Invasive, Nonnative Species* section above).

Federal Regulations

The National Environmental Policy Act (NEPA) requires full disclosure of potential impacts that proposed projects on Federal lands or with Federal involvement will have on the environment, including sensitive resources. The NEPA process would apply to projects proposed on Vandenberg AFB and projects on non-Federal lands that include a Federal nexus, such as funding or permitting by a Federal agency. The NEPA analysis, like CEQA, does not confer any protection to sensitive species, but merely discloses potential impacts. Although Federal agencies may include conservation measures for Vandenberg monkeyflower as a result of the NEPA process, any such measures are typically voluntary in nature and are not required by statute.

For example, although the Vandenberg monkeyflower is not yet a federally threatened or endangered species, it is recognized by Vandenberg AFB as a species deserving of conservation measures as demonstrated by the Air Force's recent submittal of a proposal to include Vandenberg monkeyflower in their INRMP (Air Force 2012). The Air Force could include conservation measures for Vandenberg monkeyflower and its habitat as a result of the NEPA process. The NEPA would not itself regulate activities that might affect Vandenberg monkeyflower, but it would require full evaluation and disclosure of information regarding the effects of contemplated Federal actions on sensitive species and their habitats.

The Sikes Act requires the Department of Defense to develop and implement INRMPs for military installations in the United States. INRMPs direct the management and use of the lands on a military installation and are prepared in cooperation with the Service and State fish and wildlife agencies (i.e., CDFW) to ensure proper consideration of fish, wildlife, and habitat needs (see *Conservation Measures Undertaken* section above for more discussion of Vandenberg AFB's INRMP).

Summary of Factor D

The existing regulatory mechanisms at the Federal and State levels require evaluation of potential actions that may impact Vandenberg monkeyflower and its habitat on Burton Mesa. At the Federal level, the NEPA only requires evaluation of impacts to the human environment. The Sikes Act requires military installations to develop INRMPs to ensure proper consideration of fish, wildlife, and habitat needs on their lands. However, no protections are in place at the local, State, and Federal levels that are intended to protect a plant species that is not Federally or State-listed, although Vandenberg AFB has proposed to include this species in their INRMP. Additionally, at least one incident of unauthorized grading occurred without following the required local permit process; loss of Vandenberg monkeyflower individuals and habitat was documented.

Federal and State ownership of much of the occupied Vandenberg monkeyflower habitat and the regulatory purposes that define the use of those Federal and State lands protect the species from direct losses of habitat and provide further protection from many of the forms of disturbance described above. However, the current regulatory regime does not address the majority of impacts associated with loss of Vandenberg monkeyflower habitat (i.e., development of private lands that result in habitat loss, fire and fire suppression efforts, authorized and unauthorized recreation activities, and the invasion and expansion of invasive, nonnative species). As described above under Factor A, the primary threat with the greatest severity and magnitude of impact to Vandenberg monkeyflower is invasive, nonnative species invasion and expansion. The existing regulatory mechanisms currently in place at the local, State, and national levels are inadequate to address this threat to Vandenberg monkeyflower and its habitat.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Competition for Resources With Invasive, Nonnative Species

In Factor A, we discussed how invasive, nonnative plants alter the habitat that supports Vandenberg monkeyflower. In this section, we discuss how invasive, nonnative plants compete with individuals of Vandenberg monkeyflower for light, water, and soil nutrients.

Invasion of nonnative plants and in particular nonnative grasses are a threat to Vandenberg monkeyflower because small annuals such as this species most likely cannot compete with fast-growing nonnative plants for light, water, and soil nutrients (refer to Barrows *et al.* 2009; Lambrinos 2000; D'Antonio and Vitousek 1992). Grasses have long been recognized as effective competitors with herbaceous and woody species (Davis and Mooney 1985; D'Antonio and Vitousek 1992).

(1) *Sunlight.* Rapidly growing nonnative grasses can reduce light at the soil surface and thereby reduce the photosynthetic ability of competitors (Thompson 1991, pp. 394–395). Like certain other annual *Diplacus* taxa,

Vandenberg monkeyflower only grows in habitats with little to no competition from invasive, nonnative plants (VFWO 2013). As described in *Factor A—Invasive, Nonnative Plants,* high densities of veldt grass would easily overtop Vandenberg monkeyflower because of monkeyflower's small stature, which in turn creates shaded conditions that are not suitable for germination and growth of Vandenberg monkeyflower. Additionally, Sahara mustard is able to form a canopy up to 3 ft (1 m) aboveground; this forces the native plants growing under the canopy to put more energy into growing taller at the expense of producing branches, flowers, and fruits (Barrows *et al.* 2009, p. 683). Therefore, because veldt grass and Sahara mustard grow taller in stature and more quickly than Vandenberg monkeyflower, these invading nonnative plants would likely shade and reduce the productivity and survival of Vandenberg monkeyflower where these species occur in close proximity to one another. Veldt grass in particular is of immediate concern given its presence at: (1) All of the Vandenberg monkeyflower extant occurrences; and (2) one potentially extirpated occurrence (i.e., Lower Santa Lucia Canyon (Meyer *in litt.* 2012c)), where veldt grass is a dominant species within the sandy openings and where herbs that are commonly associated with Vandenberg monkeyflower are absent.

(2) *Water and Soil Nutrients.* Nonnative grasses compete effectively with native species for water and soil nutrients (D'Antonio and Vitousek 1992, p. 70). The effective uptake of water and nutrients by grasses is the result of their dense shallow root systems. The root systems of most woody species are deeper and less dense than those of grasses; once woody species become large, they are generally thought to have access to moisture and nutrients from portions of the soil profile below grass roots (D'Antonio and Vitousek 1992, p. 70). Shallow-rooted herbs that occur in open areas were found to deplete soil moisture to a maximum depth of 1.6 ft (0.5 m); grassland plants had roots active to 2.5 ft (0.75 m); and chaparral had roots extending below 6.6 ft (2.0 m) (Davis and Mooney 1985, p. 525). Therefore, grasses are most effective as competitors against seedlings and shallow-rooted annuals rather than saplings or adults of woody species (Davis and Mooney 1985, p. 528; D'Antonio and Vitousek 1992, p. 70). However, Knoop and Walker (1985, p. 249) demonstrated that grasses can reduce water availability in the subsoil at a depth of 1 to 4.25 ft (0.3 to 1.3 m) where shrub roots are common.

Many examples exist of invasive, nonnative plants outcompeting native herbs and shrubs for water and soil nutrients, some of which include the following:

(1) Davis and Mooney (1985, p. 528) demonstrated across a grassland-chaparral ecotone in Jasper Ridge Biological Preserve (approximately 7.5 mi (12 km) west of Palo Alto, California) that bare-zone annual herbs, such as *Navarretia heterodoxa* (Calistoga pincushionplant) and *Lessingia germanorum* var. *glandulifera* (valley lessingia), would be poor competitors against grassland species, in part, because these annual plants are shallow rooted and nonnative annual grasses are able to deplete the water in shallow soil.

(2) Eliason and Allen (1997, p. 252) conducted a study in the Santa Margarita Ecological Reserve (near Temecula, California) and determined that the growth and survival of transplanted *Artemisia californica* (California sagebrush) seedlings was significantly reduced in the presence of Mediterranean annual grasses from germination through the first growing season. This effect was due to the depletion of soil water because young California sagebrush and nonnative annual grasses are both shallow rooted.

(3) Melgoza *et al.* (1990, pp. 11–12) conducted a study in Belle Flats (approximately 22 mi (35 km) north of Reno, Nevada) and demonstrated that competition with *Bromus tectorum* (cheatgrass) negatively affected the productivity and water status of native perennial species. Melgoza *et al.* (1990, pp. 7, 11–12) found cheatgrass suppressed productivity of native species for an extended period of time (12 years after a fire) once it was established in open areas around native species, thus enhancing its capability after a fire to exploit soil resources and enhance its status in the community.

Because individuals of Vandenberg monkeyflower are small in stature (growing up to 10 in (25.4 cm) tall), invasive, nonnative plants that grow taller in stature and quicker than this species (such as veldt grass and Sahara mustard; see *Factor A—Invasive, Nonnative Plants and Anthropogenic Fire* section) may inhibit the growth and production of Vandenberg monkeyflower attempting to grow nearby. Moreover, because Vandenberg monkeyflower likely is shallow rooted like other small annual plants that grow in sandy openings within chaparral, invasive, nonnative grasses that occur within and near the species are likely outcompeting it by depleting the water at shallow depths and soil nutrients that it requires. Veldt grass is of particular concern because: (1) It is present at nine (100 percent) of the Vandenberg monkeyflower extant occurrences and one potentially extirpated occurrence (i.e., Lower Santa Lucia Canyon); and (2) it has deep-reaching roots that are able to tolerate Mediterranean climates (Tothill 1962, pp 132–161). Thus, veldt grass could deplete the water and soil nutrients that would otherwise be available for Vandenberg monkeyflower.

Small Population Size and Restricted Range

According to the criteria put forth by the World Conservation Union, as modified for plants, a species that has life history, population, and distribution attributes similar to those of Vandenberg monkeyflower is considered to have a high risk of extinction in the wild in the immediate future (Keith 1998, pp. 1085–1087). Species with few populations and individuals are vulnerable to the threat of naturally occurring events, which can cause extinction through mechanisms operating either at the genetic, population, or landscape level (Shaffer 1981, pp. 131–134; Primack 1998, pp. 279–308). Environmental stochasticity is annual variation in reproduction and death rates in response to weather, disease, competition, predation, or other factors external to the population (Shaffer 1981, p. 131). Natural catastrophes or prolonged drought could also result in the extirpation of a small population (Shaffer 1981, p. 131).

The genetic characteristics of Vandenberg monkeyflower have not been investigated; therefore, the degree to which genetic characteristics contribute to the likelihood of this species being vulnerable to extinction is unknown. However, random events operating at the population and landscape levels may increase the chance of extinction for Vandenberg monkeyflower. Although data are not available to determine population trends for this species, the best available information gained from multiple survey years between 2003 and 2012 indicate that 3 occurrences (33 percent) have fewer than 100 individuals. Six occurrences (67 percent) were recently shown to harbor more than 100 individuals, and 2 of those 6 occurrences (22 percent) contained more than 1,000 individuals (see *Current Status of Vandenberg Monkeyflower* section above). Numbers of plants observed during the most recent surveys are low for the three occurrences that have historically had

fewer than 100 individuals observed (but a seed bank may still exist):

(1) Four individuals were found in 2006 at Oak Canyon, although no individuals were found during the most recent surveys in 2010 and 2012 (VFWO 2013; Air Force 2012, p. 1; Lum *in litt.* 2012b; Rutherford *in litt.* 2012).

(2) Twenty-five individuals were found in 2006 at the Santa Lucia Canyon occurrence, and one individual was found during the most recent survey in 2010 (Ballard 2006; Lum *in litt.* 2012b).

(3) Five individuals were found in 2003 at the Volans Avenue occurrence, one in 2007, and no plants were found in other years surveyed between 2004 and 2009 (Meyer *in litt.* 2007; Ballard *in litt.* 2007).

Vandenberg monkeyflower fits the profile of a species that is considered to have small population numbers for an annual plant and is vulnerable to extinction because it has a restricted geographic range, and less than 10 known occurrences with less than 10,000 mature individuals (Keith 1998, pp. 1085–1087) (see *Distribution of Vandenberg Monkeyflower—Current Status* section above). Additionally, the potential further fragmentation of habitat and resulting increased isolation of Vandenberg monkeyflower occurrences affect the species rangewide by increasing the risk of population loss and potentially subsequent loss of genetic characteristics.

Species with few populations or those with low numbers may be subject to forces at the population level that affect their ability to complete their life cycles successfully. The number and density of flowering plants in a population can be important determinants of pollinator abundance and behavior (Jennersten 1988, pp. 361–363; Bernhardt *et al.* 2008, p. 948). Reduced numbers of individuals of flowering plants may lead to a reduction in abundance of pollinators and subsequent seed set and fitness of seed progeny (Menges 1991, p. 162). Specific information is not available for Vandenberg monkeyflower; however, these studies on other plant-pollinator relationships point out the importance of pollinators that is likely applicable to Vandenberg monkeyflower.

The invasion of nonnative plants has the ability to reduce the abundance of pollinators, which can have deleterious effects on reproduction of native plants. Jennersten (1988, p. 363) found that insect diversity, insect visitation rates to *Dianthus deltoides* (maiden pink), and number of seeds produced were significantly reduced where maiden pink was in a more fragmented habitat compared to continuous habitat. Lambrinos (2000, pp. 228) found that invasion of nonnative plants such as pampas grass can reduce the abundance of pollinators because pampas grass replaces nectar- and pollen-rich flowers of native shrubs and reduces the diversity of feeding sites provided by woody perennials. Lambrinos (2000, p. 227) also noted that arthropod (spiders and insects) abundance is lower overall, and known to be absent in areas dominated by pampas grass. In contrast, Bernhardt *et al.* (2008, p. 948) found that pollination of a native species such as *Lupinus perennis* (sundial lupine) increased with both population size and population density, which significantly affected insect visitation rates. Therefore, because Vandenberg monkeyflower has less than 10 occurrences, consists of low numbers of individuals, and invasive, nonnative plants are replacing native vegetation of Burton Mesa, this species may experience reduced reproduction because of reduced visitation by insect pollinators. However, we are unaware of specific information concerning the extent to which this may be a threat for Vandenberg monkeyflower.

Annual plants that are subject to wide fluctuations in population numbers from year to year, such as Vandenberg monkeyflower, may have difficulty maintaining a viable population size after a series of poor seed-production years. Additionally, if the host plants (plants being visited by pollinators) are partially self-incompatible, reduction in population size may lead to increased self-pollination and may reduce the level of genetic variability. At the landscape level, random natural events, such as storms, drought, or fire, could destroy a significant percentage of individuals or entire populations. Because Vandenberg monkeyflower comprises a small number of locations and individuals, and is restricted to a small geographic area on Burton Mesa, this species' risk of extinction increases from such naturally occurring events. No empirical information is available to estimate trends for Vandenberg monkeyflower populations; however, the continued decrease in habitat (especially from nonnative plant invasions) is contributing to habitat fragmentation and impacting the species' ability to persist.

Recreation

Recreational use occurs on Burton Mesa within Vandenberg AFB, the Reserve, and La Purisima Mission SHP. We discussed the effects to Vandenberg monkeyflower habitat resulting from recreational use (see *Factor A—Recreation*); however, recreational activities may also result in trampling individuals of Vandenberg monkeyflower. The Volans Avenue occurrence of Vandenberg monkeyflower is adjacent to a sewer line easement that is also used for hiking and dog walking. Recreational users are encouraged to stay within existing and designated trails (see *Factor A—Recreation*). No other location where this species occurs is adjacent to designated trails. Therefore, the best available information indicates that recreational activities involving casual human use are having minimal effect on individuals of Vandenberg monkeyflower. Unauthorized recreational activities such as mountain biking and ORV use have resulted in damaged native vegetation, and squashed and sometimes broken plant parts (Meyer *in litt.* 2010c; Meyer *in litt.* 2013). Determining where the unauthorized ORV activity originates on the Reserve is difficult because of the historical network of trails and roads. Available information does not indicate the extent and degree to which ORV activity and mountain biking may be impacting Vandenberg monkeyflower individuals.

Summary of Factor E

Competition for light, water, and soil nutrients from invasive, nonnative vegetation, particularly nonnative grasses, is a threat to Vandenberg monkeyflower. Because this species has a restricted range and small population numbers, it is vulnerable to naturally occurring events such as a wildfire, storms, and drought that could negatively affect its growth and productivity. Additionally, because of the restricted range, small number of individuals at each occurrence, and the spread of invasive, nonnative plants adjacent to each occurrence, this species is vulnerable to a reduction of visits by pollinating insects. The best available information indicates that casual recreational use has a minimal impact to individuals. Unauthorized recreational uses (ORVs and mountain biking) have the potential to result in damage to the native vegetation; however, the best information available does not indicate a direct threat to individuals of Vandenberg monkeyflower. Indirect effects of potential ground disturbance could create openings in the vegetation and assist the seed spread and establishment of nonnative vegetation. Therefore, we conclude that competition for resources with invasive, nonnative species and small population size and restricted range are threats to

Vandenberg monkeyflower currently and in the future.

Combination of Factors

Many of the threats discussed above act in concert, and the resulting effects to Vandenberg monkeyflower are amplified. For example, some land uses and development or maintenance activities (Factor A) create ground disturbance and subsequent openings in the vegetation where nonnative plants (Factor A) can invade, expand, and outcompete native vegetation (Factor E). Fires on Burton Mesa (Factor A) result in an increase in nonnative vegetation (Factor A). Similarly, an abundance of nonnative vegetation, particularly grasses (Factor A and E), may result in an increase in fire frequency (Factor A). The availability of habitat and small overall population size (Factor E) may be affected in a changing climate and by events such as wildfire (Factor A). Thus, Vandenberg monkeyflower's productivity may be reduced because of these threats, either singularly or in combination. Existing regulatory mechanisms have not proven effective at protecting Vandenberg monkeyflower or its habitat from these threats (Factor D).

The presence of invasive plants is the most significant threat to this species, both alone and in combination with other Factors (e.g., anthropogenic fire, recreation). The combination of factors would likely create a cumulative or synergistic threat to the existence of Vandenberg monkeyflower. Given these circumstances, the combined effects of current threats to the population put the species at risk rangewide, although the magnitude or extent of such threats to the viability of the species is not at this time determinable from available information.

Proposed Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to Vandenberg monkeyflower. We have identified threats to Vandenberg monkeyflower attributable to Factors A, D, and E.

In the summary of the threats described in detail above, we found that Vandenberg monkeyflower suitable habitat on Burton Mesa has been displaced by military, residential, and commercial development, although the most significant ongoing threat to Vandenberg monkeyflower is the loss of habitat due to the presence and continual spread of invasive, nonnative plants (Factor A). Approximately 53 percent of Burton Mesa chaparral habitat has been lost, with only 10,057 ac (4,070 ha) of the 23,550 ac (9,350 ha) that existed before 1938 remaining.

Additionally, invasive, nonnative plants, in particular veldt grass, are present and continuing to expand at all nine extant locations. No Vandenberg monkeyflower individuals have been observed at the three smallest extant locations (in the last 3 years at one location and the last 6 years at the other two locations) even though a residual seed bank is likely present. Burton Mesa chaparral is also subject to an anthropogenic fire regime that can increase the presence of invasive plants (Factor A). Casual human recreational use and utility maintenance activities can contribute to habitat disturbance that facilitates pathways for nonnative species to invade Burton Mesa chaparral habitat (Factor A).

Furthermore, invasive, nonnative plants are likely competing with Vandenberg monkeyflower for sunlight, water, and soil resources, and the species' restricted range and small population size makes it vulnerable to changing environmental conditions due to climate change and other random, naturally occurring events (Factor E). Small population size is a highlighted concern in part due to the low number of individuals found to exist at the 3 smallest extant occurrences, in particular 3 of the 9 occurrences that have a range of 0 to 25 individuals documented between 2003 and 2012. The threats described above for Vandenberg monkeyflower occur across its entire range, resulting in a negative impact on the species' distribution, abundance, and probability of long-term persistence. Existing regulatory mechanisms are not adequate to protect the species or its habitat from these identified threats (Factor D).

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that Vandenberg monkeyflower has a restricted range and is facing ongoing and projected threats across its range. We conclude that it meets the definition of an endangered species throughout its entire range due primarily to: (1) The invasion, spread, and competition of invasive, nonnative species at all nine extant locations; and (2) small population size that makes it vulnerable to stochastic events. These impacts are heightened due to anthropogenic fire conditions that promote further invasion of nonnative species; recreation and other human activities that contribute to the spread of invasive, nonnative species; and continued development on private lands that further reduces and fragments the remaining suitable habitat. The threats to its continued existence are not commencing in the foreseeable future (which would result in a status determination of a threatened species), but are immediate and ongoing. We base this determination on the immediacy, severity, and scope of the threats described above. Therefore, on the basis of the best available scientific and commercial information, we propose listing Vandenberg monkeyflower as an endangered species in accordance with sections 3(6) and 4(a)(1) of the Act.

Under the Act and our implementing regulations, a species may warrant listing if it meets the definition of an endangered or threatened species throughout all or a significant portion of its range. The Vandenberg monkeyflower that is proposed for listing in this rule is highly restricted in its range and the threats occur throughout its range. Therefore, we assessed the status of Vandenberg monkeyflower throughout its entire range. The threats to the survival of the species occur throughout the species range and are not restricted to any particular significant portion of that range. Accordingly, our assessment and proposed determination applies to the species throughout its entire range.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the

identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed, preparation of a draft and final recovery plan, and revisions to the plan as significant new information becomes available. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. The recovery plan identifies site-specific management actions that will achieve recovery of the species, measurable criteria that indicate when a species may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (comprising species experts, Federal and State agencies, nongovernmental organizations, or stakeholders) are often established to develop recovery plans. If a final listing rule is completed for Vandenberg monkeyflower, the Service will develop and complete a recovery outline, draft recovery plan, and the final recovery plan that will be available on our Web site (*http://www.fws.gov/endangered*), or from our Ventura Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribal, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (for example, restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions may be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. Additionally, pursuant to section 6 of the Act, the State of California would be eligible for Federal funds to implement management actions that promote the protection and recovery of Vandenberg monkeyflower. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although Vandenberg monkeyflower is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agencies proposing activities within the species' habitat that may need to conference or consult or both with the Service as described in the preceding paragraph include the Department of Defense, the Bureau of Prisons, the Federal Energy Regulatory Commission, and the Federal Highway Administration. Activities potentially include management and any other landscape-altering activities on Federal lands administered by the Department of Defense or the Bureau of Prisons, issuance of section 404 Clean Water Act permits by the Army Corps of Engineers, construction and management of gas pipeline and power line ROWs licensed by the Federal Energy Regulatory Commission, and funding by the Federal Highway Administration for the construction and maintenance of roads or highways.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered plants. All prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, transport in interstate or foreign commerce in the course of a commercial activity, sell or offer for sale in interstate or foreign commerce, or remove and reduce the species to possession from areas under Federal jurisdiction. Additionally, for plants listed as endangered, the Act prohibits the malicious damage or destruction on areas under Federal jurisdiction and the removal, cutting, digging up, or damaging or destroying of such plants in knowing violation of any State law or regulation, including State criminal trespass law. Certain exceptions to the prohibitions apply to agents of the Service and State conservation agencies. Vandenberg monkeyflower is not currently designated as rare or endangered under the NPPA or the CESA (CDFW 2012).

CEQA requires a full disclosure of the potential impacts that proposed projects on non-Federal lands will have on the environment, including sensitive resources. However, CEQA does not confer any protection to sensitive species, but merely discloses potential impacts. The lead agency for CEQA analysis is the public agency with primary authority or jurisdiction over the project, and is responsible for conducting a review of the project and consulting with other agencies responsible for resources affected by the project. Under CEQA, lead agencies are required to disclose potential impacts from proposals to CNPS list 1B.1 species; this mechanism may indirectly provide some protection to Vandenberg monkeyflower.

We may issue permits to carry out otherwise prohibited activities involving endangered and threatened wildlife and plant species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.62 for endangered plant species, and at 17.72 for threatened plant species.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effects of a proposed listing on proposed and ongoing activities within the range of the species proposed for

listing. The following activities could potentially result in a violation of section 9 of the Act; this list is not comprehensive:

Removing and reducing to possession Vandenberg monkeyflower from areas under Federal jurisdiction; malicious damage or destruction of Vandenberg monkeyflower from areas under Federal jurisdiction; unauthorized collecting, handling, possessing, selling, delivering, carrying, or transport across State lines and import or export across international boundaries, except for properly documented antique specimens of these taxa at least 100 years old, as defined by section 10(h)(1) of the Act.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the Ventura Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). Requests for copies of the regulations concerning listed plants and general inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Endangered Species Permits, Regional Recovery Permit Coordinator, Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Suite 101, Carlsbad, California 92011; (telephone 760–431–9440 ext. 225; facsimile 760–930–0846).

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination is based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during this public comment period.

We will consider all comments and information received during this comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the NEPA (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as endangered or threatened under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the 10th Circuit, we do not need to prepare environmental analyses pursuant to NEPA in connection with designating critical habitat under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the 9th Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).]

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* at Docket No. FWS–ES–R8–2013–0078 and upon request from the Ventura Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this package are the staff members of the Ventura Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. In § 17.12(h) add an entry for ''*Diplacus vandenbergensis* (Vandenberg monkeyflower) to the List of Endangered and Threatened Plants in alphabetical order under Flowering Plants to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*		*
Diplacus vandenbergensis.	Vandenberg monkeyflower.	U.S.A. (CA)	Phrymaceae	E			NA
*	*	*	*	*	*		*

Dated: September 30, 2013.

Rowan W. Gould,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–25397 Filed 10–28–13; 8:45 am]

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CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

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