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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
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FEDERAL REGISTER

Vol. 79 Monday,
No. 188 September 29, 2014

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 112

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA–2011–N–0921]

RIN 0910–AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend certain specific provisions of the proposed rule, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' We are taking this action because the extensive information received in public comments has led to significant changes in our current thinking on certain key provisions of the proposed rule. We are reopening the comment period only with respect to the specific issues identified in this document.

DATES: Submit either electronic or written comments on the proposed rule by December 15, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 15, 2014 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA–2011–N–0921) 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.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1636.

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Executive Summary

Purpose of the Supplemental Notice of Proposed Rulemaking

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, FDA published the proposed rule entitled, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,'' which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). FDA proposed these standards to implement section 105 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). The comment period for the proposed rule closed on November 22, 2013.

Taking into account information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket, currently available information, and our subsequent analysis of the proposed provisions in light of this information, we are proposing certain new provisions and certain amendments to our previously proposed provisions.

Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking

We are reopening the comment period to seek public comment on the specific issues and amended and new proposed provisions that are discussed in this document, which include the following: (1) Proposed amendments to paragraph (a) of proposed 21 CFR 112.4 to exclude from coverage of the Produce Safety proposed rule those farms or farm mixed-type facilities with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of $25,000 or less (on a rolling basis); and corresponding revisions to the definitions of ''very small business'' and ''small business'' in proposed § 112.3(b) to apply the monetary value thresholds based on sales of produce; (2) proposed amendments to the definitions of ''farm'' in proposed § 112.3(c) responding to comments about overlap between the produce and preventive control rules, such that establishments that pack or hold produce that is grown or harvested on another farm would now be subject to the produce safety standards of proposed part 112 regardless of whether or not that farm is under the same ownership; and corresponding revisions to the definitions of ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' in proposed § 112.3(c); (3) proposed amendments to § 112.44(c) to update the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method in a way that is consistent with the U.S. Environmental Protection Agency's (EPA) current recreational water standard, *i.e.,* a geometric mean of samples not to exceed 126 colony forming units (CFU) of generic *Escherichia. coli (E. coli)* per 100 milliliters (mL) of water and (when applicable) a statistical threshold value of samples not to exceed 410 CFU of generic *E. coli* per 100 mL of water; (4) new proposed provisions within

§ 112.44(c) to incorporate additional flexibility and provide means to achieve the proposed microbial quality standard for agricultural water used for direct application during growing, *i.e.,* by either applying a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (proposed § 112.44(c)(1)); and/or applying a time interval (in days) between harvest and end of storage (including during activities such as commercial washing) using appropriate microbial die-off or removal rates, provided there is adequate supporting scientific data and information (proposed § 112.44(c)(2)); in addition, a new proposed provision to provide for an alternative microbial die-off rate between last irrigation and harvest in accordance with § 112.12; (5) proposed amendments to § 112.45(b) and new proposed provisions §§ 112.45(c) and (d) to provide tiered-approaches for specific testing frequency requirements to test untreated surface water as well as untreated ground water, which would enable testing at a reduced frequency than that proposed in the previously published proposed rule; (6) a new proposed provision § 112.45(e) to provide that a farm may meet the requirements related to agricultural water testing using the farm's own test results or data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represents the farm's agricultural water source(s) and all other applicable requirements are met; (7) proposed removal of the 9-month minimum application interval for use of raw manure in proposed § 112.56(a)(1)(i). FDA defers its decision on an appropriate time interval until FDA pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with the U.S. Department of Agriculture (USDA) and other stakeholders. At this time, we do not intend to take exception to the continuation of adherence to the National Organic Program (NOP) standard; (8) proposed amendments to § 112.56(a)(4)(i)) to establish that if the biological soil amendment of animal origin is treated by a composting process and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.,* time between application and harvest) is 0 days; (9) new proposed provision § 112.84 to explicitly state that part 112 would not authorize or require covered farms to take actions that would constitute the ''taking'' of threatened or endangered species in violation of the Endangered Species Act, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages; (10) new proposed provision § 112.201(b)(1) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction; (11) new proposed provisions §§ 112.201(b)(2) and 112.201(b)(3) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA must notify the farm of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the farm to respond to FDA's notification; and that FDA must consider actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption; and (12) new proposed provision § 112.213 to list the circumstances under which FDA would reinstate a farm's qualified exemption that is withdrawn.

We are seeking comment on the issues discussed in this document by December 15, 2014. The previously published proposed rule (78 FR 3504; January 16, 2013) and the proposed amendments and new provisions published in this document, taken together, constitute the entirety of the proposed rule on ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' At this time, we are not seeking comment on any other provisions of the previously published proposed rule that are not identified for public comment in this document. We will complete our review of public comments received thus far, and take into account comments received in response to this document, in issuing a final rule.

Costs and Benefits

We performed additional analyses to examine the impacts of the amended and new proposed provisions described in this document. We estimate the costs of the proposed rule as currently amended to be $386.23 million annually for domestic farms, $143.39 million annually for foreign farms covered by the rule (for a grand total of $529.62 million annually), resulting in $400.37 million annually in estimated potential net benefits.

SUMMARY OF COSTS AND BENEFITS OF THE PROPOSED RULE AS CURRENTLY AMENDED

Prevented foodborne illnesses (in millions)	Total benefits (in millions)	Total domestic costs (in millions)	Total foreign costs (in millions)	Total costs (domestic + foreign)	Net benefits (in millions)
1.57	$930.00	$386.23	$143.39	$529.62	$400.37

Compared to the previously published proposed rule, in total, this represents a cost savings of $73.33 ($459.56 − $386.23) million for domestic produce farms, and a decrease in overall net benefits of $7.19 ($400.37 − $407.56) million.

I. Background

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, FDA published the proposed rule, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (hereafter referred to as ''the Produce Safety proposed rule'' or ''the previously published proposed rule''), which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). We later issued a notice to correct technical errors and errors in reference numbers cited in the proposed rule (78 FR 17155, March 20, 2013).

In the same issue of the **Federal Register** in which the Produce Safety proposed rule was published, FDA published another proposed rule entitled, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food'' that would apply to human food and require domestic and foreign facilities that are required to register

under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, monitor results, and act to correct problems that arise (hereafter referred to as ''the Preventive Controls for Human Food proposed rule'') (78 FR 3646, January 16, 2013). These proposed rules help form the foundation of, and a central framework for, a new food safety system in the United States.

We requested comments on the Produce Safety proposed rule by May 16, 2013. We extended the comment period for the proposed rule and its information collection provisions (which are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (78 FR 11611, February 19, 2013; 78 FR 24692, April 26, 2013; 78 FR 48637, August 9, 2013; 78 FR 69605, November 20, 2013). The comment period for the proposed rule closed on November 22, 2013.

Since publication of the Produce Safety proposed rule in January 2013, we conducted numerous outreach activities. For example, we held three public meetings to solicit oral stakeholder and public comments on the proposed rule, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the proposed rule (78 FR 6762, January 31, 2013, and 78 FR 10107, February 13, 2013). We also traveled across the country and around the world to discuss the Produce Safety proposed rule, as well as the other foundational FSMA proposed rules (Refs. 1, 2, and 3).

II. Amendments to the Previously Published Proposed Rule

In December 2013, FDA issued a public statement reiterating our goal of ensuring produce safety, and indicating that, based on the extensive input we have received from produce farmers, consumers, and others in the agricultural sector, significant changes will be needed in key provisions of the Produce Safety proposed rule, including those related to water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms (Ref. 4). We also announced our intent to propose revised regulatory requirements and request comment on them, allowing the public the opportunity to provide input on our current thinking. In this document, FDA is providing our current thinking on certain issues discussed in the Produce Safety proposed rule that we previously published, including certain amended and new proposed provisions, for public comment. In addition, published elsewhere in this issue of the **Federal Register**, we are also providing our current thinking on certain issues discussed in the Preventive Controls for Human Food proposed rule that we previously published, and seeking public comment on those issues.

To date, over 15,000 electronically submitted comments have been received in the docket in response to the previously published proposed rule. We are continuing to review all electronic and paper submissions of comments to the docket. Taking into account information received at public meetings, and based on a preliminary review of written comments submitted to the docket, currently available information, and our subsequent analysis of the proposed provisions in light of this information, we are reopening the comment period to seek public comment on certain specific issues described in this section.

Importantly, the amended and new proposed provisions we have included in the regulatory text are based on a preliminary review of the comments. We will complete our review of comments previously submitted and consider the comments responsive to this document in developing the final rule.

The previously published proposed rule and the proposed amendments and new provisions published in this document, taken together, constitute the entirety of the proposed rule on ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' Throughout this document, we discuss amendments and additions to the previously proposed part 112 and, in the codified section of this document, we list each of the amended and new proposed provisions of proposed part 112. For the convenience of readers and ease of reference, we prepared a separate document to identify the changes to the previously published codified provisions and provide the complete proposed part 112, as amended through this document (Ref. 5).

A. Proposed Subpart A—General Provisions

In the previously published proposed rule, under subpart A of proposed part 112, we proposed various provisions to establish the scope of, and definitions applicable to, the Produce Safety regulation, and to identify who would be subject to the requirements of part 112. Proposed subpart A also described the proposed modified requirements and procedures governing qualified exemptions from the regulations. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3534 through 3551).

We are reopening the comment period to solicit public comment on our current thinking on two specific issues related to the general provisions in subpart A: (1) Farm sizes based on monetary value of total food sales to determine those farms that are not covered by the rule and those that would qualify for extended compliance periods and (2) definition of ''farm''. We describe our current thinking on these two issues in this section.

1. Farms Sizes Based on Monetary Value of Total Food Sales

In the previously published proposed rule, we proposed to apply the Produce Safety regulation only to farms and farm mixed-type facilities with an average annual monetary value of food (as defined under the FD&C Act and including seeds and beans used to grow sprouts) sold during the previous 3-year period of more than $25,000 on a rolling basis (proposed § 112.4). We explained that farms below this $25,000 limit collectively account for only 1.5 percent of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. Based on a tentative conclusion that such businesses do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated, we tentatively concluded that imposing the proposed requirements of part 112 on these businesses is not warranted because it would have little measurable public health impact. We also noted that such farms are and would continue to be subject to the applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of the Produce Safety proposed rule (78 FR 3504 at 3518 and 3549).

In addition, we proposed to apply certain monetary value thresholds based on total food sales to define those very small and small businesses that would be eligible for our proposed extended time periods to comply with the Produce Safety regulation. In proposed § 112.3(b)(1), we proposed to define ''very small business'' to mean a business that is subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under the FD&C Act and including seeds and beans used to

grow sprouts) sold during the previous 3-year period is no more than $250,000. In addition, under proposed § 112.3(b)(2), we proposed to define ''small business'' to mean a business that is subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under the FD&C Act and including seeds and beans used to grow sprouts) sold during the previous 3-year period is no more than $500,000, and which farm is not a ''very small business.''

a. Relevant comments. We received several comments opposing our tentative decision to identify farm sizes based on total food sales either for coverage by the rule or for extended compliance periods. Commenters recommended that farm sizes should be based on the sale of ''covered produce'' or ''regulated'' produce, rather than on the sale of all food. Some of these commenters noted that the proposed coverage of farms based on their total food sales would make it difficult for midsize farms to diversify their operations. Other commenters maintained that covering farms based on their total food sales would have an adverse impact on diversified farms that primarily raise food grains or dairy cattle (and produce dairy products) by forcing them to comply with produce safety standards. Some commenters that recommended identifying farm sizes (both those that would not be covered and those that would be covered and considered as ''small businesses'' or ''very small businesses'') based on monetary value of sales of ''covered produce'' also recommended similarly applying the qualified exemptions provided under proposed § 112.5 to farms based on an average annual monetary value of $500,000 or less of sales of covered produce, rather than on sales of all food.

b. FDA's consideration of comments. In response to comments received, we considered what, if any, revisions are needed to the proposed $25,000 limit as the threshold above which farms would be subject to the Produce Safety regulation.

As noted in the previously published proposed rule, farms with an average annual monetary value of food sold of $25,000 or less collectively account for 1.5 percent of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. Applying the $25,000 limit to an average annual monetary value of produce (rather than food) sold would account for an estimated total of 4 percent of covered produce acres and about 3.1 percent of all produce acres in the United States. The amended proposal would remove farms with produce sales of $25,000 or less from coverage, resulting in removal of an additional 2.1 percent of produce acres from coverage (after removal of acres as a result of the provisions related to the qualified exemption, produce that is rarely consumed raw, and produce destined for commercial processing that eliminates pathogens of concern). Under this scenario, as with the previous proposed approach, such businesses would not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, would have little measurable public health impact. We believe that applying the $25,000 limit to *produce* sales would accommodate the concerns expressed by some comments without adversely affecting the level of public health protection, envisioned under our previous proposal.

We also considered applying the $25,000 limit to average annual monetary value of ''covered produce'' sold, as requested by some commenters. This scenario presented a number of challenges, including the difficulty of determining the scope and public health impact of excluding farms based on the sales of covered produce, particularly considering the likely variability in produce commodities grown year to year; variability resulting from provisions under which certain commodities would not be considered ''covered produce'' (for example, produce that is rarely consumed raw); changes in the amount of produce that is used for personal consumption or for consumption on the farm or another farm under the same ownership; and whether and how to account for produce that would be eligible for exemption under certain conditions, which may be inherently variable based on market conditions (for example, produce that is destined for commercial processing). Given these confounding factors and based on available data, at this time, we are unable to determine the extent to which businesses with an average annual monetary value of ''covered produce'' sold of more than $25,000 would contribute to the overall produce market or the public health impact of not covering such businesses under part 112. In addition, the likely frequent change to a farm's covered or non-covered status may also be challenging for compliance and enforcement purposes.

For these reasons, we are proposing to amend paragraph (a) of proposed § 112.4 to establish that if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a ''covered farm'' subject to this part, and that if you are a ''covered farm'' subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on ''covered produce.''

In addition, we are proposing corresponding revisions to the definitions of ''very small business'' and ''small business'' to apply the monetary thresholds consistently across three size-based categories of businesses that we proposed in the previously published proposed rule. As revised, a very small business defined under proposed § 112.3(b)(1) would mean a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce (as defined in proposed § 112.3(c)) sold during the previous 3-year period is no more than $250,000. As revised, a small business defined under proposed § 112.3(b)(2) would mean a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce (as defined in proposed § 112.3(c)) sold during the previous 3-year period is no more than $500,000; and the farm is not a very small business. Applying the monetary value limits for very small and small businesses to produce rather than to food, as previously proposed, would not alter the coverage of these businesses under the Produce Safety regulation, although we expect that a greater number of farms would likely fit within the revised definitions of very small business and small business and, therefore, qualify for the extended compliance periods we proposed for these businesses in the previously published proposed rule. See Table 1 for summary of these three proposed size-based categories, as revised.

We seek comment on our current proposal to cover farms with an average annual monetary value of ''produce'' sold of more than $25,000, and the corresponding revisions to apply the relevant monetary thresholds to the sales of produce to define small businesses and very small businesses that would be subject to this regulation for the purpose of establishing extended compliance periods. We also seek comment on whether and how these monetary thresholds may be applied to covered produce only.

TABLE 1—SUMMARY OF PROPOSED QUALIFICATIONS

[On a rolling basis, average annual monetary value of produce (as defined in proposed § 112.3(c)) sold during the previous 3-year period]

Above $250,000 and no more than $500,000.	Small Business.
Above $25,000 and no more than $250,000.	Very Small Business.
$25,000 or less	Not covered.

We also considered applying the monetary value limit to covered produce sales, rather than to total food sales, in the criteria applicable to farms that would be eligible for a qualified exemption under proposed § 112.5. In the previously published proposed rule, we proposed that a farm would be eligible for a qualified exemption and associated modified requirements in a calendar year if: (1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in proposed § 112.3(c)) you sold directly to qualified end-users (as defined in proposed § 112.3(c)) during such period exceeded the average annual monetary value of the food you sold to all other buyers during that period; and (2) the average annual monetary value of all food (as defined in proposed § 112.3(c)) you sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation (proposed § 112.5(a)). As explained in the proposed rule, proposed § 112.5(a) establishes the criteria for eligibility for a qualified exemption and associated special requirements based on average monetary value of all food sold and direct farm marketing, as mandated by section 419(f) of the FD&C Act (21 U.S.C 350h(f)). The criteria established in proposed § 112.5(a), including the requirement that ''all food'' be considered in calculating sales, are derived from section 419(f) of the FD&C Act. We, therefore, as a result of the statutory language, cannot apply the monetary value limit to covered produce sales, but instead must apply it to total or ''all'' food sales. Therefore, we are not able to make any change to the provision that the average annual monetary value of all food (as defined in proposed § 112.3(c)) sold during the 3-year period preceding the applicable calendar year must be less than $500,000, as proposed in § 112.5(a)(2)).

2. Definition of ''Farm'' (and ''Covered Activity,'' ''Harvesting,'' ''Holding,'' and ''Packing'')

In the previously published proposed rule, under subpart A of proposed part 112, we proposed definitions for various terms used in part 112. In proposed § 112.3(c), we proposed to define ''farm'' to mean 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. As proposed, the term '' farm'' included: (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. We also proposed definitions for ''farm mixed-type facility'' and related activities, such as ''manufacturing/processing,'' ''packing,'' and ''holding.'' In developing these definitions, we considered the interrelationship between farms and facilities, and articulated five organizing principles to explain the basis for the proposed definitions that would classify activities on-farm and off-farm for the purpose of the Produce Safety regulation. See the discussion of this issue in the previously published proposed rule (78 FR 3504 at 3539 through 3544).

a. Relevant Comments. We received numerous comments regarding the proposed definition of a ''farm,'' including concerns related to packing or holding activities that routinely take place on a farm that commenters believed should be considered under the farm definition but would be instead covered under the proposed definition of a ''mixed-type facility.'' In particular, commenters noted that, as proposed, packing or holding of produce would be subject to either the Preventive Controls for Human Food regulation or the Produce Safety regulation, depending on whether or not the produce was grown on a farm under the same ownership. Commenters expressed various concerns with this proposed approach, including that: (1) This divergence in requirements does not have a public health basis given that the activities of packing or holding would present similar food safety risks regardless of the ownership of the farm on which the produce was grown; (2) subjecting a farm to the requirements of two different food safety regulations would be burdensome and is arbitrary; (3) it is common practice for a farm to buy and resell produce from other farms in order to fill out the necessary scale of supply (for example, when supplied to restaurants, retail establishments, or large wholesale markets), to pack produce for a neighbor who lacks a packing house, hold produce with a long shelf-life for a neighboring farm with limited storage space, or to pack or hold produce grown on farms of different ownership given costs associated with packing or holding activities; and (4) some farms sell their produce through ''Community Supported Agriculture'' arrangements and such deliveries often include produce grown by other farms not under the same ownership. We also received another comment that opposed broadening the proposed ''farm'' definition due to concerns that such changes could undermine the public health objectives of the rule.

b. FDA's Consideration of Comments. We tentatively concur with commenters who stated that packing or holding of produce presents similar reasonably foreseeable hazards regardless of whether the produce is grown and harvested on farms under the same or different ownership, and that such hazards associated with packing or holding activities would best be addressed through the standards established under the Produce Safety regulation.

In response to the comments described above and similar public comments received on the Preventive Controls for Human Food proposed rule, elsewhere in this issue of the **Federal Register**, we are issuing a notice to reopen the docket and seek public comment on certain specific issues related to that proposed rule (referred to as ''amendments to the Preventive Controls for Human Food proposed rule''). In that document, we are proposing a revised definition of ''farm'' to mean an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. As revised, the term ''farm'' would include establishments that, in addition to these activities: (1) Pack or hold raw agricultural commodities (RACs); (2) pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in subparagraph (3)(ii)(A) of the ''farm'' definition; and (3) manufacture/process food, provided that: (i) All food used in such activities is consumed on that farm or another farm under the same ownership; or (ii) Any manufacturing/processing of food

that is not consumed on that farm or another farm under the same ownership consists only of: (A) Drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and (B) Packaging and labeling RACs, when these activities do not involve additional manufacturing/processing. Under this amended proposed definition of ''farm,'' farms that pack or hold produce RACs that are grown on a farm that is under a different ownership would no longer necessarily be ''farm mixed-type facilities'' subject to the requirements of the Preventive Controls for Human Food regulation. Rather, packing or holding others' produce RACs on a covered farm would now be subject to the Produce Safety standards of proposed part 112 (unless the produce is not covered by part 112, as described in proposed § 112.2). Similarly, we are proposing in that document to amend the definitions of ''harvesting,'' ''holding,'' and ''packing,'' consistent with this amendment to the farm definition and in response to other issues discussed in that document. We refer you to the discussion of this issue in section V of that document.

Consistent with our proposed amendments to the definition of ''farm'' as it applies to proposed 21 CFR part 117, we are proposing to amend the definition of ''farm'' as it applies to proposed part 112 to include within that definition establishments that pack or hold RACs that are grown or raised on another farm, whether or not under the same ownership. In addition, we are proposing corresponding revisions to the proposed definitions of ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' in proposed § 112.3(c) to remove the previous proposed restriction to encompass only RACs grown on farms under the same ownership. As revised, ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' would encompass relevant activities regardless of the ownership of the farm where the RACs are grown.

In the amendments to the Preventive Controls for Human Food proposed rule, we are also proposing certain other amendments to the definitions of ''farm,'' ''holding,'' and ''packing,'' taking into account comments received. For example, as amended, the proposed definition of ''farm'' also includes establishments that manufacture/process food by drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing. The amended proposed definition of ''farm'' also includes manufacturing/processing food by packaging and labeling RACs, when these activities do not involve additional manufacturing/processing. In addition, the amended proposed definition of farm would refer to ''establishments'' rather than to ''facilities,'' a term used in the previous proposed definition. In addition, as a conforming change relevant to this substitution, we are adding to the ''farm'' definition the criterion that the establishment is ''under one ownership,'' to retain that aspect of the current ''farm'' definition in the revised definition. As amended, the proposed definition of ''holding'' also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets)). Finally, as amended, the proposed definition of ''packing'' also includes activities performed incidental to packing a food (*e.g.,* activities performed for the safe or effective packing of that food (such as sorting, culling and grading)). We refer you to the discussion of these issues in section V of that document. Consistent with our proposed amendments to these definitions as they apply to proposed part 117, we are proposing to amend the definitions of ''farm,'' ''holding,'' and ''packing'' as they apply to proposed part 112.

Taken together, we are proposing to amend the definition of ''farm'' in proposed § 112.3(c) to mean an establishment under one ownership 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 establishments that, in addition to these activities: (i) Pack or hold RACs; (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in subparagraph (iii)(B)(1) of the ''farm'' definition; and (iii) Manufacture/process food, provided that: (A) All food used in such activities is consumed on that farm or another farm under the same ownership; or (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of: (1) Drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and (2) Packaging and labeling RACs, when these activities do not involve additional manufacturing/processing.

As amended, ''harvesting'' would apply to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on RACs on a farm. Harvesting does not include activities that transform an RAC, as defined in section 201(r) of the FD&C Act (21 U.S.C. 321(r)), 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 RACs grown on a farm are examples of harvesting.

In addition, as amended, ''holding'' would mean storage of food and also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same RACs and breaking down pallets)), but does not include activities that transform an RAC, 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Finally, as amended, ''packing'' would mean placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (*e.g.,* activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform an RAC, 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. (For reference, we previously proposed to define ''packaging'' (when used as a verb) to mean placing food into a container that directly contacts the food and that the consumer receives.)

The defined term ''covered activity,'' which establishes what activities are subject to proposed part 112, is directly related to and affected by the scope of the definitions of ''farm,'' ''harvesting,'' ''packing,'' ''holding,'' and ''manufacturing/processing.'' We are proposing to amend the definition of ''covered activity'' to mean growing, harvesting, packing, or holding covered produce on a farm. ''Covered activity''

includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on RACs and only to the extent that such activities are within the meaning of ''farm'' as defined in this chapter. This part does not apply to activities of a facility that are subject to 21 CFR Part 110 of this chapter.

We are proposing these changes to the definition of ''covered activity'' to reflect the changes we are proposing to the definitions of ''farm'' and related terms. First, we have removed the limitation ''provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership'' to reflect our proposed expansion of the farm definition to include packing and holding of others' produce RACs. Second, because we are proposing to add some additional, limited types of ''manufacturing/processing'' to the definition of ''farm,'' (and to reclassify some activities from ''packing'' to ''manufacturing/processing'') those activities should be subject to proposed part 112 when they are performed on a covered farm on covered produce. For example, because the proposed definitions would now provide that packaging RACs would be manufacturing/processing (rather than ''packing''), and would be within the farm definition if the packaging does not include additional manufacturing/processing, that activity should be covered by proposed part 112 when performed on a covered farm on covered produce. For example, a covered farm placing strawberries in a plastic ''clamshell'' package should be considered a ''covered activity''.

We seek comment on the amended definition of ''farm,'' and the corresponding changes to the definitions of ''harvesting,'' ''holding,'' ''packing,'' and ''covered activity.'' In addition, we seek comment on whether the phrase ''in one general physical location'' should be included in the farm definition in the final rule. We are aware that numerous produce farms own and grow crops in non-contiguous parcels of land in various geographical locations, such as in multiple States or even in more than one country. If finalized as proposed, how should we interpret ''in one general physical location'' for the purposes of enforcing this regulation? For example, farms that are in separate geographical locations, although under the same ownership, could be considered as different ''farms'' under this proposed definition and, therefore, such businesses might qualify for extended compliance periods that we proposed for ''small business'' and ''very small business'' farms.

In addition, we seek comment on whether to include in the final rule a requirement that a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its name, complete business address, and description of the produce in any individual shipment. Under these circumstances, is it appropriate to also require the farm that receives the shipment to maintain such record of information and, if so, for what specified period of time? Farms that pack or hold produce that is grown and harvested on farms under a different ownership and that are currently subject to the recordkeeping requirements of Subpart J of 21 CFR Part 1 may no longer be required to establish or maintain such records, if they fit within the amended proposed ''farm'' definition. Information about where the produce was grown or harvested may be important to trace contaminated product during an illness outbreak or other adverse event related to that produce and, therefore, we seek comment on whether we should require such farms to continue to be subject to recordkeeping requirements.

Finally, we seek comment on whether on-farm packinghouses under cooperative ownership by multiple growers should be considered under the same ownership as any or all of the growers' farms, for the purposes of this regulation.

3. Summary of FDA's Revisions and Request for Comment

We are proposing to: (1) Revise paragraph (a) of proposed § 112.4 to so that farms or farm mixed-type facilities with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of $25,000 or less (on a rolling basis) would not be covered by the Produce Safety regulation; and to make corresponding revisions to the definitions of ''very small business'' and ''small business'' in proposed § 112.3(b) to apply the monetary value thresholds based on sales of produce; (2) revise the definition of ''farm'' in proposed § 112.3(c) such that establishments that pack or hold produce RACs that are grown or harvested on another farm would now be subject to the Produce Safety standards of proposed part 112 regardless of whether or not that farm is under the same ownership; and corresponding revisions to the definitions of ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' in proposed § 112.3(c); and (3) revise the definitions of ''farm,'' ''holding,'' and ''packing'' as they apply to proposed part 112, consistent with the proposed amendments as these terms apply to proposed part 117.

We seek comment on our amended proposed provisions, including our current proposal not to cover farms with an average annual monetary value of ''produce'' sold of $25,000 or less and whether (and, if so, how), as an alternative, we should apply this monetary threshold to covered produce only. We also seek comment on the amended proposed definitions of ''farm,'' ''harvesting,'' ''packing,'' ''holding,'' and ''covered activity,'' and whether the phrase ''in one general physical location'' should be included in the farm definition in the final rule. In addition, we seek comment on whether, in instances where a farm supplies its produce to another farm to pack, hold, or store the produce, the farms involved should be subject to a requirement to establish and maintain a record of such produce shipment for tracking purposes in the event of an illness outbreak. We also seek comment on whether on-farm packinghouses under cooperative ownership by multiple growers should be considered under the same ownership as any or all of the growers' farms for the purposes of this regulation.

B. Proposed Subpart E—Standards Directed to Agricultural Water

Under subpart E of proposed part 112, we proposed science-based minimum standards directed to agricultural water. Specifically, we proposed various measures regarding agricultural water sources and distribution systems (proposed §§ 112.41 and 112.42); requirements for treating agricultural water (proposed § 112.43); requirements for testing agricultural water (proposed § 112.44) and at certain specified frequencies (proposed § 112.45); requirements for water used in harvesting, packing, and holding activities (proposed § 112.46); and certain record-keeping requirements (proposed § 112.50). We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3559–3573).

We are reopening the comment period to solicit public comment on our current thinking on three specific issues related to the provisions for agricultural water: (1) Microbial quality standard for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method; (2) frequency of testing agricultural water; and (3) use of third party agricultural water testing

data. We describe our current thinking on these three issues in this section.

1. Microbial Quality Standard for Agricultural Water Used During Growing Activities for Covered Produce (Other Than Sprouts) Using a Direct Water Application Method

In the previously published proposed rule, under proposed § 112.44(c), we proposed to require that when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. We also proposed that if you find that there is more than 235 CFU (or most probable number (MPN), as appropriate) generic *E. coli* per 100 mL for any single sample or a rolling geometric mean (n = 5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in proposed § 112.44(c). Moreover, before you may use the water source and/or distribution system again for the uses described in proposed § 112.44(c), we proposed that you must either reinspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of proposed § 112.43.

As explained in the proposed rule, our review of available scientific literature led us to tentatively conclude that the above described standards, which are consistent with the EPA recreational water standards, provide an appropriate basis to establish the microbial quality standard for agricultural water that is applied to produce using a direct application method. We explained our rationale and acknowledged the challenges related to identifying an appropriate microbial quality standard for such use of agricultural water where the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. For example, we acknowledged that these EPA standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers rather than to consumption of produce. These epidemiological studies were performed in beach areas subject to point source fecal contamination rather than non-point sources (*e.g.,* birds, agricultural and livestock runoff), which may impact agricultural water. We also noted that risks of adverse health outcomes resulting from full-body contact in contaminated water may be different than risks associated with consuming produce irrigated with contaminated water, given the differences in the expected routes of infection and pathogen mortality rates in the different environments (bodies of water for the EPA recreational water standards; soil, plants, and produce for this proposed rule). We considered other options, including proposing a standard based on the EPA drinking water standard or proposing a second lower microbial quality criteria for water used in growing, but where the water used for direct application is not reasonably likely to contact the edible portion of the covered produce. However, we did not find sufficient scientific support for such options. Moreover, we noted that we are aware that some industry groups have adopted the generic *E. coli* component of the EPA recreational water standards in the absence of sufficient information to support a pathogen-based microbiological standard for water used in the production of produce (78 FR 3504 at 3563 and 3569).

Therefore, we tentatively concluded that the above described generic *E. coli* criteria would serve to minimize risk of known or reasonably foreseeable hazards when used as a standard for agricultural water used on produce (other than sprouts) during growing in a direct water application method. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3563 and 3569).

a. Relevant Comments. We received an extensive number of comments on this issue, and a majority of them either questioned the scientific rationale for the proposed microbial quality standard, emphasized the burden placed on growers due to the stringency of this standard, and/or urged us to consider other factors that would allow the safe use of agricultural water that does not meet the proposed microbial water quality standard in direct application during growing activities. Commenters identified various concerns with the proposed microbial quality standard for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method, including the following: (1) The lack of adequate data to inform a complete and thorough understanding of produce contamination resulting from irrigation water. Some commenters noted that there are relatively few confirmed cases of irrigation water as a source of pathogens in any food borne illness outbreaks, while other commenters thought that the proposed microbial quality standard appeared to address risks that are unidentified and unsubstantiated, without sufficient or meaningful underlying scientific rationale; (2) concerns with using the water quality standards developed for *recreational* water to determine acceptable levels of indicator organisms in *agricultural* water. Commenters opposed using the EPA standards and argued that it is not scientifically sound to apply the recreational water standards that are developed based on epidemiological data to irrigation water. Commenters also noted other limitations to this approach, including that using a recreational standard for water quality does not take into account the rapid die-off rate that occurs post irrigation and prior to harvest; (3) the need for education, guidance, and training to ensure growers understand the elements embedded in the proposed requirement and know how to properly sample, test, and make the necessary calculations to then determine whether or not their water meets the proposed microbial quality standard. Commenters also recommended simplifying the standard to eliminate the requirement for a rolling geometric mean (n = 5) of no more than 126 CFU (or MPN, as appropriate) per 100 mL of water, such that the single sample limit would then be maintained as the requirement. One commenter suggested that this proposed requirement would create an opportunity for confusion and noncompliance due to miscalculation or misunderstanding of the complex equation; (4) concerns that the proposed water quality threshold is either more stringent than or differs from other national or international best practices, recommendations, or guidelines. Commenters noted that the FDA proposed standard is more stringent than the World Health Organization (WHO) thresholds and urged us to amend the provisions to be more in line with WHO quality thresholds. Other commenters recommended following the Codex Alimentarius Commission's global standard (1,000 *E. coli* CFU/mL), the more stringent Canadian standard (77 *E. coli* CFU/100mL), or other thresholds established in the European Union; (5) concern that current science is inadequate to justify a fixed, generally applicable test organism, quantitative

microbial quality threshold, or testing requirements. For example, one commenter asserted that a different microbial standard should be considered for overhead irrigation water that is applied prior to fruit set or more than 14 days before harvest because, under field conditions, water that does not meet recreational water quality standards would be quite safe for such use. Another commenter cited the lack of adequate scientific information to develop a generally applicable microbial quality standard, and recommended that FDA employ the generic *E. coli* standard as a voluntary measure until such time that more scientific information is generated and FDA develops an appropriate standard. Still others urged us to delay the use of a quantitative standard to allow for new scientific information to evolve in the future that would enable identifying microbial quality thresholds specific to different regions and types of water; (6) concern with the use of generic *E. coli* as an indicator to test safety of agricultural water, including water used in direct application. One commenter suggested including *E. coli* O157:H7, non-O157 Shiga toxin *E-coli, Listeria monocytogenes,* and *Salmonella spp.* as pathogens to be tested in water quality tests. Another commenter noted that researchers have found that levels of *E. coli* present in water used for crop sprays do not represent the microbial load on the surface of tomatoes at harvest. This commenter also pointed out that tests conducted by a major U.S. grower have demonstrated that the generic *E. coli* standard can be exceeded without human pathogens being present, and it can be met when human pathogens are actually present in high quantities, thus, bringing into question the reliability of generic *E. coli* as an appropriate indicator. Another commenter urged FDA to provide for flexibility to allow alternative indicators of water safety. This commenter pointed out that several States have replaced water testing programs with a risk based computer modeling approach to address recreational water safety, and instead of using test results to determine if recreational water is safe, computer modeling programs that calculate the risks of a given source are designed to accurately predict when water will be outside acceptable ranges. The commenter recommended that the final rule should allow flexibility within the agricultural water section to allow this approach when an appropriate model has been designed; and (7) concern that, in identifying the microbial standard for direct application, FDA failed to consider certain significant factors that affect whether and how the microbial standard is applied to irrigation water used in different regions of the country and for different types of crops. For example, it was noted that farms in Maine use a wide variety of water sources, from city water to wells to open water sources. Even with open water sources there is a wide variety including rivers, ponds, streams and some water bodies affected by ocean tides, which require site-specific timing for water use. Another commenter stated that, in the Treasure Valley, irrigation systems mix clean water with runoff water, and such inter-mixing results in high counts of *E. coli* in irrigation water throughout large parts of the water distribution systems during the growing season. We also received a comment stating that surface water in some regions or watersheds may regularly fail the generic *E. coli* test, and that 30 percent of the samples of water collected at 22 surface water sites in the southeastern Vermont region in 2012 had generic *E. coli* levels that exceeded 235 CFU per 100 mL. The commenter further explained that, without a real scientific justification, the rule would remove an important source of agricultural irrigation to farmers in that region at critical periods throughout the growing season. Yet another commenter pointed out that, in eastern Oregon, growers downstream will inherently have higher microbiological contaminant loads than those upstream, due to runoff reuse systems and other water conservation measures, and as proposed, the Produce Safety regulation will undoubtedly injure downstream growers by preventing them from utilizing their water for the use stated on their water permit or certificate. Finally, we also received a comment that asserted that, in some parts of the western United States where farmers do not control the water, it would be extremely burdensome for FDA to require testing and mitigation for unidentified and unsubstantiated risks that may not, in fact, exist.

We also received several other comments in relation to the proposed requirement for testing water used for direct application. A commenter pointed out that the scientifically observed rates of microbial decline reported by some authors are vastly greater than the rates assumed in FDA's assessment of risks. The commenter disagreed with FDA's proposed microbial quality standard, and argued that FDA has chosen to regulate all directly applied agricultural water over the entire production season even though its own analysis supports regulating agricultural water only within a short window of a few days before harvest, thereby substantially increasing the costs associated with water quality testing with little substantiated benefit. Another commenter urged FDA to explicitly permit growers to use water testing data compiled by other entities. According to the commenter, municipalities in New Hampshire routinely test *E. coli* levels for recreational purposes, and it would be unnecessary to require growers to test the same water source for the same pathogens separately.

In contrast, some other comments generally agreed with the use of a numerical standard for testing water quality. These commenters suggested that a numerical standard is necessary, particularly where the effectiveness of individual control measures, such as to protect the source of agricultural water from contamination, are either not properly implemented or not fully known. In such cases, a numerical standard would serve as an objective tool to monitor the water quality on a specified schedule and trigger corrective actions, where necessary.

b. FDA's Consideration of Comments. As explained in the previously published proposed rule, based on a qualitative assessment of risk, we identified agricultural water as one of the most likely sources of produce contamination. Our tentative conclusions included: (1) There is a significant likelihood that surface waters may contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources; (2) susceptibility to runoff significantly increases the variability of surface water quality; (3) water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce; (4) timing of water application in produce production before consumption is an important factor in determining likelihood of contamination; and (5) microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices (78 FR 3504 at 3522, 3523). Consequently, our proposed standards for agricultural water including those for microbial quality of water and testing frequencies for ground water and surface water, address these potential contributing factors.

We do not believe that FDA should reconsider the use of generic *E. coli* as an indicator to test safety of agricultural water, including water used in direct application. As discussed in the previously published proposed rule, we proposed to use generic *E. coli* as an indicator of fecal contamination. We acknowledge that the presence of generic *E. coli* will not always correlate to the presence of pathogens in water. However, the presence of fecal contamination, especially as indicated by high levels of generic *E. coli,* may increase the likelihood of pathogen contamination in water (Refs. 6, 7, and 8). Therefore, the intent is to manage the presence of fecal contamination as a proxy for potential pathogen contamination, similar to use of fecal contamination as an indicator for the quality of water at swimming beaches and waters for harvesting molluscan shellfish (Refs. 9 and 10). In addition, several commenters noted that generic *E. coli* is an appropriate organism to use to characterize water quality and agreed with our proposal to require such characterization; these commenters expressed that generic *E. coli* provides the best and most practicable quantitative criterion at this time. Further, testing for pathogens to determine the appropriateness of the water would be more costly than testing for generic *E. coli* because of the need to test for multiple pathogens.

We also acknowledge the limitations of a general requirement for agricultural water for growing using direct application that is based on a single microbial indicator and associated quantitative microbial quality threshold, in that it may not adequately account for differences in risk associated with irrigation practices used for different commodities. Although we are proposing to retain a single microbial quality requirement that would apply to all agricultural water for growing using direct application, our proposed new provisions in §§ 112.44(c)(1) and 112.44(c)(2) provide for flexibility in order to address comments that requested us to account for the wide range of irrigation water sources, irrigation practices in different regions of the country, and different types of crops. We also tentatively determined that a quantitative microbial standard that is enforceable and facilitates necessary action by industry to ensure the safe use of water when used for direct application would be more appropriate than a qualitative water quality standard.

Taking into account comments received, currently available information, and upon further analysis, we are proposing amendments to proposed §§ 112.44(c), 112.44(d), and 112.50(b) that, collectively, result in the following changes: (1) Update the quantitative microbial quality requirements in a way that is consistent with the 2012 recreational water quality criteria (RWQC); (2) provide an allowance for microbial die-off between irrigation and harvest using a specified microbial die-off rate; (3) provide an allowance for microbial reduction between irrigation and end of storage; and (4) allow the use of an alternative in lieu of our specified microbial die-off rate between irrigation and harvest.

The scheme outlined above, each element of which is discussed in more detail in the sections immediately below, is consistent with the construct of the standard recommended by the WHO, although less restrictive than that standard. The WHO approach rests on a multistep process to achieve incremental microbial reductions to meet the overall necessary scheme, yielding a tolerable disease burden due to raw produce consumption that is no greater than that adopted for drinking water (non-detectable *E. coli* per 100 mL) (Refs. 11a and 11b). The initial step of the multibarrier process begins with wastewater treatment, which is followed by subsequent preventive measures to achieve the final health-based target of $\leq 10^{-6}$ DALY (disability-adjusted life year) per person, per year. Two specific examples of the multi-barrier process discussed in the guidelines are water qualities of 10^4 or 10^3 CFU *E. coli* per 100 mL, post-wastewater treatment, for use on surface and root crops, respectively, followed by subsequent mitigation strategies (Ref. 11a). According to the WHO analysis, using water of this microbial quality is dependent upon a 2-log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1-log reduction attributed to washing prior to consumption. The WHO analysis recognizes the variable nature of die-off values, ranging from 0.5 to 2.0 log per day. FDA's previously proposed standard of 235 CFU generic *E. coli* per 100 mL for any single sample (or a rolling geometric mean of no more than 126 CFU per 100 mL) defined a microbial level for agricultural water used during growing activities using a direct water application method that would minimize the risk of serious adverse health consequences or death throughout the diversity of agricultural conditions, in addition to which alternatives could be developed to provide for the reductions assumed in the WHO standard for die-off in the field and during distribution and from activities such as washing. In response to comments asking for consideration of die-off and greater flexibility and to align with international recommendations from WHO and also Codex, we are again proposing a generally applicable microbial level for all agricultural water, but now allowing a standard reduction due to die-off in the field before harvest and consideration of additional die-off from activities such as storage or commercial washing. As described in the sections immediately below, these reductions would provide additional means to achieve our proposed microbial quality standard for agricultural water used in a direct application method of a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water or a geometric mean (GM) of 126 or less CFU of generic *E. coli* per 100 mL of water, where known microbial reduction occurs after application. We believe that this approach is strongly supported by comprehensive risk management frameworks and associated recommendations for managing health risks in recycled wastewater use in agriculture (Refs. 11a and 12).

As will be discussed in detail in section II.B.2., we are also proposing certain amendments to proposed §§ 112.45 that, collectively, result in a proposed tiered approach to testing untreated surface water and untreated groundwater. The proposed approach would allow farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results; and ultimately reduce the required frequency of testing.

i. Updating the quantitative microbial quality requirements. We continue to find that the EPA generic *E. coli* criteria for recreational water quality provides a quantitative microbial standard that is generally applicable to minimize the risk of known or reasonably foreseeable hazards associated with the use of agricultural water on produce other than sprouts during growing in a direct water application method. Further, the EPA analysis supporting the RWQC, while not perfect for our purposes, was developed using the necessary scientific rigor and describes illness rates due to incidental ingestion that can be generalized across different bodies of water (Ref. 13).

In addition, while commenters objected to the use of RWQC to establish microbial quality requirements for agricultural water for growing using

direct application, there is no consensus among commenters as to other appropriate alternative criteria or methodology. A majority of the concerns with using the RWQC appeared to center around the need to account for circumstances that are unique to produce growing and irrigation, such as die-off after application, which are factors that would not have been accounted for in formulating water quality requirements for recreational water purposes. We acknowledge these shortcomings, but we also believe that our complete set of amendments to proposed § 112.44(c), including new provisions in paragraphs (c)(1) and (c)(2), address these concerns.

Therefore, we continue to see the value in using the EPA RWQC as the starting point for a quantitative microbial water quality standard for water that is used for growing of produce (other than sprouts) in a direct application method in proposed § 112.44(c) (with additional provisions in proposed §§ 112.44(c)(1) and (c)(2), as explained in sections II.B.1.b.ii. and II.B.1.b.iii.). In the previously published proposed rule, we proposed to use the EPA recreational water criteria that were published in 1986 for this purpose. In November 2012, EPA recommended new RWQC to update their 1986 criteria (Ref. 14) (hereafter referred to as ''the 2012 RWQC''). Unlike the previous criteria, the 2012 RWQC specify a STV in conjunction with a recommended GM to describe the magnitude of the relevant bacterial indicators. The STV approximates the 90th percentile of the water quality distribution and is intended to be a value that should not be exceeded by more than 10 percent of the samples taken. The 2012 RWQC recommend a culturable *E. coli* level of a GM of 126 CFU per 100 mL of water and an STV of 410 CFU per 100 mL of water.

The 2012 RWQC are based on several recent health studies and use a broader definition of illness to recognize that symptoms may occur without a fever, including a number of stomach ailments. Among other evidence, EPA considered the latest research that demonstrates a link between fecal contamination in recreational waters and illness, and designed the criteria to protect primary contact recreation where immersion and ingestion are likely. We refer you to EPA's 2012 RWQC and accompanying documents for a full description of the new criteria and the underlying scientific rationale (ibid.).

Consistent with this new analysis, we are proposing to amend the microbial water quality standard in § 112.44(c) to reflect *E. coli* levels that are consistent with the recommendations in both the GM and STV values specified in the 2012 RWQC. As amended, proposed § 112.44(c) would require you to develop and verify the water quality profile of the water source as described in § 112.45(b)(1), and using your water quality profile as described in § 112.45(b)(1), take certain actions if you find that (when applicable) the estimate of the STV of samples exceeds 410 CFU of generic *E. coli* per 100 mL of water, or if you find that the GM of samples exceeds 126 CFU of generic *E. coli* per 100 mL of water, in order for you to use this water for direct application during growing of covered produce (other than sprouts).

As amended, proposed § 112.44(c) would no longer include a maximum threshold of *E. coli* in a single sample of 235 CFU per 100 mL. Rather, a STV of water quality distribution of 410 CFU per 100 mL would be used when there are sufficient numbers of samples to calculate it, in conjunction with the GM in all cases. This standard would be similar to the 2012 RWQC in that regard. Adoption of the STV, which approximates the 90th percentile of the water quality distribution, as a criterion acknowledges the inherent variability of *E. coli* measurements in water systems, while continuing to be sufficiently protective of public health. In addition, use of the STV does not establish a single value that, if exceeded, would require immediate corrective action. Instead, any value above 410 CFU per 100 mL may be acceptable, as long as those values (each corresponding to a water sample) do not result in a calculation of STV that exceeds 410 CFU per 100 mL. For example, a water source found to contain 2,100 CFU generic *E. coli* per 100 mL in one of 10 samples analyzed may be appropriate to use in direct application during growing, if the remaining 9 samples are such that the STV (based on all 10 samples) is 410 CFU or less of generic *E. coli* per 100 mL of water.

We seek comments on the absence of such a maximum level of generic *E. coli,* particularly in light of evidence that suggests that pathogen levels can increase at higher levels of generic *E. coli* or other indicators (Refs. 6, 7, and 8). In providing comments, we ask that you take into account that pathogens can survive for months in the soil and in crop tissue if they permeate that tissue, that soil or fecal material on the surface of produce may permeate cut tissues and create conditions to enhance the probability of growth of pathogens and other microorganisms, and that colonization and biofilm development may result in conditions that are protective for pathogens (Refs. 15 and 16).

Some public comments, too, recommended that we consider the WHO recommended levels of 1,000 CFU per 100 mL and 10,000 CFU per 100 mL for root crops and surface crops, respectively, as adequate maximum *E. coli* levels. Note, however, that the WHO values are better explained as illustrations of how specific health protection measures could be used together after treatment (*e.g.,* treatment, die-off, and washing or treatment and drip irrigation) to achieve the additional log reductions recommended for waste water reuse. As such, those values are not to be viewed as absolute end point or maximum permitted levels. Rather, under new proposed provisions §§ 112.44(c)(1) and 112.44(c)(1), we are proposing to provide for a WHO-type scheme that could be used to satisfy the proposed requirements for microbial quality of water. For example, under this proposed approach, there would be no maximum threshold for a baseline of generic *E. coli* above which the agricultural water would be precluded from use in direct application during growing such that you would not be able to apply an appropriate time interval between last irrigation and harvest or between harvest and end of storage. We seek comment on whether we should establish a maximum level of *E. coli* (GM and/or STV) above which the water should not be permitted for use in direct application (until specific followup actions are taken to ensure it meets the recommended microbial quality requirements) and, if so, what would be an appropriate maximum level.

As amended, proposed § 112.44(c) would continue to include a GM value of no more than 126 CFU per 100 mL of water, which is intended to be used in conjunction with the proposed STV explained above, consistent with the 2012 RWQC. However, we are removing the previously proposed requirement for a ''rolling geometric mean (n = 5)'' based on the sampling criteria we proposed in amended § 112.45(b), which is discussed in section II.B.2.b.

According to the 2012 RWQC, the waterbody GM should not be greater than 126 CFU per 100 mL during any 30-day interval, and there should not be greater than a 10 percent excursion frequency of 410 CFU per 100 mL based on the calculated STV during the same 30-day period (Ref. 14). We considered whether to apply the 30-day interval of the 2012 RWQC as a sampling frequency, and tentatively conclude that this criterion would be difficult to apply

in the context of our proposed sampling scheme. Instead, we are proposing amendments to proposed § 112.45 (see section II.B.2.) that would establish specific sampling frequencies ranging from 2 years for baseline characterization of water quality to annual verification of water quality.

We agree with comments that cited the need for education to ensure that growers and other relevant staff are appropriately informed and trained to properly test and perform the necessary calculations to determine how best to use their water, particularly when it does not meet the proposed microbial quality requirements. We have tentatively determined that both the GM and STV values (when there are sufficient samples to calculate STV), which reflect the central tendency (*i.e.,* the extent to which statistical values fall around a middle value) of the water and its variability, respectively, are necessary parameters to properly characterize the water. We expect to issue guidance document(s) to assist with education and training to help farmers understand and implement any final requirements in § 112.44(c).

We seek comment on our proposed amendments, including our decision to retain general microbial quality requirements and update them consistent with the 2012 RWQC; the use of GM and STV values to establish general microbial quality requirements; and the absence of a maximum generic *E. coli* threshold.

ii. Allowance for microbial die-off between irrigation and harvest. In the previously published proposed rule, we acknowledged that in specific circumstances an alternative standard (*e.g.,* a standard that applies a time between application and harvest in place of the proposed § 112.44(c) standard, but is specific to a specific commodity or commodity group and region) may be appropriate if the alternative standard is shown to provide the same level of public health protection as the standard in proposed § 112.44(c) and not to increase the likelihood that the covered produce will be adulterated. Accordingly, under proposed § 112.44(d), we provided for the use of alternatives to the requirements in proposed § 112.44(c). We also noted that we are working with stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce other than sprouts as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier) (78 FR 3504 at 3553).

Comments, however, included concerns from growers that buyers would demand that the grower meet the standard established in the Produce Safety regulation rather than meet an alternative that had not been explicitly sanctioned by FDA. A number of commenters that opposed our previously proposed microbial quality requirements also cited the lack of allowance for microbial reduction due to natural die-off in the field after application and prior to harvesting of the crop. On further consideration of this issue and relevant available scientific information, we are proposing to add a new provision under proposed § 112.44(c) to explicitly provide for use of water that meets the proposed microbial quality standard after accounting for microbial die-off, if applicable to your crop and practices on your farm. We discuss new proposed provision § 112.44(c)(1) in this section.

Proposed § 112.44(c)(1) would provide one option by which you would be able to achieve the microbial quality requirements for agricultural water specified in § 112.44(c). Under this option, you must apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and of your STV to 410 CFU or less per 100 mL of water. Examples of 0.5 log per day calculations follow this discussion.

Based on a review of currently available scientific literature, we tentatively determined that it would be appropriate to provide an allowance for microbial die-off between last irrigation and harvest using a proposed die-off rate of 0.5 log per day (Ref. 17). Survival of pathogens and other microorganisms on produce commodities is dependent upon several environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Generally, pathogens and other microbes die-off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool, and wet conditions. The impact of these variables results in a range of microbial die-off rates of 0.5 to 2.0 log per day (Refs. 11a and 12). We have evaluated the relevant studies and acknowledge that die-off rates below 0.5 log per day have been reported in the literature for particular crop and pathogen types, but we conclude that a rate of 0.5 log per day provides a reasonable estimate of die-off under a broad range of variables to include pathogen characteristics, environmental conditions, crop type, and watering frequency.

FDA is currently engaged in research activities in this area. In an effort to support scientific research in the area of agricultural water, one of FDA's Centers of Excellence, the Western Center for Food Safety at University of California, Davis, partnered with the Center for Produce Safety to provide seed money through a competitive grants program to fund produce safety projects focused on agricultural water issues that are topical and/or region specific. Research areas that have received funding through this process include transfer and survival of organisms on produce after exposure from contaminated surface irrigation water, application of biocide technology on manure-contaminated irrigation water, the potential role of overhead sprinkler irrigation systems in the contamination of produce, and the survival of pathogens during the growing, harvesting, and storage of dry bulb onions after exposure with contaminated water.

We seek comment on the appropriateness of the proposed 0.5 log per day die-off rate. Note also that the proposed provisions in § 112.44(d) would allow you to establish and use an alternative microbial die-off rate between last irrigation and harvest (in lieu of the proposed rate of 0.5 log per day), provided you satisfy the requirements of proposed § 112.12.

When applying a microbial die-off rate of 0.5 log per day, as proposed, the time interval (*i.e.,* number of days) you apply between last irrigation and harvest are the days necessary to achieve the reductions in both the GM and STV values of generic *E. coli* to levels at or below those expected on produce if it were irrigated with agricultural water that satisfied the microbial quality requirements proposed in § 112.44(c). We tentatively conclude that use of such a time interval would provide the same level of public health protection as the standard in proposed § 112.44(c) and not increase the likelihood that the covered produce will be adulterated.

This provision assumes that, for any given crop, the microbial levels found on produce after accounting for die-off when it is irrigated with water under the provisions of § 112.44(c)(1) would be approximately equal to or below the levels found if the crop were, instead, irrigated with water of higher quality (*i.e.,* that met our proposed microbial quality criteria). Reductions to achieve

both GM and, when applicable, STV criteria are necessary to ensure that risk thresholds determined in the 2012 RWQC are not exceeded.

For example, if you determined (using the procedures described in proposed §§ 112.45(b) or 112.45(c), as applicable), that your agricultural water which is to be used for the purposes described in § 112.44(c) has generic *E. coli* levels with a GM value of 241 CFU per 100 mL and a STV value of 576 CFU per 100 mL, your water would not meet the microbial quality specified in § 112.44(c), in that your values exceed both the GM value of 126 CFU per 100 mL and STV value of 410 CFU or less per 100 mL. Under proposed § 112.44(c)(1), you would be able to use this water by applying a calculated time interval of 1 day between your last irrigation event (by direct application method) and harvest of the crop. Using a microbial reduction rate of 0.5 log per day, a 1-day time interval would be sufficient to meet the microbial quality requirements specified in § 112.44(c) because it would reduce your GM and STV values to 76 CFU per 100 mL and 182 CFU per 100 mL, respectively.

As another example, if you determined that your agricultural water has generic *E. coli* levels with a GM value of 241 CFU per 100 mL and a STV value of 4,600 CFU per 100 mL, your water would not meet the microbial quality requirements specified in proposed § 112.44(c). Under proposed § 112.44(c)(1), you would be able to use this water by applying a calculated time interval of 3 days between your last irrigation event (by direct application method) and harvest of the crop. Using a microbial reduction rate of 0.5 log per day, 3 days between irrigation and harvest would be sufficient to achieve a 1.5 log total reduction and reduce your GM and STV to 8 CFU per 100 mL and 145 CFU per 100 mL, respectively.

We agree with comments that cited the need for education to ensure growers understand the elements embedded in our proposed requirements for agricultural water during growing using direct application. Relevant staff would need to be appropriately trained to properly sample, test, and make the necessary calculations to determine how best to use their water. We expect to work with the Produce Safety Alliance, and will also plan to issue guidance document(s), as needed, to further clarify our provisions and assist with such education and training, if these proposed provisions in § 112.44(c) are finalized, as proposed. In addition, there are resources available that would enable simply entering sample data into a form and automatically deriving the GM and STV values and/or calculating the appropriate time interval between irrigation and harvest, such that a farmer would not need to perform the necessary calculations. We plan to identify and provide such resources, if this proposal is finalized.

We seek comment on our proposed approach and tentative conclusions, including the appropriateness of permitting an adequate time interval between last irrigation and harvest as a means to achieve the specified microbial quality requirements, and the appropriateness of using a microbial reduction rate of 0.5 log per day. In addition, we seek comment on whether we should require farms to establish and maintain any documentation in relation to the option to apply an adequate time interval between last irrigation and harvest, as provided in proposed § 112.44(c)(1). For example, should we require that farms must keep records that identify the time interval applied, how the time interval is calculated, and/or the dates of last irrigation and harvest corresponding to that time interval?

iii. Allowance for microbial reduction between harvest and end of storage. A number of comments that opposed our previously proposed microbial quality requirements also cited the lack of allowance for microbial reduction due to natural die-off during storage and/or due to pathogen removal during certain post-harvest activities, such as commercial washing, prior to consumption. On further consideration of these issues and relevant available scientific information, we are proposing to add another new provision under proposed § 112.44(c). We discuss the new proposed provision § 112.44(c)(2) in this section.

Proposed § 112.44(c)(2) would provide a second option by which you would be able to achieve the microbial quality requirements specified in § 112.44(c). Under this option, you must apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL, provided you have adequate supporting scientific data and information. You may apply this time interval in addition to the time interval in accordance with 112.44(c)(1). This provision would allow you to apply appropriate microbial die-off or reduction rates post harvest (*i.e.,* between harvest and end of storage, and during activities such as commercial washing), provided you have adequate supporting scientific information. As discussed in the section immediately above, we expected that farms would consider such factors as microbial die-off or microbial reduction post irrigation and prior to consumption, as they are applicable to their commodity and/or practices on the farm, and apply appropriate scientifically-supported alternatives (such as time intervals) under the provisions we proposed in § 112.44(d). However, based on comments, we are proposing new provision § 112.44(c)(2) to incorporate additional flexibility into our agricultural water quality standards, and provide farms with yet another means by which to safely use agricultural water by achieving our proposed microbial quality requirements, without compromising the safety of produce that comes into contact with such water. As previously noted, the WHO study attributed a 1-log reduction in microbial load to washing (Ref. 11a). In addition, it is reasonable to expect some die-off during post-harvest storage, though the rate would be highly dependent upon the conditions of storage. Farms would be able to more narrowly define die-off rates associated with their specific production practices and apply a time interval (in days) between harvest and end of storage, calculated using microbial die-off rate(s) for the period between harvest and end of storage, including any microbial removal rate(s) as a result of commercial washing, as applicable to their commodity. Regardless of the microbial rates applied, the total log reduction necessary and the time interval required would need to be calculated based on a comparison of the GM and (when applicable) STV values of your agricultural water with the proposed microbial quality requirements (GM of 126 CFU or less per 100 mL and STV of 410 CFU or less per 100 mL) in § 112.44(c).

At this time, we are not proposing to establish a specific microbial die-off rate(s) between harvest and end of storage or a specific microbial removal rate(s) during post-harvest activities such as commercial washing that can be broadly applied to calculate an adequate time interval between harvest and end of storage. We do not have sufficient information to support the derivation of an appropriate broadly applicable microbial reduction rate(s) between harvest and end of storage, or during activities such as commercial washing. However, under this option, you would

be able to establish and apply an adequate time interval using a microbial die-off rate(s) that is relevant to your covered produce and dependent on practices and conditions on your farm, provided you have adequate scientific data or information to support your conclusions.

As we noted in the previously published proposed rule, we are working with our stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce (other than sprouts) as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier). We will disseminate the results of these investigations, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their current use of agricultural water, as appropriate.

In addition, we are proposing to add a new provision, *i.e.,* proposed § 112.50(b)(8), to require you to establish and keep records of such scientific data or information you rely on to support the microbial die-off or removal rate(s) that is used to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *E. coli* in accordance with the provision in § 112.44(c)(2). This record-keeping requirement would enable us to verify the scientific basis for your time interval, should you choose to employ the approach permitted in § 112.44(c)(2). As in the case of alternatives permitted under § 112.12, we are not proposing to require farms to submit scientific data or information relied on to support the microbial die-off or removal rate applied in accordance with § 112.44(c)(2) to us for review or approval prior to marketing produce grown under those conditions. However, we would require that farms maintain a record of any such scientific data or information, including any analytical information, and make such data and information available to us to evaluate upon request.

We seek comment on this proposed provision, including on whether there is a specific microbial die-off rate(s) or microbial removal rate(s) that we should establish within this provision. We also seek comment on whether and, if so, how we should introduce additional flexibility.

iv. Provision for use of an alternative microbial die-off rate. As explained in section II.B.1.b., we are proposing to add a new provision § 112.44(c)(1) related to agricultural water used in a direct application method to permit the use of an adequate time interval between last irrigation and harvest, based on a microbial die-off rate of 0.5 log per day, to achieve water quality that meets the proposed microbial standard.

We acknowledge that practices and conditions on a farm and circumstances unique to a specific commodity or types of commodities could result in higher die-off rates, especially under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little precipitation. To account for such variability, we are proposing a new provision, i.e., proposed § 112.44(d)(2), to specify that you may establish and use an alternative microbial die-off rate (in lieu of the 0.5 log per day microbial rate that we proposed under § 112.44(c)(1)), to determine the time interval (in days) between last irrigation and harvest, provided you satisfy the requirements of § 112.12. Among other requirements, the use of an alternative microbial die-off rate would necessitate you to have adequate scientific data and information to support your conclusions. We refer to section V.B of the previously published proposed rule for a discussion of the requirements of § 112.12.

Finally, as amended, proposed § 112.44(c) would continue to retain the previously proposed option to discontinue the use of water that does not meet the proposed microbial quality requirements and take corrective actions, prior to using that water for the same purposes. Proposed § 112.44(c)(3) would establish a third option, in lieu of following the procedures in §§ 112.44(c)(1) or 112.44(c)(2), where if water does not meet the proposed microbial quality requirements, you would immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in § 112.44(c). Before you may use the water source and/or distribution system again for those uses, you would be required to either reinspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

2. Frequency of Testing Agricultural Water

In the previously published proposed rule, under proposed § 112.45, we proposed to establish requirements related to frequency of testing agricultural water that is subject to the requirements of proposed § 112.44. Specifically, proposed § 112.45(a) would require that you test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every 3 months thereafter during the growing season, except that there would be no requirement to test water that meets certain conditions specified in proposed § 112.45(a)(1) to (a)(3) (i.e., treated water and water from a public water system).

As explained in the previously published proposed rule, water testing frequencies recommended by various industry documents vary widely, in part, because there is a lack of publicly available information pertaining to the quality of agricultural waters. Recommendations range from monthly testing to once each year, for sources with a history of compliance with commodity specific recommendations. Even for sources considered reliable (*e.g.,* well water), a 1-year period between testing may not minimize the risk of known or reasonably foreseeable hazards because microbiological water quality is often too variable for this frequency of testing to be protective (*e.g.,* effects of flooding, runoff). Alternatively, we tentatively concluded testing well water more frequently than every 3 months would not significantly improve the accuracy of your assessment of ground water quality and would therefore be unnecessary. We also considered proposing testing frequencies as a function of commodity, irrigation method (*e.g.,* furrow, seep, subsurface drip, foliar), and timing of application (days prior to harvest), and concluded that the most effective approach is to test at a frequency related to the reliability of the agricultural water sources. We requested comments on whether we should allow for adjustment of ground water testing frequencies dependent on historical test results, for example, testing ground water sources every 3 months for 1 year and yearly after that if the ground water consistently met the standard. We also requested public comments on any other alternative testing frequencies that can be supported by water quality data (78 FR 3504 at 3570).

In addition, under proposed § 112.45(b), we proposed to establish testing frequency requirements for the use of untreated surface water for purposes that are subject to the requirements of proposed § 112.44. As proposed, if the untreated surface water is from any source where a significant quantity of runoff is likely to drain into the source (for example, a river or natural lake), then you must test the water at least every 7 days during the growing season (proposed § 112.45(b)(1)). If the untreated surface water is from any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (for example, an on-farm manmade water reservoir), then you must test the water at least once each month during the growing season (proposed § 112.45(b)(2)).

In proposing these testing frequencies, we tentatively divided untreated surface water into two categories based upon their potential to be adversely affected by runoff and the degree to which you reasonably could be expected to exercise protection and control over them. We tentatively concluded that runoff is the most important variable among the various environmental factors that may affect the microbial quality of surface water, because it has the potential to increase the number of pathogens in the water column if its origins include human, livestock or wildlife feces and because it has the potential to increase the amount of suspended sediments, which are likely to harbor pathogens. We also considered other factors, such as precipitation and its effects (*e.g.,* discharge and flow rate) along with temperature, which are common factors reported to affect the microbial quality of watersheds with agricultural land inputs. However, we did not propose a surface water testing frequency based on these factors because such an approach would require full characterization of its effects on the quality of surface water sources that are not likely to be generally useful across all farms, States, or regions (78 FR 3504 at 3571).

We also noted that our approach to testing untreated surface water was to propose practical intervals of testing both because they are likely to capture transient events that may degrade quality and because they are useful regardless of geographic location. The sampling and testing frequencies we proposed in § 112.45(b) are the minimum that we tentatively concluded provide sufficient information concerning your source surface water quality for you to use in determining the method of application for which the water is safe and of adequate sanitary quality. We asked for public comments on our proposed testing frequencies, including any alternative approaches and examples where testing should be more or less frequent based on your experience or observation, and specifically if you believe that surface waters can be thoroughly characterized when tested at frequency less than that proposed in § 112.45 (78 FR 3504 at 3571).

a. Relevant Comments. We received a number of comments on our proposed requirements for frequency of water testing, many of which voiced concerns and requested that FDA reduce the required testing frequencies and apply a flexible approach that considers the specific risks associated with the particular source of water and its use. Comments related to the frequency of water testing highlighted various issues, including the following: (1) Commenters recommended that FDA should employ and allow the use of risk-based testing strategies that account for the variability in risk associated with the specific source of water and its use. For example, commenters noted that the proposed testing frequencies do not consider the wide range of sources of agricultural water, which include municipal water to rural rain water catchment. Commenters also noted that frequent testing is either not necessary or does not provide meaningful information where there is inherently high variability in water quality due to rainfall or other natural events. Commenters stated that microbial growth and survival varies significantly by region and water source, and some open water sources have sufficient microbiological stability that weekly testing is unnecessary. In addition, commenters argued that the testing frequency requirements should recognize the reduced risk (and consequently, less frequent need for testing) associated with proper design and maintenance of the water source to encourage growers to implement preventive measures; (2) commenters stated that there is a need to incorporate flexibility into the testing frequency requirements so growers can determine appropriate frequencies, considering factors specific to their source of water and its use. For example, commenters asserted that testing frequencies should be tailored for farms using short-term or intermittent irrigation. In addition, some commenters stated that an assessment of risks associated with ground water should be farm-based because not all ground water is equal or merits the proposed testing frequency, and that FDA must permit alternative practices for water testing based on sound science; (3) commenters suggested that appropriate testing frequencies should be determined depending on historical test results. Commenters maintained that a more effective approach than the one proposed by FDA would be to take baseline samples to determine water quality and then schedule routine future testing based on the results of the baseline testing; (4) commenters argued that scientific data to support the proposed testing frequencies are lacking. For example, commenters opposed the specific requirements related to testing of untreated surface water in proposed § 112.45(b), and asserted that general water testing requirement in proposed § 112.45(a) to test agricultural water at the beginning of the growing and every 3 months thereafter during the growing season, coupled with the requirements in proposed § 112.42 to regularly inspect and maintain agricultural water systems, is adequate. Commenters who opposed the weekly testing requirement in proposed § 112.45(b)(1) pointed out that, although they acknowledge the need to test surface water sources more frequently than ground water sources, there is no basis for the proposed weekly testing of untreated surface water. One commenter also pointed out that a WHO analysis of tolerable risk for irrigation water determined that harvesting 5 days after last irrigation has a significant reduction in contamination. Other commenters argued that human pathogens do not survive well on produce in the field and, therefore, contamination that occurs early in a growing season may not survive to harvesting, such that a requirement to test at the beginning of each growing season would be of no value. Some commenters requested more clarity regarding the frequency of testing water that is used in harvest and post-harvest activities, and the data that FDA used to determine the adequate testing frequency for such use of water. Commenters also urged FDA to revisit the scientific data supporting the testing intervals and validate the quality of those data. Still other commenters encouraged FDA to create a separate rule or guidance on testing frequency requirements after further research is completed; and (5) commenters argued that the proposed testing frequencies would pose an undue financial burden without providing clear public health benefits. Commenters strongly opposed the weekly testing frequency, in

particular, and stated that farms do not have the necessary resources or facilities to accommodate such frequent testing, and some growers would have to ship their water samples to testing laboratories. Some commenters also noted that many growers use more than one pond for irrigation and using up to four ponds is not uncommon, such that costs of testing could become prohibitively expensive. One commenter estimated that the total cost associated with water testing requirements could amount to about $11,550 annually (including costs of labor and laboratory testing). Another commenter urged FDA to explicitly permit growers to use water testing data compiled by other entities. According to the commenter, municipalities in New Hampshire routinely test *E. coli* levels for recreational purposes, and it would be unnecessary to require growers to test the same water source for the same pathogens separately.

Commenters also recommended specific alternative testing frequencies in lieu of our proposed provisions. Some commenters mentioned that a more prudent testing requirement would be within a timeframe closer to harvest, while others suggested that it would be beneficial to require water testing at the outset for a new operation or when a new water source is first brought into use. Other notable suggestions included seasonal water sampling, or using the current USDA's Good Agricultural Practices requirements for testing surface waters at the beginning and the peak of the growing season and at harvest time.

Conversely, a few commenters agreed with the testing frequencies that we proposed, stating that the proposed schedule of water testing ensures the safety of water initially and during growing, harvesting, and post-harvest activities.

Overall, a majority of the concerns with the proposed testing frequencies centered on the financial burden imposed on farms, in particular, under a weekly testing requirement; that FDA did not provide scientific data in support of the proposed testing frequencies; and the need for a more flexible approach accounting for the variability in water quality associated with various water sources and the particular use of the water during growing, harvesting, or post-harvest activities.

b. FDA's Consideration of Comments. As noted above, a key objective of our proposed approach to water testing was to establish a testing frequency sufficient to adequately characterize the quality of the agricultural water such that the information could lead farms to make informed and appropriate decisions about its use and/or the need for any appropriate corrective actions, prior to such use. Commenters generally agreed with our intent to characterize the quality of the water source, but argued that the frequency intervals proposed were too short; and, as a consequence, would require more tests (and associated costs) than necessary to accomplish the desired outcome, without a commensurate gain in public health benefit. In view of comments received, we reviewed our previous proposed frequencies to characterize the quality of untreated surface water and untreated ground water sources.

Taking into account comments received, currently available information, and upon further analysis, we are proposing certain amendments to proposed §§ 112.45 that, collectively, result in a proposed tiered approach to testing untreated surface water and untreated groundwater. The proposed approach would allow farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results; and ultimately reduce the required frequency of testing.

In the case of both untreated surface water and untreated ground water, we are proposing to more narrowly focus the period of characterization of water quality to those when the risk is greatest, *i.e.,* during periods when agricultural water is used immediately prior to harvest. Currently available information indicates that the risk to consumers is greater in relative terms when produce contamination via agricultural water occurs closest to consumption. That is, agricultural water used early in the growing season (*e.g.,* seeding, plant establishment) generally has less inherent risk associated with its use than water used in harvest (*e.g.,* field wash) or post-harvest activities (*e.g.,* washing, cooling). Requiring that water characterization focus on periods when the risk is greatest reconciles public comments with the scientific literature on the relative risks associated with the timing of use of agricultural water. This approach is supported by the discussion above concerning die-off rates between application of water and harvest. With die-off rates of 0.5 log or greater per day the impact of water quality more than a couple of weeks prior to harvest is minimal. We expect this time period (*i.e.,* immediately prior to harvest) to be variable and dependent on the crop and length of time harvest activities are performed. It is reasonable to conclude that it would include periods immediately prior to active harvest of one commodity or variety, even though another continues to mature but is not yet ready for harvest. To permit farms to tailor their sampling of water to the unique circumstances relevant to their crop(s) and practices and conditions on their farm, we are proposing as a requirement that the samples required to be collected include those ''collected during a time period(s) as close as practical to harvest.'' We recognize that the timing of the use of agricultural water using a direct application method varies by crop, region, season, and/or from year to year. By using the term ''practical,'' we intend to convey that agricultural water should be collected for analysis when, during the characterization or verification period, agricultural water is applied to covered produce, and not that samples would be collected from the source water when it is not being applied to the crop. Timing of the samples should be such that the last applications of agricultural water prior to harvest are targeted, again recognizing that in some circumstances such applications may not be preplanned (*e.g.,* early frost or unusually hot, dry weather). Further, timing of sample collection should occur in the time period during growing and near harvest, and be designed to represent events that can reasonably be expected to both impact water quality (*e.g.,* rainfall, high river stage, wildlife and domesticated animal movement through upstream water systems) and occur in the time period during growing and/or near harvest.

At this time, we are not proposing to further specify an appropriate time period prior to harvest for sampling. We seek comment on whether it would be practical to require sample collection during a certain time period(s) such that the test results based on such samples would be available in sufficient time to determine any changes to water quality and, if necessary, adjust harvesting times accordingly or take other corrective actions.

i. Tiered approach to testing untreated surface water. We are proposing to amend proposed § 112.45(b) to establish a new proposed tiered approach to testing untreated surface water that is used for the growing of produce (other than sprouts) using a direct application method. As amended, proposed § 112.45(b) would establish that if you use untreated surface water for purposes that are subject to the requirements of proposed § 112.44(c), you must take the following steps for each source of the untreated surface water: (1) Conduct a baseline survey to develop a water quality profile

of the agricultural water source. (i) You must conduct a baseline survey in order to initially develop the water quality profile of your water source. You must determine the appropriate way(s) in which the water may be used based on your water quality profile in accordance with § 112.44(c)(1) through 112.44(c)(3). (ii) The baseline survey must be conducted over a minimum period of 2 years by calculating the GM and the STV of generic *E. coli* (CFU per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. The water quality profile initially consists of the GM and STV of generic *E. coli* calculated using this data set. (iii) You must develop a new water quality profile: (A) At least once every 10 years by recalculating the GM and STV values using a minimum total of 20 samples collected during your most recent annual surveys (which are required under paragraph (b)(2) of this section); and (B) when required under paragraphs (b)(2) and (b)(3) of this section. (2) Conduct an annual survey to verify the water quality profile of your agricultural water source. (i) After the baseline survey described in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, you must test the water annually to verify your existing water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. (ii) If the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile and, as appropriate, modify your water use based on the new water quality profile in accordance with § 112.44(c)(1) through (3) as soon as practical and no later than the following year. To develop a new water quality profile, you must calculate new GM and STV values using either: (A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or (B) your current annual survey data, combined with new data, to make up a data set of at least 20 samples; and (3) if you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in paragraph (b)(2) of this section (for example, if there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the quality of your water source), you must develop a new water quality profile. To develop a new water quality profile, you must calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you must modify your water use based on the new water quality profile as soon as practical and no later than the following year.

The approach proposed in § 112.45(b) is responsive to comments that requested us to establish a risk-based, flexible testing approach that accounts for variability in water quality from different sources, considers the specific use of water from a particular water source, and contemplates the reduced likelihood of contamination from well-designed and adequately maintained water systems. In addition, this approach also provides for use of longer-term ''good'' results as a basis to support a reduced frequency of testing (compared to that previously proposed) resulting in overall reduced economic burden associated with testing of water. We also acknowledge comments that requested us to consider how best to ensure that growers understand and are able to implement our proposed requirements. We plan to provide guidance regarding the proposed water testing requirements, if finalized.

Proposed § 112.45(b) would apply only to untreated surface water that is used for the purposes specified in § 112.44(c), *i.e.,* for the growing of produce (other than sprouts) using a direct application method. As proposed, the tiered approach for testing of such agricultural water consists of three major elements.

First, you must conduct a baseline survey over a minimum period of 2 years to develop a water quality profile of your water source, based on which you would be able to determine whether the water meets the microbial quality requirements established in § 112.44(c). If it does not satisfy those requirements, then you must consider and implement any one of the options provided in §§ 112.44(c)(1), (c)(2), and (c)(3), as appropriate for your commodity and practices and conditions on your farm, if you wanted to continue to use the water source for the growing of produce (other than sprouts) using a direct water application method.

Second, every year after this initial baseline survey, you must conduct an annual survey to verify your water quality profile and ensure that the way in which you are using the water continues to be in accordance with § 112.44(c). If your annual survey verifies your water quality profile is still likely to be representative of the quality of your water source, no additional steps would be necessary in that year. If, however, the annual survey results are sufficiently different from your existing water quality profile to suggest that the profile is no longer representative of the quality of your water source, you would be required to develop a new water quality profile and make adjustments to the way in which you are using the water in accordance with § 112.44(c), as necessary. When developing a new water quality profile for this purpose, you would be allowed to rely on existing test results.

Third, you would be required to develop a new water quality profile on a regular, 10-year schedule and as needed when you know or have reason to believe that your water profile no longer represents the quality of your water source (for reasons other than your annual survey results). In both cases you would also be required to make corresponding adjustments to the way you use the water, as necessary. In the former case, you would be allowed to rely on existing test results when developing your new water quality profile. In the latter case, you would be required to use new test results to develop your new water quality profile.

The steps identified in proposed § 112.45(b) (*i.e.,* the baseline survey, annual verification testing and, as needed, development of new water quality profiles) would be required to be performed separately for each untreated surface water source used for direct water application to covered produce (other than sprouts) during growing. For example, if you have a surface water impoundment on your farm that stores groundwater to be used for this purpose, but you also sourced water from a river for the same purpose, you would need to evaluate both bodies of water individually in compliance with the requirements of proposed § 112.45(b), as each delivers water that is distinctly different in origin and likely to differ in overall composition and characteristics.

We are proposing that the water quality profile of untreated surface water sources include both a GM and a STV value, as reflected in the proposed baseline survey and annual surveys used for verification. This proposed

requirement is intended to serve two purposes. First, requiring both GM and STV values would correspond to the microbial quality requirements we proposed in § 112.44(c) and, thus, allow a comparison of the values derived from your surveys to the proposed microbial quality standard. Second, using both GM and STV values would provide a profile of the quality of your water source that reflects both its central tendency (the GM) and the variation in its quality (the STV). This information could be used to understand the effects of factors, such as precipitation, flow rate, and changes in adjacent land use on water quality, especially if characterization data are analyzed over additional years.

To increase the accuracy of the water quality profile and the annual survey data, samples should be collected at intervals over the period immediately preceding harvest and under a variety of environmental conditions (*e.g.,* after precipitation), as appropriate. We expect farms to determine the appropriate time period for sampling to meet our proposed requirement that samples be collected during a time period(s) as close as practical to harvest, while recognizing that samples of water taken more than a few weeks prior to harvest are unlikely to be relevant to the safety of the crop. In addition, we would not consider samples collected in a single day solely to satisfy the minimum sample number to provide adequate variation as the distribution estimates resulting from such a sampling plan would defeat the purpose of the survey.

We do not intend to limit data sharing among farms if, by inspection, the characteristics of the shared water source are found to be similar and no significant source of contamination is identified between sampling sites of the different farms. In fact, we encourage such sharing when appropriate. We have included a new proposed provision (§ 112.45(e)) that would explicitly allow data sharing under certain circumstances.

Similarly, we do not expect farms to incur additional sampling costs to satisfy the baseline survey requirement proposed in § 112.45(b)(1), if they already possess sufficient water quality data (consisting of the minimum required number of samples) collected during the required time period.

a. Baseline Survey—For the baseline survey described in § 112.45(b)(1)(i) and (ii), we are proposing that the survey must be conducted over a minimum period of 2 years, by calculating the GM and STV values of generic *E. coli* (CFU per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. You would be required to test these samples for generic E. coli in accordance with one of the appropriate analytical methods in subpart N, and to develop a water quality profile consisting of the GM and statistical threshold value STV of generic *E. coli* calculated using this dataset. We tentatively conclude that sampling an untreated surface water source over a period of 2 years is the minimum necessary to provide an adequate representation of its quality to enable informed decisions about its use in a direct application method. We also tentatively determined 20 samples to be the minimum necessary for the purposes of conducting such a baseline survey. We incorporated a certain degree of flexibility in this proposed requirement to allow farms to independently determine the appropriate number of samples required to characterize an untreated surface water source based on their knowledge of the water system, its inherent variability, and the vulnerability of their water source to contamination. We seek comment on these tentative conclusions.

Our analysis suggests that a minimum number of samples required in ''average'' surface water sources would be 20 samples. We based our determinations of the minimum necessary sample size for the baseline survey on an assessment of the relative precision of estimation of the GM and STV (approximation of the 90th percentile) afforded by different sample sizes when generic *E. coli* levels are log-normally distributed (Refs. 18, 19, and 20). The precision of estimation of GM and STV (approximation of the 90th percentile) of log-normally distributed data depends upon the variation (*i.e.,* standard deviation), which is likely to be different for different sources of water and uncertain with respect to any particular source of water. Precision of estimation will be lower when variability is higher. However, for the purpose of determining an appropriate sample size for ''average'' surface water sources a standard deviation of 0.4 (of log abundance of *E. coli*) was assumed based on estimates of variability of measurements of culturable *E. coli* in samples of recreational waters as determined by EPA in the 2012 RWQC. Based on this assessment of precision, we propose a minimum of 20 samples for the baseline survey in order to adequately characterize the water in a manner that provides initial estimates of GM and STV of *E. coli* distribution of sufficient precision to allow for a determination of the appropriate use (or conditions of use) of an untreated surface water source (Ref. 21). We would encourage farmers to sample more than the minimum required 20 samples to build a robust baseline characterization.

b. Annual Verification Survey—For the annual verification survey described in § 112.45(b)(2), we are proposing that the survey must be conducted by calculating the GM and STV values of generic *E. coli* (CFU per 100 mL) using a minimum number of five samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method. The purpose of the annual verification survey is to verify the water quality profile described in § 112.45(b)(1) and to confirm that the way(s) in which the water is used continues to be in accordance with § 112.44(c). If your annual verification survey detects a change in water quality that is no longer consistent with current water use, you would be required to develop a new water quality profile. As described in § 112.45(b)(2)(ii), to develop a new water quality profile, you would calculate new GM and STV values using either: (A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or (B) your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you would be required to modify your water use based on the new water quality profile as soon as practical and no later than the following year.

We have tentatively determined five samples to be the minimum number necessary to calculate a GM and STV value appropriate for annual verification purpose. Although the precision of estimation afforded by five samples for annual verification is less than that afforded by the 20 samples proposed for the baseline survey, our assessment indicates that five samples would be sufficient to provide adequate probability of detecting large and substantial deviations in the GM (*e.g.,* 0.5 log or greater change from that of the baseline survey) for ''average'' water sources characterized by a standard deviation of 0.4 (of log abundance of *E. coli*). Consequently, a sample size of five is judged to be sufficient for annual verification of the water quality profile and that the way(s) in which the water

is used, based on that profile, continues to be appropriate (Ref. 21).

Where the outcome of annual sampling provides a GM or STV value that is inconsistent (*e.g.,* 0.5 log or greater change) with the current water quality profile GM or STV values, we expect the annual verification to be used, in combination with previously or subsequently conducted test result data to develop a new water quality profile, and for farms to alter their current water use practices as necessary during the current harvesting season if practical, and if not, to modify practices for the following year. The new water quality profile could be developed by combining the current year's annual survey data (of a minimum of test results from five samples) with data obtained by either collecting (and testing) additional, new samples (as described in § 112.45(b)(2)(ii)(B)), or using the test results from the most recent previous years' annual or baseline surveys (as described in § 112.45(b)(2)(ii)(A)), in either case the data set must contain at least 20 samples. For such revisions to the GM or STV values, we may consider stipulating a time period beyond which the data would not be appropriate to use because they would not be expected to provide a current representative profile of the water quality. For example, should we specify that when revising the baseline GM or STV values based on annual survey results, the annual verification data may be used, in combination with previously or subsequently collected baseline or annual survey data, but not including data sampled beyond the previous 3 years?

For example, in Year 1, Farm A conducts a baseline survey by taking 20 samples of its water source and testing them for generic *E. coli,* as described under § 112.45(b)(1)(i) and (ii), which indicates a GM of 125 CFU/100 mL and STV of 400 CFU/100 mL. This is the farm's initial water quality profile for this water source. The farm's GM and STV are below the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). Thus, based on this water quality profile, the farm would not be required to and does not implement any of the mitigation measures specified in §§ 112.44(c)(1) through (c)(3) in Year 1. In Year 2, Farm A conducts an annual survey by taking five samples of its water source and testing them for generic *E. coli,* as described in § 112.45(b)(2), and determines that the GM and STV values based on these five samples are 500 CFU/100 mL and 1600 CFU/100 mL, respectively. The farm finds that these Year 2 values are not consistent with the existing water quality profile because there is greater than a 0.5-log difference between the annual survey values and the water quality profile values. Therefore, as required by § 112.45(b)(2)(ii), the farm develops a new water quality profile. To do this, the farm uses its 5 test results from Year 2's annual survey, combined with 15 test results representing the most recently collected samples from the farm's earlier baseline data set to make up a data set of 20 samples, as described in § 112.45(b)(2)(ii)(A). The farm uses these 20 test results to develop a new water quality profile. The farm's new water quality profile GM and STV values are 200 CFU/100 mL and 600 CFU/100 mL, respectively. The farm's water quality profile GM and STV are now above the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). As a result, as required by §§ 112.45(b)(2)(ii) and 112.44(c), the farm must either apply a time interval as a mitigation measure (§ 112.44(c)(1) or (2)) or discontinue using the water for direct water application during growing covered produce until the water meets the water quality standard (§ 112.44(c)(3)). A 1-day time interval between last water application and harvest (under § 112.44(c)(1)) would be sufficient to meet the microbial quality requirements specified in proposed § 112.44(c) because it results in calculated GM and STV values of 63 CFU/100 mL and 190 CFU/100 mL, respectively. The timing of the Year 2 crop cycle is such that the farm is able to develop its new water quality profile and take action prior to the end of the current harvesting season, and the farm chooses to apply a 1-day interval between last water application and harvest.

As another example, all of the circumstances for Farm B are the same for Farm A, except that Farm B's Year 2 annual survey test results are not available prior to the end of the current harvesting season. In this example, the farm would modify its practices in Year 3 based on the new water quality profile values developed in Year 2. Farm B chooses to apply a 1-day interval between last water application and harvest, as required under § 112.44(c)(1), during Year 3.

As another example, Farm C conducts a baseline survey by taking 20 samples of its water source and testing them for generic *E. coli,* as described under § 112.45(b)(1)(i) and (ii). Using these test results, the farm calculates a GM of 241 CFU/100 mL and STV of 576 CFU/100 mL. This is the farm's initial water quality profile for this water source. The farm's GM and STV are above the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). As a result, as required by §§ 112.45(b)(2)(ii) and 112.44(c), the farm must either apply a time interval as a mitigation measure (§ 112.44(c)(1) or (2)) or discontinue using the water for direct water application during growing of covered produce until the water meets the water quality standard (§ 112.44(c)(3)). The farm chooses to apply a one-day interval between last water application and harvest. In Year 2, Farm C conducts an annual survey by taking five samples of its water source and testing them for generic *E. coli,* as described in § 112.45(b)(2). The farm calculates that the GM and STV values based on these five samples are 3000 CFU/100 mL and 5800 CFU/100 mL, respectively. The farm finds that these Year 2 values are not consistent with the existing water quality profile because there is greater than 1-log difference between the annual values and the water quality profile values. Therefore, as required by § 112.45(b)(2)(ii), the farm develops a new water quality profile. To do this, the farm uses its 5 test results from Year 2's annual survey, combined with 15 test results representing the most recently collected samples from the farm's earlier baseline data set to make up a data set of 20 samples, as described in § 112.45(b)(2)(ii)(A). The farm uses these 20 test results to develop a new water quality profile. The farm's new water quality profile GM and STV values are 475 CFU/100 mL and 1050 CFU/100 mL, respectively. These values are different from the ones the farm used in Year 1 to calculate its time interval under § 112.44(c)(1). The farm must now use the Year 2 new water quality profile GM and STV values to reconsider and implement one of the mitigation measures specified in §§ 112.44(c)(1) through (c)(3). A 2-day time interval between last water application and harvest would be sufficient to meet the microbial quality requirements specified in proposed § 112.44(c) because, using the Year 2 water quality profile values, a 2-day interval would result in calculated GM and STV values of 48 CFU/100 mL and 105 CFU/100 mL, respectively. The farm is able to modify its practices during the current season and applies a 2-day interval between last water application and harvest.

c. Other Requirements to Update Water Quality Profiles—Under proposed § 112.45(b)(1)(iii)(A), we are proposing to require farms to develop a new water

quality profile every 10 years. We tentatively conclude that re-establishing the GM and STV values at least once every 10 years is necessary to reevaluate your agricultural water source and its use in light of potential changes over time of your farm's practices and conditions and changes in the watershed from which you source your water, even if the farm's annual survey data in any single year of the 10 years does not reveal a substantial deviation from the values in the farm's then-current water quality profile. As proposed, a farm would be able to use the test results obtained from annual verification testing to develop the new water quality profile, so this provision would not require any additional testing. For example, a farm that conducts annual verification survey using five samples a year would be able to use these data gathered over the previous 4 years to make up the minimum number of 20 samples. All that would be required is for the farm to use these 20 test results to calculate a new GM and STV value, which would then represent the farm's water quality profile. The farm would then use the new water quality profile to determine what water use is appropriate under § 112.44(c), including whether any steps need to be taken under §§ 112.44(c)(1) through (3). We expect this proposed provision would serve to guide water management decisions with minimal additional cost or resources expended.

Proposed § 112.45(b)(3) would require you to develop a new water quality profile if you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in § 112.45(b)(2) (*i.e.,* reasons not based on annual survey test results). Then, as necessary and required by § 112.44(c)(1) through (3), you would be required to modify your water use based on the new water quality profile as soon as practical and no later than the following year.

For example, if you know or have reason to believe that there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the water quality profile, you would be required to develop a new water quality profile under this section. In this provision, we listed some examples of events (such as land erosion) that may degrade the quality of surface water sources such that the development of a new water quality profile may become necessary, but we do not intend this list to be all-inclusive. Alternatively, there may be circumstances that lead to water quality improvements (for example, changes in upstream water management practices) that result in a higher water quality and may permit its wider use or use without specific time intervals. We limited the application of this provision, which *requires* development of a new water quality profile, to changes reasonably likely to have adverse effects on water quality. We note that a farm may become aware of a change likely to have a positive effect on water quality and choose to voluntarily develop a new water quality profile to evaluate whether the change has indeed improved the water quality to an extent that could justify changes in water use practices under § 112.44(c).

When developing a new water quality profile under proposed § 112.45(b)(3), you would be required to calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. This is an important difference from all the other circumstances in proposed § 112.45 in which a farm would be required to develop a new water quality profile, because in this circumstance, the farm would not be allowed to use existing test results predating the current annual survey test results for this purpose. The farm would be required to conduct some new sampling and testing to make up its new data set of at least 20 test results (unless it opted to exceed the minimum annual survey requirements and already conducted at least 20 tests as part of its current annual survey).

d. Requests for Comment on Proposed § 112.45(b)—We ask for comment on our proposed approach, described in amended provision § 112.45(b), to testing untreated surface water that is used for the growing of produce (other than sprouts) using a direct application method. In particular, we seek comment on our tentative conclusions related to the tiered approach (including the baseline survey, annual verification testing, and requirements to develop new water quality profiles), sampling requirements (including minimum sample sizes, minimum sampling periods), and our determination that such an approach would provide for a reduced required frequency of testing while ensuring the quality and safe use of untreated surface water.

We acknowledge that there are certain limitations to our proposed approach, particularly regarding whether and how annual verification data (which can be based on as few as 5 data points, as proposed) may be used to identify the need for changes to water use practices in the current season and/or the need for a new water quality profile. We request comment on whether there are scenarios that should warrant the development of a new water quality profile using 15 new test results (in addition to the 5 annual survey test results to meet the minimum number of 20 samples), such as where the magnitude of the deviation from the existing water quality profile GM and STV values that formed the basis for the manner in which the water is currently used suggests that those prior sample values are no longer representative of the current agricultural water. For example, is there a threshold based on magnitude of deviation indicated in an annual survey (*e.g.,* a 1 to 2-log change in the GM or STV value compared to the GM or STV of the existing water quality profile) that would suggest that the existing water quality profile is no longer representative of the current water quality such that none of the sample data from that existing water quality profile should be used to determine the current quality of the agricultural water?

We plan to provide guidance to assist farmers to implement the water testing requirements, if finalized. Among other guidance, we expect to develop a tool(s) that you can use to derive the GM and STV values based on your input of water testing data. We recognize that there are different ways to determine STV values, including through sample-based empirical estimation and model-based calculation. We request comment on whether there is a specific statistical method(s) that we should either require or recommend be used for the derivation of GM and/or STV values.

We also request comment on whether we should require farms to alter practices in the current season based solely on the annual survey data under certain circumstances, such as where the annual survey test results suggest a public health concern that must be addressed in a timely manner. This would be different from what we are proposing, which is to use the annual survey data set (which may be as small as 5 test results) solely for verification purposes, which may lead to development of a new water quality profile (using at least 20 test results), upon which farms would determine the need for changes to their water use practices. If there are circumstances in which farms should be required to change water use practices based solely on the smaller annual survey data set, what results obtained in an annual survey should require such immediate changes? For example, should a substantial deviation in the GM or STV value indicated in an annual survey (*e.g.,* a 1 to 2-log change in the GM or STV value compared to the GM or STV

in the existing water quality profile) require farms to institute immediate corrections to current water use practices (such as application of a time interval between irrigation and harvest) based solely on the annual survey results? Note that under our proposed approach, an annual survey can be based on a minimum number of five samples. Should annual surveys be required to include more than five samples? Should annual survey data based on greater than five samples be used to support immediate changes to current practices?

We request comment on whether there are scenarios that might appropriately trigger both of the potential requirements discussed immediately above (*i.e.,* development of a new water quality profile using new test results and, in the interim, immediate changes to water use practices based solely on annual survey test results).

In our analysis related to the number of samples needed in annual verification surveys of untreated surface water, we used an estimate of average standard deviation of $\log_{10}$ *E. coli* abundance measurements in surface waters of 0.4 to characterize the variability of an average water source (Ref. 21). We request comment on whether, for a highly variable water source (*e.g.,* moving water body), we should require more than a five-sample annual verification survey. For example, should we require that you establish a new water quality profile annually using a minimum of 20 samples made up of the annual survey data combined with data from the previous survey(s)?

We also seek comment on whether there are other data sources that can be used in conjunction with water testing data to determine the need for immediate changes to current practices. For example, would data obtained through sanitary surveys conducted by farms be useful to identify the need for immediate changes to current use of the agricultural water?

In addition, we request comment on whether we should stipulate a time period beyond which data would not be appropriate to use in a water quality profile because the test results would not be expected to provide a currently representative profile of the water quality. For example, should we specify that whenever a farm is required to develop a water quality profile under this proposed rule, the data relied upon may only include samples collected within the last three calendar years?

As previously noted, in certain cases, such as where multiple crops are grown in a single year, harvesting will likely occur while the total required five samples for annual verification are collected such that it may be impractical to rely on the results of this verification to determine the appropriate use of that agricultural water for any one or more of those crops for the current harvesting season. We seek comment on this issue, including whether there is an alternative sampling scheme (in lieu of the one we proposed) that would be more responsive to crop cycles and facilitate the use of annual survey testing to make any necessary adjustments to water use during the current harvesting season.

Although we proposed a tiered approach that is based on a baseline survey, annual verification and, as necessary, developing new water quality profiles, we acknowledge that there may be alternative schemes to sampling and testing water quality. We seek comment on any such alternative schemes we should consider.

e. Testing Untreated Surface Water for Other Purposes—New § 112.45(d) would provide that if you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard and that you must have adequate scientific data or information to support your testing frequency. As described in the previously published proposed rule, the uses of agricultural water listed in proposed § 112.44(a) are agricultural water that is: (1) Used as sprout irrigation water; (2) applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities; (3) used to make a treated agricultural tea; (4) used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; and (5) used for washing hands during and after harvest activities.

As proposed, the testing requirements in § 112.45(b) apply when the untreated surface water is used during growing for purposes of direct application as specified in § 112.44(c) only. We anticipate that the primary use of untreated surface water would be in growing activities (*e.g.,* irrigation, crop protection sprays) although we are not restricting it solely for those activities. For example, we are not specifically prohibiting a farm from using untreated surface water for any purpose described in § 112.44(a), provided it meets the water quality requirements for those purposes, as described in that section. Although, in accordance with proposed § 112.44(a), untreated surface water that is used for any purpose described in § 112.44(a) would be required to meet the water quality parameters established in that provision, at this time, we are not proposing, in amended § 112.45, specific testing frequency requirements applicable to untreated surface water when used for the purposes described in § 112.44(a). Instead, we are proposing to include new § 112.45(d), which would provide that if you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard and that you must have adequate scientific data or information to support your testing frequency. We are also proposing to require records of your supporting data in new § 112.50(b)(9).

We seek comment on the prevalence of use of untreated surface water for those purposes listed under § 112.44(a), and on an appropriate approach(es) to sampling and testing of untreated surface water intended for such uses. Further, we acknowledge the challenge associated with designing a sampling scheme that would provide sufficient confidence that a source of untreated surface water, given its inherent variability, will consistently meet the water quality standard in proposed § 112.44(a).

Under the Surface Water Treatment Rule (40 CFR 141.70–141.75), EPA requires public water systems to treat surface water or ground water sources under the direct influence of surface water to meet the requirements of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300f *et seq.*). We seek public comment on whether we should likewise require treatment of surface water sources used for the purposes specified in § 112.44(a), rather than provide for a testing scheme, if the latter is not practical.

ii. Tiered approach to testing untreated ground water. Similar to the tiered approach for testing untreated surface water for direct application during growing, we are proposing a tiered approach to testing ground water that is used for any of the purposes established in § 112.44. New proposed § 112.45(c) would establish that if you use untreated ground water for purposes that are subject to the requirements of

§ 112.44, you must test the quality of each source of the water at least four times during the growing season or over a period of 1 year, using a minimum total of 4 samples collected during a time period(s) as close as practical to harvest. If the samples tested meet the applicable microbial standard in § 112.44 (i.e., no detectable generic *E. coli* per 100 mL under 112.44(a) or a GM of generic *E. coli* of 126 CFU or less per 100 mL under 112.44(c), as applicable), you may test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. You must resume testing at least four times per growing season or year if any annual test fails to meet the applicable microbial standard in § 112.44. We are not proposing that the STV component of the standard under § 112.44(c) be applied in the case of ground water because the minimum number of samples that we are proposing for collection would not be sufficient for a reliable calculation of that value. However, we expect you to apply the STV component of the standard in § 112.44(c) if the number of samples you collect allow for its calculation.

Under this approach, each ground water source would be required to be tested initially by sampling a minimum of four times during the growing season or over a period of 1 year using a total of at least four samples (i.e., a minimum of one sample collected at each sampling occasion). If the results of this initial testing show that the samples meet the microbial quality requirements for their intended use (i.e., either § 112.44(a) or § 112.44(c), as appropriate), then subsequent testing can be conducted only once per year using a minimum of one sample. However, the failure of any annual test to meet the appropriate requirement would result in resumption of the four times per growing season or year testing frequency. We tentatively conclude that our proposed testing frequency and sampling plan is the minimum necessary to ensure the quality of ground water sources for their intended use. We would encourage farmers to sample more than the minimum required four samples to build a robust baseline characterization. With this approach, we are responding to public recommendation for less frequent ground water testing based upon historically satisfactory test results in light of other requirements, most notably the inspection requirements of proposed § 112.42(b).

We seek comment on our proposed approach. We also request comment on whether, similar to § 112.45(b)(3) for untreated surface water, we should require the development of a new water quality profile if you know or have reason to believe that the existing water quality profile no longer represents the quality of your untreated ground water. For example, a compromised well seal, well casing or back flow prevention device may lead to a rapid decline in well water quality.

iii. Sharing of water testing data. Under new proposed provision § 112.45(e), we are proposing that you may meet the requirements related to testing of agricultural water that is required under § 112.45(b), (c), or (d) using test results from your agricultural water source(s) performed either by you or by someone else acting on your behalf; or, alternatively, you may use data collected by a third party or parties provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of part 112 are met. This provision would provide flexibility for you to determine the appropriate means by which to meet the proposed testing requirements in proposed § 112.45. You may conduct the necessary tests on your water source(s) or have those tests conducted for you by an appropriate person, group, or organization. Alternatively, you may use data collected by a third party or parties, such as water distribution districts or cooperatives, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water and all other applicable requirements of the proposed rule are met.

A water source sampled by a third party would adequately represent your water source if the third party takes its samples from the same water source you use (*e.g.,* the same canal, stream, or reservoir) and there is no reasonably identifiable source of likely microbiological contamination (*e.g.,* an untreated sewage discharge point, a source of significant amounts of untreated animal feces such as a livestock farm) between the point(s) at which the third party collects its samples and the point(s) at which you draw the water. Thus, under this provision, farms that share a water source may share testing data from that water source to meet the proposed testing requirements if there is no reasonably identifiable source of likely microbiological contamination between the sampling site(s) and the farm(s) involved. For example, where there is water that is held in a reservoir, and multiple farms draw from the reservoir, those farms are using the same water source. The farms drawing from the reservoir may share their testing data as long as there is no reasonably identifiable source of likely microbiological contamination between the points at which the farms sample and draw the reservoir water as agricultural water. We seek comment on whether and what specific conditions we should establish in this provision to identify circumstances where a third party's data would not adequately represent your agricultural water source and to preclude reliance on shared water testing data in such cases.

Under this proposed provision, farms using data collected by a third party or parties must still satisfy all applicable requirements of the proposed rule related to agricultural water testing. For example, the proposed rule includes requirements related to the timing of collection of samples and the number of samples collected (see proposed §§ 112.45(b), (c), and (d)), and recordkeeping (see proposed § 112.50). The proposed rule also includes other applicable requirements such as specified analytical method(s) to be used for testing (see proposed § 112.151). For example, covered farms sourcing water from a water distribution district may consider using water testing data from the district sampling program. A covered farm considering the district sampling program data would need to determine whether the water source(s) sampled adequately represent the covered farm's agricultural water. The covered farm would also need to consider whether the district's data set includes samples collected during a time period(s) as close as practical to the covered farm's harvest time; whether the district's data set satisfies the minimum number of samples the farm is required to have under the rule; and whether the district's data were obtained using appropriate test methods, as described in proposed subpart N of part 112. In addition, the covered farm would need to get and keep records of the district's testing that satisfy the rule's recordkeeping requirements.

We seek comment on this provision and on additional means FDA could consider to provide flexibility for covered farms to meet the proposed agricultural water testing requirements.

iv. Removal of general testing provision. Finally, with the proposed tiered approaches described above for testing untreated surface water used for the purposes of § 112.44(c) and for testing ground water used more broadly for purposes of § 112.44, we find our previous proposed general provision for testing of agricultural water in proposed

§ 112.45(a) to be unnecessary. Therefore, under proposed § 112.45(a), we are proposing to remove the previous proposed provision that stated ''You must test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every 3 months thereafter during the growing season,'' and to simply retain the exceptions to that provision that we previously proposed. As amended, proposed 112.45(a) would establish that there is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when: (1) You receive water from a public water system, as defined under the SDWA regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; (2) you receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or (3) you treat water in accordance with the requirements of § 112.43. We refer you to a discussion of these circumstances under which testing would not be required in section V.E.3.d of the previously published proposed rule (78 FR 3504 at 3571).

3. Summary of FDA's Revisions and Request for Comment

With respect to the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method, we are proposing to: (1) Amend proposed provision § 112.44(c) to update the microbial quality standard in a way that coincides with the current EPA recreational water standard, *i.e.,* a GM of samples not to exceed 126 CFU of generic *E. coli* per 100 mL of water and (when applicable) a STV of samples, as an approximation of the 90th percentile, not to exceed 410 CFU of generic *E. coli* per 100 mL of water; (2) add two new provisions within proposed § 112.44(c) to incorporate additional flexibility for the use of agricultural water for direct application during growing, i.e., either apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and of your STV to 410 CFU or less per 100 mL (proposed § 112.44(c)(1)); and/or apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and of your STV to 410 CFU or less per 100 mL, provided you have adequate supporting scientific data and information (proposed § 112.44(c)(2)); and (3) provide for the use of alternatives to the microbial quality standard in proposed § 112.44(c) and the microbial die-off rate in proposed § 112.44(c)(1).

With respect to frequency of testing agricultural water, we are proposing to amend proposed § 112.45(b) and add new provision § 112.45(c) to provide for a tiered-approach to testing that would enable testing at a reduced frequency than that proposed in the previously published proposed rule. Specifically, we are proposing in amended proposed § 112.45(b) that if you use untreated surface water during growing of produce (other than sprouts) using a direct application method, you must conduct a baseline survey to develop the water quality profile of your agricultural water source(s); conduct an annual survey to verify the water quality profile of the water; and develop a new water quality profile at least once every 10 years (using data collected during the annual surveys) or sooner, if you know or have reason to believe that your existing water quality profile no longer represents the quality of the water. In addition, we are proposing to add a new provision, *i.e.,* proposed § 112.45(c), to require testing of ground water used as agricultural water at least four times during the growing season or over a period of 1 year, and if the samples tested meet the requirements of proposed § 112.44, testing may be done once annually thereafter. Testing frequency must return to at least four times per growing season or year if any annual test fails to meet the requirements of proposed § 112.44. We are proposing to add new provision § 112.45(d), which would require that, if you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard, and that you must have adequate scientific data or information to support your testing frequency. Finally, in proposed § 112.45(e), we are proposing that you may conduct the necessary tests on your water source(s) or have those tests conducted for you by an appropriate person, group, or organization, or alternatively, you may use data collected by a third party or parties, such as water distribution districts or cooperatives, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water and all other applicable requirements of the proposed rule are met.

We seek comment on our amended and new proposed provisions. With respect to the amended microbial quality standard, we seek comment on our decision to retain the general microbial quality requirements and update them based on the 2012 RWQC; the use of GM and STV values to establish general microbial quality requirements; and the absence of a maximum generic *E. coli* threshold. We also request comment on the appropriateness of permitting an adequate time interval between last irrigation and harvest using a microbial reduction rate of 0.5 log per day as a means to achieve the specified microbial quality requirements. In addition, we seek comment on whether there is a specific microbial die-off rate(s) or microbial removal rate(s) that we should establish for applying an appropriate time interval between harvest and end of storage. Finally, we request comment on whether there are other provisions that we should consider to introduce additional flexibility, for example, to allow alternative indicators of water safety.

With respect to the use of untreated surface water for the purposes listed under § 112.44(a), we seek comment on the prevalence of use of untreated surface water for those purposes, and on an appropriate approach(es) to sampling and testing of untreated surface water intended for such uses. We seek public comment on whether we should require treatment of surface water sources used for the purposes specified in § 112.44(a), rather than provide for a testing scheme, if the latter is not practical.

With respect to the specific frequencies we have proposed for water testing, we seek comment on our proposed tiered approach for testing untreated surface water and ground water, including sampling requirements, and our determination that such an approach would provide for a reduced required frequency of testing while ensuring the quality of agricultural water. We list a number of specific, detailed requests for comment on issues related to testing frequencies for untreated surface water in section

II.B.2.b.i. These include questions regarding whether there are scenarios that should warrant the development of a new water quality profile using 15 new test results (in addition to the 5 annual survey test results to meet the minimum number of 20 samples); whether we should require farms to alter practices in the current season based solely on the annual survey data under certain circumstances; whether annual surveys be required to include more than five samples; whether there are scenarios that might appropriately trigger both development of a new water quality profile using new test results and, in the interim, immediate changes to water use practices based solely on annual survey test results; whether we should require more than a five-sample annual verification survey for highly variable water sources; whether there are other data sources that can be used in conjunction with water testing data to determine the need for immediate changes to current practices; whether we should stipulate a time period beyond which data would not be appropriate to use in a water quality profile because the test results would not be expected to provide a currently representative profile of the water quality; whether there is an alternative sampling scheme that would be more responsive to crop cycles and facilitate the use of annual survey testing to make any necessary adjustments to water use during the current harvesting season; and identification of any alternative schemes we should consider.

We also request: (1) Data or information gathered from scientific studies and/or surveys on the prevalence and population levels of generic *E. coli* in untreated surface water sources of agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method; (2) data or information gathered from scientific studies and/or surveys regarding the regional- and/or commodity-specific microbial die-off rates of generic *E. coli* between last irrigation and harvest of covered produce; (3) data or information gathered from scientific studies and/or surveys regarding the regional- and/or commodity-specific microbial reduction rates of generic *E. coli* due to natural die-off during storage and/or due to pathogen removal during certain post-harvest activities, such as commercial washing; (4) information related to specific protocols for testing, and reliability of specific methods for testing generic *E. coli* in agricultural water; (5) information on seasonal water use of agricultural water during the growing and harvest of covered produce; and (6) information on current concerns based on the revised proposed provisions on the microbial quality standard for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method and frequency of testing agricultural water.

C. Proposed Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

In the previously published proposed rule, under subpart F of proposed part 112, we proposed to establish various standards related to the use of biological soil amendments of animal origin. Specifically, we proposed to establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (proposed §§ 112.51 and 112.52); prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses or equivalent regulatory requirements (proposed § 112.53); establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that satisfy certain specific microbial standards (proposed §§ 112.54 and 112.55), and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.56), and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and require certain records, including documentation of application and harvest dates relevant to application intervals, documentation from suppliers of treated biological soil amendments of animal origin, periodic test results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.60). We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3573 through 3585).

We are reopening the comment period to solicit public comment on our current thinking related to two issues: (1) The minimum application interval for the use of an untreated biological soil amendment of animal origin when it is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application; and (2) the minimum application interval for the use of a biological soil amendment of animal origin that is treated by a composting process when it is applied in a manner that minimizes the potential for contact with covered produce during and after application. We describe our current thinking on these issues in this section.

1. Minimum Application Interval for Untreated Biological Soil Amendment of Animal Origin

In the previously published proposed rule, we proposed that, if the biological soil amendment of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.,* time between application and harvest) must be 9 months (proposed § 112.56(a)(1)(i)). As described in the proposed rule and in the conclusions of the Qualitative Assessment of Risk, soil amendments can be a source of contamination to produce and biological soil amendments of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those that do not contain animal waste. We also noted that human pathogens in untreated or composted biological soil amendments, once introduced to the growing environment, will eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors (78 FR 3504 at 3523).

As described in the proposed rule, we evaluated current scientific evidence to determine an appropriate minimum application interval for the use of untreated biological soil amendments of animal origin in a manner where there is a reasonable possibility that it will contact covered produce after application of the amendment (despite the fact that application must be made in a way to minimize the potential for such contact). We investigated the potential for survival of many enteric pathogens of public health concern and determined that across various pathogens and their potential environments, pathogen survival and die-off time in soils amended with raw manures are extremely varied. One consistency across many trials was an observed rapid early die-off of many pathogens, followed by a prolonged survival of the remaining low populations. It is unclear in the existing literature at what point the population is low enough to minimize the potential

for contamination of covered produce, and it is reasonable to suggest that once pathogen populations fall below detection limits, their risks are minimized.

Some of the longest survival times involved organisms present at very high initial populations (*e.g., E. coli* O157:H7 in sheep manure surviving for 21 months) or involved certain pathogens such as encysting parasites (*Cryptosporidium parvum* cysts surviving for over a year or the eggs of parasitic flatworms (*Ascaris* ova) surviving for over 15 years). Some enteric pathogens are reported to be more resilient to deleterious effects of the environment than others (most notably, *Salmonella* seems better attuned for survival outside of a host than does *E. coli* O157:H7); those microorganisms that produce spores are especially hardy. We noted that basing all manure application standards on these extreme cases (*i.e.,* spore-formers) would be unnecessary. The majority of survival studies showed that most enteric pathogens of public health importance, under the most common conditions, would not survive in the soil past 1 year. Further, organisms most commonly associated with produce outbreaks (such as *E. coli, Salmonella,* and *Listeria*) are unlikely to survive at detectable population levels in soil past 270 days. Therefore, we tentatively concluded that utilizing a 9-month waiting period between the application of an untreated biological soil amendment of animal origin and the harvest of covered produce would be protective for the preponderance of environments in situations where covered produce is reasonably likely to contact the soil after application of untreated biological soil amendments of animal origin. We further noted that this time interval, although somewhat less restrictive, would not be inconsistent with the 12-month restriction used by some segments of the produce industry (78 FR 3504 at 3582).

Moreover, as described in the previously published proposed rule, we tentatively concluded that, under certain circumstances, the application interval of 9 months may be more than what is necessary for minimizing the likelihood that covered produce that is grown in soils amended with an untreated biological soil amendment, and is reasonably likely to contact the soil after application, pose to the public health. Under certain circumstances, an alternative standard may be appropriate if it is shown to provide the same level of public health protection as the 9-month minimum application interval requirement in proposed § 112.56(a)(1)(i), and not to increase the likelihood that the covered produce will be adulterated. For example, alternatives to the proposed 9-month minimum application interval could take into account specific characteristics of the locality, crop and the agro-ecological environment. Such alternatives could consider differences in soil amendment feedstock, application methods, and treatment methods, especially given the potential for new innovations in such methods. Therefore, under proposed § 112.12(a)(3), we proposed that you may establish an alternative to the requirement for a minimum application interval of 9 months, provided you have adequate scientific data and information and satisfy other requirements established in proposed § 112.12 (78 FR 3504 at 3553 and 3584).

a. Relevant Comments. We received an extensive number of comments on this issue, a large majority of which expressed strong concerns with the proposed 9-month minimum application interval. Key concerns noted by commenters included the following: (1) There is no conclusive scientific evidence to support a 9-month minimum application interval requirement, and in developing this proposed application interval, FDA relied on the findings of a small number of published studies whose methods and designs do not include the range and variety of important factors and variables (*e.g.,* climates, soils, management practices) that can dramatically affect the viability of pathogens that may be present in these materials; furthermore, FDA used certain scenarios to assess pathogen risk from manure resulting in a cautious approach based on selective science, which is inconsistent with FDA's mandate to develop science-based produce safety rules; (2) a 9-month application interval is not appropriate as a general requirement applicable to all commodities, regions, and agro-ecological conditions; for example, such an extended time period between application and harvest is either not necessary or not practical in certain regions, such as the northeastern and northwestern regions, of the United States considering their climatic conditions and shorter growing seasons; (3) farmers currently comply with the standards established under the USDA's NOP, which specify a minimum application interval of 120 days for crops in contact with the soil and 90 days for crops not in contact with the soil, and the proposed 9-month application interval would be excessively burdensome, *i.e.,* a 9-month application interval could interfere with full compliance with the USDA organic regulations by impeding soil fertility and crop nutrient management practices and crop rotation practices (see 7 CFR 205.203 and 205.205); (4) a 9-month application interval requirement would have a negative impact on farmers' ability to rely on raw manure as a primary source of nitrogen for growing of crops; (5) a 9-month application interval requirement would disrupt current crop rotation cycles and is likely to limit the production of produce to only one cropping cycle per season; (6) raw manure has a long history of use and the proposed requirement to apply a 9-month application interval would pose severe economic and practical burdens on farmers; (7) the infrastructure necessary to make the transition from raw manure to compost is either lacking or not widely established; and (8) a 9-month application interval could mean that manure is handled in a less sustainable manner, could also result in greater use of chemical fertilizer, and would run counter to the Natural Resources Conservation Service's (NRCS) national campaign to dramatically increase soil health in part by reintroducing manure into farming systems. Commenters urged FDA to engage in a discussion of the growing body of research regarding the importance of biologically active soils in promoting pathogen die-off, and the harmful effects of soil sterilization through chemical-intensive fertilization and pest management practices. Some commenters also requested us to consider allowing raw manure that has been tested to a known safety standard to be held to lesser application restrictions.

In contrast, a few other commenters emphasized the public health concerns associated with the improper use of manure as a fertilizer, and supported FDA's proposed minimum application intervals, including the 9-month interval for use of untreated biological soil amendments in a manner where the crop is reasonably likely to contact the soil after application, urging us to maintain this waiting period to protect public health. One of these commenters, however, also noted that FDA must acknowledge that manure—raw and composted—plays an important role in sustainable agriculture by returning nutrients to the soil and reducing the need for chemical fertilizers.

Overall, there was widespread concern among commenters that the proposed 9-month minimum application interval would be impractical and/or unnecessarily

burdensome. Commenters urged FDA to evaluate and address concerns identified for each specific commodity sector and region, and develop and enforce a rule that sets a minimum standard for food safety that would be appropriate nationwide. In addition, a majority of commenters agreed that FDA should establish a process to engage the wider produce community in discussions about currently available scientific evidence on this issue; gaps in current scientific understanding; and the need for concerted efforts among various stakeholder groups to not only fill the research gaps but also build the necessary infrastructure to support and promote practical and effective produce safety strategies. Several commenters also urged FDA to publish a second set of revised proposed provisions and provide an additional opportunity for public input prior to finalizing the produce safety regulation.

b. FDA's Consideration of Comments. We considered the comments that objected to the 9-month interval on the basis that it is not scientifically sound. As described in the previously published proposed rule, FDA relied on currently available scientific evidence to identify the 9-month application interval as a general requirement broadly applicable for all crops, soils, types of manure, and growing regions. Our review of existing literature indicated a pattern of rapid early die-off of pathogens, followed by a prolonged period of survival of the remaining low populations. However, current data do not allow for a determination of the point at which pathogen populations would be considered too low to affect the potential for contamination of covered produce. Nevertheless, it is reasonable to expect that the likelihood of contamination is minimized when pathogen populations are below detection limits and, therefore, we considered this in identifying a minimum application interval. As explained in the previously published proposed rule, the majority of survival studies indicate that most enteric pathogens of public health importance, under the most common conditions, would not survive in the soil past 1 year. Moreover, organisms most commonly associated with produce outbreaks (such as *E. coli O157:H7, Salmonella,* and *Listeria monocytogenes*) are unlikely to survive at detectable population levels in soil past 270 days. Consequently, we proposed 9 months as the minimum application interval.

We also acknowledged that shorter waiting periods may be appropriate for some specific commodities and/or agro-ecological conditions, although conclusive evidence is lacking. Recognizing the limitations of available data, we provided for alternative application intervals to be used where there is adequate scientific data and information to support such alternative time intervals. Furthermore, recognizing the time and resources necessary to conduct the scientific investigations and/or gather the necessary data, we provided for compliance periods of 2 to 4 years, depending on the size of the farm.

We considered comments that recommended using the application intervals for raw manure established under the NOP. Under 7 CFR 205.203(c)(1), raw animal manure must be composted unless it is: (i) Applied to land used for a crop not intended for human consumption; (ii) incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or (iii) incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles. The restriction on the application of raw manure is in addition to the USDA organic requirements in § 205.203(c), which states in part that organic producers are required to ''manage plant and animal materials . . . in a manner that does not contribute to contamination of crops, soil, or water by . . . pathogenic organisms.'' In establishing this regulation, the Agricultural Marketing Service (AMS) acknowledged that this raw manure standard is based on organic crop production practices and noted the scarcity of scientific data on the regulation of raw manure use and food safety. Specifically, in the final rule that established this regulation, AMS noted the following: ''Although public health officials and others have identified the use of raw manure as a potential food safety concern, at the present time, there is no science-based, agreed-upon standard for regulating the use of raw manure in crop production. The standard in this [NOP] rule is not a public health standard. The determination of food safety demands a complex risk assessment methodology, involving extensive research, peer review, and field testing for validation of results.'' This statement was provided by AMS in response to comments on a broader discussion about the application of raw manure under NOP requirements. The AMS also stated that it ''does not have a . . . capacity with which to undertake a comprehensive risk assessment of the safety of applying raw manure to human food crops'' and that ''the standard in this rule is a reflection of AMS' view and of the public comments that this standard is reasonable and consistent with current organic industry practices and the NOSB [National Organic Standards Board] recommendations for organic food crop production.'' Finally, AMS noted that ''should additional research or Federal regulation regarding food safety requirements for applying raw manure emerge, AMS will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard'' (65 FR 80548 at 80567; December 21, 2000). Therefore, we believe that the current NOP application intervals for raw manure are not intended as science-based minimum standards for the safe production and harvesting of produce or measures reasonably necessary to minimize the risk of serious adverse health consequences or death, which is the underlying basis for the standards we proposed under part 112. Moreover, peer-reviewed literature suggests that a 90-day or 120-day interval, as required under the NOP regulations, does not sufficiently minimize the likelihood of contamination in all circumstances (Refs. 22 and 23).

Some of the comments expressed concerns about field crops that rely on the use of raw manure as a means of land-applied disposal of waste raw manures produced through animal husbandry. We believe crops used in such disposal of raw manure primarily include food grains such as dent or flint corn, wheat, and rye. As proposed in the previously published proposed rule, produce does not include food grains meaning 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, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans (see definition of ''Produce'' under proposed § 112.3). Some non-food crops, such as cotton, may also be used for disposal of raw manure, but non-food crops are outside of the scope of this rule. Therefore, we do not expect the current practice of use of raw manure in the growing of food grains or non-food crops to be affected by the produce safety regulation.

We also considered comments that opposed the 9-month application

interval citing limitations related to the use of raw manure as a source of nutrients. We recognize that nitrogen release from raw manure is highest immediately following application of the manure to the soil, and that nitrogen may be rapidly lost by volatilization (particularly if surface applied) or leaching (when rainfall or irrigation follow application) (Refs. 24, 25, and 26). Further, we recognize that many covered produce crops have a shorter than 9-month growing period, which complicates the synchronization of crop demand with nutrient availability from manure application. We note however, that soil amended with manure continues to benefit from manure applications after the initial nitrogen release, both by slow release of nitrogen as organic sources of nitrogen are mineralized, and by numerous benefits associated with the enhancement of soil microbial community structures and improvement of many soil physical and chemical properties, including an increase in nutrient cycling (Refs. 27, 28, and 29). A waiting period (either our previously proposed 9-month period, that imposed by the NOP, or another waiting period) may affect the benefit of raw manure as a nutrient supplement, but it is not expected that these waiting periods will completely negate the value of raw manure as a soil amendment. In addition, composted manure has stabilized forms of nitrogen, which are less susceptible to leaching or runoff (Ref. 30), but also retains many other key values of manure, including supply of carbon to support diverse and abundant soil microbial communities, which serve critically important functions in nutrient cycling, conditioning of soil physical and chemical properties (Ref. 31) and, in some cases, provide crop protection from phytopathogenic diseases (Ref. 32). We recognize that some loss of nitrogen during the composting process is likely and that adjustments to fertility management will be necessary when either allowing for a waiting period after applying raw manure or shifting to use of composted manure (Refs. 31 and 33). We believe increased use of composted manure offers significant food safety benefits and retains much of the agronomic value of manure as a resource for farmers, particularly those with animal components in their farm operations. Overall, no new studies have been published since the issuance of the previously published proposed rule that would refute the scientific basis for our proposed 9-month waiting period. Nevertheless, we recognize the limited body of scientific evidence, the limitations associated with the studies we relied on, the use of a no detectable pathogen level as the basis for identifying a minimum application interval, and the need for additional research in this area. The use of raw manure at a time close to harvest, during organic or conventional production, presents a significant likelihood of contamination of covered produce if produce is reasonably likely to contact the soil. We continue to believe that a science-based minimum standard to address this potential for contamination by such use of raw manure must include an appropriate quantitative minimum application interval. As noted in the previously published proposed rule, we are currently working with USDA and other stakeholders to conduct research on application intervals necessary to ensure the safety of covered produce when raw manure is applied to a growing area and covered produce is reasonably likely to contact the soil. We expect such research will help fill the current gaps in science, and enable us to identify specific agro-ecological or commodity-specific conditions that would support alternative minimum application intervals.

FDA also believes that progress toward its food safety goal can be achieved by facilitating the transition of farming practices, to the extent feasible, toward the safer option of using composted manure rather than raw manure. Our review of the scientific literature suggests that, regardless of the source, composting that is properly conducted (including proper turning of feedstock) can minimize the expected pathogen load and subsequent likelihood of produce contamination. Compost use can also result in a variety of environmental benefits, including that compost enriches soils, helps cleanup (remediate) contaminated soil, and helps prevent pollution (*e.g.,* by reducing the potential for nutrient rich run off as compared to raw manure use), and also offers economic benefits (*e.g.,* reduces the amount of irrigation water, fertilizers, and pesticides needed, and acts as an alternative to routing organic materials to landfills) (Ref. 34). A transition of farming practices from raw manure to composted manure use would require a concerted effort by the regulatory agencies, agricultural marketing agencies, academia, and the regulated community. We acknowledge the various concerns—*e.g.,* economic, scientific, and practical—that we heard from stakeholders across the country and foreign trading partners. We are also fully cognizant of not only the need for additional scientific information but also resources to build the necessary infrastructure to facilitate the use of appropriate composting treatments.

Considering the strong concerns expressed by stakeholders, our ongoing effort to build the scientific knowledge and infrastructure in this area, and our overall commitment to adopt practical and effective produce safety strategies, we have tentatively concluded that the appropriate approach is to remove the 9-month minimum application interval for use of raw manure that is specified in proposed § 112.56(a)(1)(i) and defer our decision on an appropriate minimum application interval until such time as necessary for us to pursue the following actions.

First, we will conduct a risk assessment on the safe use of raw manures in covered produce fields. Variables that may be considered in such a risk assessment include the source and type of manure (for example, animal type and animal diet); method of application (for example, broadcast, incorporated, and subsurface incorporation); climatic conditions (for example, temperature, days of sunlight, sunlight intensity, and expected rainfall); type of commodity; and the characteristics of the soil (for example, pH and moisture holding capacity). We will also work with USDA and other stakeholders to develop and implement a robust research strategy that will allow us to supplement the science currently available on this issue, and further develop our risk assessment model. As we explained in the previously published proposed rule, we are currently working with USDA and other stakeholders to conduct research on application intervals necessary to ensure the safety of covered produce when raw manure is applied to a growing area and covered produce is reasonably likely to contact the soil. Our research will address various issues, including and, in particular, whether and how application intervals can be tailored for specific commodities, types of commodities, growing environment and any other agro-ecological conditions. We encourage the farming community and others to partner with us on this effort, including by participating with academia, industry, and government on necessary research activities.

Second, we will work with USDA and other stakeholders to encourage the transition of the produce grower community to the use of compost rather than raw manure. As noted above, use of compost is a safer practice from a public health standpoint, and is also considered to be a more sustainable

environmental practice. We encourage the farming community and others to partner with us on this effort.

Third, although there will be no minimum application interval requirement in § 112.56(a)(1)(i) while we pursue the avenues of scientific research and infrastructure development identified above, we continue to believe that a quantitative application interval standard, established in the produce safety regulation, is necessary to minimize the likelihood of contamination of produce resulting from the use of raw manure in a manner that contacts the crop. Our view remains that a quantitative standard rather than a qualitative one (suggested by some commenters) is the more effective and enforceable public health standard. We are committed to revisiting this issue and identifying an appropriate minimum application interval(s) for such use of raw manure taking into account new information gathered from our ongoing risk assessment and research efforts. We anticipate that these efforts will take 5 to 10 years to complete. Following the completion of the risk assessment and research work, we expect to: (1) Provide stakeholders with data and information gathered from scientific investigations and risk assessment; (2) consider such new data and information to develop tentative scientific conclusions; (3) provide an opportunity for public comment on our tentative decisions; and (4) consider public input to establish an appropriate minimum application interval(s).

We acknowledge the comments that pointed out that many growers currently employ the NOP standard of 90 days or 120 days, as specified in 7 CFR 205.203(c)(1), and we recognize that such growers will likely continue their current practice to use this standard in organic crop production, in the absence of an FDA regulation that establishes a food safety standard for minimum application intervals associated with the use of raw manure. Given that the scientific literature demonstrates that the probability of pathogen survival decreases as the length of time between application of raw manure and harvest increases, and that more rapid die-off occurs during the months immediately following application (*e.g.,* 3 to 4 months) as compared to subsequent months (followed by prolonged survival of pathogens at low levels), we believe adherence to the NOP standard to be a prudent step toward minimizing the likelihood of contamination while the above described research program is ongoing. At this time, we do not intend to take exception to the continuation of this practice.

We request comment on our current thinking described above. In addition, we seek: (1) Data or information gathered from scientific studies on the persistence of human pathogens in raw manure in an open environment (published or unpublished data) under various agro-ecological conditions and the expected transfer of pathogens to various commodities grown in soils amended with raw manures; (2) information related to specific protocols for testing, and reliability of specific methods for testing pathogens in manure; (3) information on nitrogen availability and the costs associated with various fertilizer options currently available to produce farms; (4) information on the methods of use and prevalence of use of raw manure, including practices by small farms; and (5) information on current barriers that will need to be addressed to enable transition from use of raw manure to use of compost.

2. Minimum Application Interval for Biological Soil Amendment of Animal Origin Treated by a Composting Process

In the previously published proposed rule, we proposed that, if the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements we proposed in § 112.54(c) to meet the microbial standard we proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.,* time between application and harvest) must be 45 days (proposed § 112.56(a)(4)(i)).

As explained in the previously published proposed rule, we tentatively concluded that process controls for composting can be expected to be more prone to failure than process controls during chemical or physical treatments and, therefore, proposed to apply a minimum application interval of 45 days as part of a multiple hurdle approach. For example, heat treatments are often conducted in enclosed heat-treatment chambers (*i.e.,* ovens), often with various means of agitation (such as stirring rods, etc.), that can be accurately monitored and controlled to reach the required treatment conditions throughout the material being treated. Conversely, composting usually occurs outdoors, is exposed to fluctuating environmental pressures and wildlife activity, and is not homogeneous in nature and prone to having ''cold-spots'' that are not completely treated (even with proper turning). In general, during composting, there is a higher likelihood of having a systems failure, which is also more likely to go undetected, should it occur. Composting may result in a treated biological soil amendment of animal origin that may continue to harbor human pathogens of food safety concern, although any such pathogens that may be present can be expected to be present at low populations and unlikely to survive for extended periods under normal environmental conditions after application. Therefore, we proposed to impose an additional mitigation measure in situations where covered produce is reasonably likely to contact the soil after application of biological soil amendments of animal origin treated by composting by requiring a minimum application interval of 45 days. This time period has been shown to be effective when the population of the pathogen is minimal, as can be expected of a fully composted biological soil amendment of animal origin (78 FR 3504 at 3583).

a. Relevant Comments. We received a number of comments on this issue, many of which objected to the proposed 45-day minimum application interval. Comments also included relevant data and factual information. Concerns noted by commenters included the following: (1) Farmers currently comply with the standards established under the NOP for the use of composted animal manures to build organic matter in production fields, in part, to avoid use of synthetic fertilizers, and the NOP does not require any minimum application interval for composted manures; (2) the proposed 45-day application interval would be excessively burdensome; (3) there is a lack of scientific basis for the 45-day interval for compost and FDA has failed to show how the literature supports this conclusion; (4) farmers who use compost would be severely limited by the proposed 45-day interval in their ability to utilize crop rotations for short-season crops and/or to maintain or increase biodiversity, and in their use of compost during the growing season for side-dressing; and (5) the burden on farms from using a 45-day wait period for compost is unscientific, especially considering the wealth of data showing that soil treated with compost is more suppressive of human pathogens than soil not treated with compost. In addition, commenters recommended eliminating the 45-day minimum application interval for fully composted manures where the soil has no contact with the crop, and where the soil amendment is handled in accordance with the proposed time, temperature, holding, and microbial testing requirements. Some other commenters recommended retaining the 45-day

waiting period only where the soil has contact with the crop and where there is no testing conducted to confirm that the composting process was properly implemented.

In contrast, some commenters suggested that FDA would do much more for food safety if it required composting of all raw manure, or if it required raw manure to be tested for pathogens and then be composted if the pathogen load exceeded a certain quantity. Another commenter suggested that all animal manure that is used for ''organic farming'' must be composted for a minimum of 2 years, and tested for proper temperature range on a monthly basis, before its use on the farm.

b. FDA's Consideration of Comments. We proposed to use the 45-day minimum application interval as part of a multiple hurdle approach to the safe use of composted manures. Proposed § 112.56(a)(4)(i) refers to the use of composted manure under certain specified mitigation measures: (1) It is properly treated in accordance with our proposed requirements in § 112.54(c); (2) it is properly treated to meet the microbial standard we proposed in § 112.55(b); (3) it is applied in a manner that minimizes the potential for contact with covered produce during and after application; and (4) there is a minimum application interval of 45 days. Under the same treatment and microbial standard requirements, but where the composted manure is applied in a manner that does not contact covered produce during or after application, we proposed no minimum application interval, *i.e.,* 0 days (proposed § 112.56(a)(4)(ii)). Therefore, our proposal to use 45 days as a minimum application interval was intended as one among multiple mitigation measures that would be implemented in situations where covered produce is reasonably likely to contact the soil after application of the biological soil amendment of animal origin.

Further, we proposed to require certain records to document that composting processes conducted by farmers or independent composters are properly conducted and that the proposed minimum time between application and harvest was observed, when applicable (proposed § 112.60).

Overall, we believe that the use of proper composting methods in accordance with appropriate handling, storage, treatment, and microbial standard requirements that we proposed in §§ 112.51, 112.52, 112.54(c), and 112.55(b) are sufficient to minimize the likelihood of composted manure acting as a source of contamination and to provide reasonable assurance that produce is not contaminated. This approach also satisfies FDA's goal to reduce the risk to public health when using composted manures, and to encourage and facilitate the transition of farming practices that currently use raw manure to the safer option of using composted manure. Further, the AMS, NRCS, EPA, and other organizations support the use of composted manure given its benefits to soil, cropland, and the environment, and/or recommend the use of composted manure over raw manure (Refs. 35, 36, 37, 38, and 39). FDA has considered this widespread understanding of the benefits of use of compost, and the impact of proper composting treatments on the microbial populations in composted manure.

In recognition of the expected benefit to public health when composted manures are properly treated and handled, and to further facilitate the use of composted manure rather than raw manure, we are proposing to eliminate the 45-day minimum application interval for use of composted manure in proposed § 112.56(a)(4)(i). As amended, proposed § 112.56(a)(4)(i)) would establish that if the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements we proposed in § 112.54(c) to meet the microbial standard we proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.,* time between application and harvest) is 0 days.

We seek comment on these amendments.

3. Corresponding Proposed Amendments

As a consequence of eliminating the 9-month minimum application interval in proposed § 112.56(a)(1)(i) and of revising the 45-day minimum application interval to 0 days in proposed § 112.56(a)(4)(i), by cross-reference, we are also proposing certain corresponding amendments. We are proposing to remove the proposed provisions §§ 112.12(a)(3), 112.12(a)(4), 112.56(b), which would have provided for the use of alternative application intervals in lieu of the previously proposed minimum application intervals, as these provisions would no longer be needed. We are also proposing to remove proposed provisions §§ 112.60(b)(1) and 112.60(b)(5) thus eliminating the documentation requirements relevant to the previously proposed 9-month and 45-day minimum application intervals. In addition, we are proposing to remove proposed §§ 112.182(d) and 112.182(e), which listed variances from the 9-month and 45-day minimum application intervals as examples of permissible types of variances.

Our current intent is that we will consider provisions for alternative application intervals, documentation requirements, and variances at the same time as provisions for an appropriate minimum application interval(s) for the use of an untreated biological soil amendment of animal origin (that is used in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application), after we first complete the actions discussed in section II.C.1.b.

4. Summary of FDA's Revisions and Request for Comment

We are proposing to: (1) Remove the minimum application interval in proposed § 112.56(a)(1)(i) and defer our decision on an appropriate minimum application interval while FDA pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. Following the completion of risk assessment and research work, FDA expects to share with stakeholders its tentative conclusions, taking into account new data and information, and consider public input to establish an appropriate minimum application interval(s) for the use of an untreated biological soil amendment of animal origin that is used in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application; (2) amend proposed § 112.56(a)(4)(i)) to establish that if the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements we proposed in § 112.54(c) to meet the microbial standard we proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (i.e., time between application and harvest) is 0 days; and (3) in light of the revisions explained in (1) and (2), eliminate the provisions to permit the use of alternative application intervals or variances, or require certain documentation related to the previously proposed 9-month and 45-day intervals (*i.e.,* delete proposed §§ 112.12(a)(3), 112.12(a)(4), 112.56(b), 112.60(b)(1), 112.60(b)(5), 112.182(d), and 112.182(e)).

We request comment on our current thinking on the issues described above. Specifically with respect to the use of untreated biological soil amendments of animal origin, we seek comment, including scientific data or information on the persistence of human pathogens in raw manure under various agro-ecological conditions, and the transfer of pathogens to various commodities grown in soils amended with raw manures; specific protocols for testing, and the reliability of specific methods for testing pathogens in manure; nitrogen availability and the costs associated with current options for fertilizers; information on the methods and prevalence of use of raw manure on small farms; and current barriers related to use of compost.

D. Proposed Subpart I—Standards for Domesticated and Wild Animals

In the previously published proposed rule, under subpart I of proposed part 112, we proposed certain standards related to domesticated and wild animals. Proposed subpart I includes standards that would be directed to the potential for biological hazards from animal excreta to be deposited by your own domesticated animals (such as livestock, working animals, and pets), by domesticated animals from a nearby area (such as livestock from a nearby farm), or by wild animals (such as deer and wild swine) on covered produce or in an area where you conduct a covered activity on covered produce. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3585 through 3587).

Specifically, in proposed § 112.82, we proposed that if animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, you must employ, at a minimum, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce. In addition, in proposed § 112.83, we proposed to establish requirements for measures related to animal intrusion in those areas that are used for covered activities for covered produce when, under the circumstances, there is a reasonable probability that animal intrusion will contaminate covered produce. We proposed to require that you monitor these areas as needed during the growing season, based on the covered produce being grown and your observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). In addition, in proposed § 112.83(b), we proposed to require that, if animal intrusion occurs, as evidenced by observation of significant quantities of animals, animal excreta or crop destruction via grazing, you must evaluate whether the covered produce can be harvested in accordance with the requirements of proposed § 112.112.

As noted in the proposed rule, consistent with sections 419(a)(1)(A), 419(a)(3)(E), and 419(a)(3)(D) of the FD&C Act, we consulted with the NOP and USDA's NRCS, U.S. Fish and Wildlife Service, and the EPA to ensure that environmental and conservation standards and policies established by those agencies were appropriately considered in developing the requirements proposed in subpart I. We tentatively concluded that the provisions of proposed subpart I do not conflict with or duplicate the requirements of the NOP. In addition, we tentatively concluded that the provisions of proposed subpart I are consistent with existing conservation and environmental practice standards and policies while providing for enforceable public health protection measures. We also noted that the produce safety regulation would not require the destruction of habitat or the clearing of farm borders.

Specifically in relation to proposed § 112.83, we noted that this proposed provision should not be construed to require the ''taking'' of an endangered species, as the term is defined in the Endangered Species Act (ESA) (16 U.S.C. 1532(19)) (*i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), or to require farms to take measures to exclude animals from outdoor growing areas or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

We are reopening the comment period to solicit public comment on our current thinking on an issue related to the standards for domesticated and wild animals, i.e., the potential impact of this proposed rule on wildlife and animal habitat. We describe our current thinking on this issue in this section.

1. Relevant Comments

We received various comments that expressed the concern that the proposed rule, if finalized as proposed, would adversely affect wildlife, including threatened or endangered species, and animal habitat. Other comments noted that animal habitat, habitat connectivity, and wildlife populations would be at risk if our proposed provisions related to animal intrusion are perceived by produce growers to mean that less habitat and/or more fencing in the production environment is a necessary management strategy. Citing some of our statements in the preamble of the proposed rule, comments acknowledged FDA's interest in comanagement of both food safety and wildlife conservation, and urged us to provide similar language in the regulation.

2. FDA's Consideration of Comments

In publishing the Produce Safety proposed rule, we relied on a categorical exclusion from the need to prepare an Environmental Assessment (EA) or Environmental Impact Statement (EIS) under 21 CFR 25.30(j) (78 FR 3504 at 3616). However, as explained in the Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (NOI), based on currently available information, including comments received, and upon further analysis, FDA has determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)), and therefore, an EIS is necessary for the final rule (78 FR 50358, August 19, 2013). In the EIS that will accompany the Produce Safety final rule, FDA will evaluate the potential environmental effects of the rule, including those resulting from the standards of domesticated and wild animals established in subpart I of part 112.

In response to concerns that the Produce Safety regulation may inadvertently promote practices that may adversely affect wildlife and animal habitat, including impacts on threatened or endangered species, we are proposing to include a new provision, i.e., proposed § 112.84, within subpart I of proposed part 112. We consulted with USDA's NRCS and the U.S. Fish and Wildlife Service to inform our current thinking on this issue.

Proposed § 112.84 would provide that the regulation in part 112 does not authorize or require covered farms to take actions that would constitute the ''taking'' of threatened or endangered species in violation of the ESA, as that term is defined by the ESA, *i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Proposed § 112.84 would also state that part 112 does not require covered farms to take measures to

exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

As discussed in the previously published proposed rule, we encourage the application of practices that can enhance food safety and that are also consistent with sustainable conservation. We believe that the provisions of proposed part 112, including subpart I, are consistent with existing conservation and environmental practice standards and policies. By adding proposed § 112.84, we are proposing to codify into the produce safety regulation that the requirements of proposed part 112 do not require or permit the use of practices in violation of the ESA, and that the regulation does not require the use of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to the produce field. Rather, we encourage the comanagement of food safety, conservation, and environmental protection. One set of examples of biodiversity and conservation practices that may enhance food safety is available from the Resource Conservation District of Monterey County, CA (Ref. 40). We provide this information as a resource and do not intend for it to suggest that we require or endorse a single approach.

Growers of produce should also be aware that clearing or manipulation of habitats, including activities affecting water resources, groundwater or natural vegetative cover, can affect species listed as threatened and endangered. Growers can determine whether any listed species may be present in their area by checking the U.S. Fish and Wildlife Service's Endangered Species Web site and the Information, Planning, and Conservation System Web site. You should coordinate with your local U.S. Fish and Wildlife Service office on any activity that could potentially affect listed species or critical habitat. We ask that you contact your local U.S. Fish and Wildlife Service office for any additional information.

3. Summary of FDA's Revisions and Request for Comment

We are proposing to add a new provision § 112.84 to state that part 112 does not authorize or require covered farms to take actions that would constitute the ''taking'' of threatened or endangered species in violation of the ESA, and that part 112 does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. We seek comment on our current thinking, including on proposed § 112.84.

E. Proposed Subpart R—Withdrawal of Qualified Exemption

In the previously published proposed rule, under subpart R of proposed part 112, we proposed to establish the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of proposed § 112.5. Specifically, proposed § 112.201 listed the circumstances under which FDA may withdraw a qualified exemption applicable to a farm, while §§ 112.202 and 112.203 specified the procedure and information that FDA would include in an order to withdraw such qualified exemption. In addition, proposed §§ 112.204 through 112.207 provided for a process whereby you may submit a written appeal (which may include a request for a hearing) of an order to withdraw a qualified exemption applicable to your farm, and proposed §§ 112.208 through 112.211 provided a procedure for appeals, hearings, and decisions on appeals and hearings. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3611 through 3616).

We are reopening the comment period to solicit public comment on our current thinking on two specific issues related to the provisions for withdrawal of qualified exemptions: (1) The process under which FDA would withdraw a qualified exemption and (2) provisions for reinstatement of a qualified exemption that is withdrawn. We describe our current thinking on these two issues in this section.

1. Process for Withdrawal

As described in the previously published proposed rule, proposed § 112.201 would establish the circumstances under which FDA may withdraw an exemption applicable to a farm. Consistent with section 419(f)(3)(A) of the FD&C Act, we proposed that we may withdraw a qualified exemption: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm (proposed § 112.201(a)) or (2) if we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm (proposed § 112.201(b)).

a. Relevant Comments. We received several comments expressing concern that the circumstances under which FDA would withdraw a qualified exemption, which are specified in proposed § 112.201, are unclear. In addition, some commenters urged us to provide for intermediary steps prior to resorting to withdrawal of an exemption, and recommended a three-tiered process that would include the issuance of a warning letter, followed by a temporary conditional withdrawal, and then a full withdrawal, as applicable. They noted that such a flexible approach would allow a farm to take corrective actions before having its exempt status fully withdrawn. Some other commenters suggested partially withdrawing a qualified exemption, thus requiring compliance with only those regulatory requirements that are related to the reason(s) for which the exemption is withdrawn. Several commenters also recommended that we establish a process that would require FDA to provide justification to a farm of FDA's decision to withdraw the farm's qualified exemption, and would provide an opportunity for the farm to respond to and/or submit arguments challenging FDA's decision to withdraw the exemption.

b. FDA's Consideration of Comments. We are proposing certain amendments, including taking into account comments that suggested that FDA consider other actions prior to invoking the provisions of subpart R to withdraw a qualified exemption. Depending on the circumstances, FDA may take a variety of actions, including education and warning letters, as well as enforcement actions such as administrative detention, seizure, and injunction to protect the public health and prevent or mitigate a foodborne illness outbreak. FDA may consider taking such actions prior to or in conjunction with a consideration to withdraw the qualified exemption.

To make our intent clear that we would consider other actions, as appropriate, before issuing an order to withdraw a qualified exemption, we are proposing to add a new provision under § 112.201. Proposed § 112.201(b) would establish that before FDA issues an order to withdraw your qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction (proposed § 112.201(b)(1)). If these other actions address the circumstances that could lead FDA to withdraw the

exemption, then FDA would likely determine that withdrawal of an exemption is not needed. We have provided two examples of potential scenarios and actions FDA might choose to take in such scenarios. Nothing in the discussion below should be construed to bind FDA in any future situation, however.

For example, consider the situation in which Farm A is growing, harvesting and packing heirloom tomatoes for sale to local restaurants. An outbreak of salmonellosis is epidemiologically linked to raw heirloom tomatoes served at those restaurants. The tomatoes are traced back to the farm. An inspection of Farm A reveals that conditions and practices at the farm appear to be generally consistent with good agricultural practices and that management appears to be committed to food safety, as evidenced by company policy documents, standard operating procedures (SOPs), and the conditions and practices of the operation. Inspectors note that the farm has two water sources, a holding pond used for drip irrigation of tomatoes and a deep well for any water use in the field where water directly contacts the tomatoes and for post-harvest practices such as washing. Inspectors sample pond water and find it is positive for *Salmonella* and that the isolate matches the outbreak strain. Upon further investigation, several workers admit that, when things are busy, especially close to harvest, they mix crop protection sprays with pond water because the pond is more conveniently located than the well, even though the farm's SOP specifies that only well water should be used for activities where water has direct contact with tomatoes.

We, in conjunction with State and local (or, if applicable, foreign) officials, may provide education to Farm A to reinforce awareness of the importance of ensuring that water that contacts produce is safe and sanitary for its intended use, especially close to harvest, and of managing water quality and use to minimize the potential for contamination of food. We may ask the farm to correct its water management procedures to minimize the potential for future illnesses from contaminated agricultural water. The farm's corrective actions might include taking steps, such as, remedial training, enhanced oversight, and/or other procedural changes. If a recall occurred, we may also work with the farm on its recall of any implicated tomatoes that may still be on the market. If we find, during a future inspection, that the farm has instituted procedures to minimize the likely reoccurrence of the problem, we might not proceed to withdrawal of the qualified exemption. However, if we find, during a future inspection, that the farm has not voluntarily taken appropriate steps to correct the conditions or conduct that led to the outbreak, we may consider other actions, which could include withdrawal of the qualified exemption.

As another example, consider the situation where routine surveillance sampling results in positive sample findings for *Shigella* in or on green onions. A traceback investigation identifies the source of the green onions as Farm B, which grows, harvests, packs, and holds its own green onions. An inspection of Farm B reveals a number of conditions and conduct that are material to the safety of the food, specifically: The farm does not have a training program for worker health and hygiene, it has an inadequate number and servicing of portable toilets for the number of people living at the farm, and it does not have procedures for what to do in the event of leakage or spilling of portable toilets in the field or housing area. In addition, water used for all growing activities and for washing green onions is from a well that is located in a depression and is not adequately designed or constructed to protect it from surface contamination; the farm does not test the microbiological quality of the well water that contacts produce during growing or washing; the farm adds chlorine to wash water but does not appear to have adequate procedures to accurately measure the amount of chlorine added to wash water or to monitor the levels of free chlorine available to maintain water quality over time.

We may inform Farm B of our concerns, noting conditions that may contaminate their food. We may ask the farm to correct their procedures to minimize the potential for future illnesses from ill workers or contaminated water. If the farm did not respond to FDA with the corrections it will take as a result of our observations, or if we did not believe the actions were adequate or timely, we may issue a warning letter to the farm. (In the case of foreign farms, we may refuse produce offered for import into the United States.) If a recall occurred, we may also work with the farm on its recall of any implicated food that may still be on the market. We, in conjunction with our State, local (or, if applicable, foreign) counterparts may provide education to the farm to ensure awareness of the importance of managing hazards such as waste and sewage disposal, worker health and hygiene practices and ensuring water that contacts produce is safe and sanitary for its intended use to minimize the potential for contamination.

If, during a subsequent inspection, we find continued conditions or conduct that could result in unsafe food, we may decide that withdrawal of the exemption is necessary to protect the public health and prevent or mitigate a foodborne illness based on these conditions and conduct. As an alternative to withdrawal of the exemption, or in addition to it, we may seek an injunction to prevent the farm from producing adulterated food.

We are also proposing amendments to proposed § 112.201 to ensure that, before FDA issues an order to withdraw a farm's qualified exemption, the farm has the opportunity to respond to the problems identified by FDA, and for FDA to consider the farm's response prior to proceeding with issuance of an order to withdraw the exemption. This intermediate step prior to FDA issuing an order to withdraw the exemption would provide an additional opportunity for a farm to submit information relevant to circumstances that may lead FDA to withdraw the exemption (including, as appropriate, any corrective actions taken by the farm), and for FDA to consider this information in making a determination regarding whether or not to proceed with issuing an order to withdraw the exemption.

Therefore, proposed § 112.201(b) would also state that before FDA issues an order to withdraw your qualified exemption, FDA must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 10 calendar days of the date of the notification, to FDA's notification (proposed § 112.201(b)(2)); and FDA must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption (proposed § 112.201(b)(3)).

Finally, we are also proposing corresponding amendments to proposed § 112.202 under paragraphs (a) and (b) of that section. As amended, proposed § 112.202(a) would make it clear that before an order to withdraw a qualified exemption is issued, such order must be approved by an FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)), or an FDA official senior to such Director, must approve an

order to withdraw the exemption before the order is issued. In addition, as amended, proposed § 112.202(b) would establish that any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with proposed § 112.202(a).

We seek comment on our current thinking on this issue, including new proposed provisions §§ 112.201(b), 112.202(a), and 112.202(b).

2. Reinstatement of a Qualified Exemption That Is Withdrawn

In the previously published proposed rule, under subpart R of proposed part 112, we proposed to establish the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of proposed § 112.5. Our proposed procedures did not include provisions for reinstatement of a qualified exemption once it is withdrawn.

a. Relevant Comments. We received several comments requesting that FDA provide for a process that would allow qualified farms to regain their exempt status after corrective actions are taken. Some commenters noted that FDA has a history of providing opportunities for facilities to fix a problem identified by FDA prior to suspending a facility's registration or starting an enforcement action, and that FDA should provide the same opportunities to farms that have a qualified exemption to fix the problems leading to the order to withdraw the exemption. Conversely, at least one commenter argued that FSMA provides no authority for restoring a qualified farm's exempt status after its withdrawal, and opposed any changes to the procedures in subpart R to provide for reinstatement of the exemption once it is withdrawn.

b. FDA's Consideration of Comments. We are proposing certain amendments, including taking into account comments that recommended providing a process for restoring the qualified exemption that was withdrawn. We also considered legal arguments presented by the commenter that opposed reinstatement of a qualified exemption. We have tentatively concluded that the absence of a specific provision in FSMA for the reinstatement of a qualified exemption that was withdrawn does not preclude FDA from providing for such a process if FDA determines that continued withdrawal is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

Therefore, proposed § 112.213 would list the process under which FDA would reinstate a qualified exemption that was withdrawn. Specifically, this new provision would establish that if the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) determines that the farm has adequately resolved problems with the conduct or conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) shall, on his own initiative or at the request of a farm, reinstate the qualified exemption (proposed § 112.213(a)). FDA would then notify the owner, operator, or agent in charge of the farm of such reinstatement of the qualified exemption.

In addition, proposed § 112.213(b) would provide that a farm may request FDA to reinstate a qualified exemption that has been withdrawn under the procedures of subpart R using the following procedure: (1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) and (2) present, in writing, data and information to demonstrate that you have adequately resolved the problems with the conduct or conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

Under proposed § 112.213(c), we are proposing that if your qualified exemption is withdrawn under § 112.201(a)(1) (*i.e.,* in the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm), and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

Finally, under proposed § 112.213(d), we are proposing that if your qualified exemption is withdrawn under both § 112.201(a)(1) (i.e., in the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm) and § 112.01(a)(2) (*i.e.,* if we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm), and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of proposed § 112.213(b). Unlike under the provisions of proposed § 112.213(c) where FDA would on its own initiative reinstate the qualified exemption, under this proposed provision § 112.213(d) we are proposing that the owner, operator, or agent in charge of the farm submit a request (in accordance with proposed § 112.213(b)) to demonstrate that the problems with the conduct or conditions associated with the farm that formed the basis, in part, for the withdrawal have been adequately resolved and that these corrections will be maintained if the exemption is reinstated.

We seek comment on our tentative decision to provide for reinstatement of a qualified exemption that is withdrawn, the proposed circumstances under which FDA would reinstate the qualified exemption, and the proposed procedures for such reinstatement.

3. Summary of FDA's Revisions and Request for Comment

We are proposing to: (1) Add a new proposed provision § 112.201(b)(1) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction; (2) add new proposed provisions §§ 112.201(b)(2) and 112.201(b)(3) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA must notify the farm of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the farm to respond to FDA's notification; and that FDA must consider actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption; (3) make corresponding amendments to proposed §§ 112.202(a) and 112.202(b) to clarify the procedure for issuing an order to withdraw a qualified exemption; and (4) add a new proposed

provision § 112.213 to list the circumstances under which FDA would reinstate a farm's qualified exemption that is withdrawn.

We seek comment on our new and amended proposed provisions, including our tentative decision that we may consider other actions, as appropriate, and we must provide certain specified intermediate steps before issuing an order to withdraw a qualified exemption. We also seek comment on our tentative decision to provide for reinstatement of a qualified exemption that is withdrawn, the proposed circumstances under which FDA would reinstate the qualified exemption, and the proposed procedures for such reinstatement.

Finally, in the amendments to the Preventive Controls for Human Food proposed rule, we are proposing to amend the timeframe for a facility to comply with an order to withdraw an exemption from the previous proposed ''within 60 days of the date of the order'' to ''within 120 days of the date of receipt of the order'' (see section XIII.D. of that document). We seek comment on whether, similar to these amendments to proposed part 117, we should amend the relevant provisions in proposed part 112 (*i.e.,* proposed §§ 112.203(d), 112.204(a), 112.205(b)), which would require compliance within 60 calendar days of the date of the order, to require that a farm comply with an order to withdraw its qualified exemption within 120 days of the date of receipt of the order.

III. Preliminary Regulatory Impact Analysis

A. Overview

As explained in the Produce Safety proposed rule, FDA performed the necessary analyses to examine the impacts of the previously published proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA also provided the analyses for public input (78 FR 3504 at 3616).

We performed additional analyses to examine the impacts of the amended and new proposed provisions described in this document 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). The Agency believes that this proposed rule is a significant regulatory action as defined by Executive Order 12866. We present our additional analyses, including the total estimated costs and benefits of the Produce Safety proposed rule as amended (Ref. 41). We seek comment on our additional analyses.

B. Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA tentatively concludes that the proposed rule will have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) defines farms involved in crop production as ''small'' if their total revenue is less than $750,000 (Ref. 42). Approximately 95 percent of all farms that grow covered produce are considered small by the SBA definition.

The proposed rule reduces the burden on small entities in part through the use of exemptions: Certain small entities are eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (proposed § 112.5). The proposed rule additionally reduces the burden on small entities by not covering farms with $25,000 or less of average annual monetary value of produce sold (proposed § 112.4(a)).

The proposed rule additionally provides all farms flexibility for alternative practices to be used for certain listed requirements with adequate scientific support. The proposed rule also provides for States and foreign countries to submit a request for a variance for one or more requirements of the proposed rule. To be granted, the procedures, processes, and practices to be followed under the variance must be reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of the proposed rule.

Farms defined as small businesses have an additional 2 years to comply with most provisions of the rule after the effective date of FDA's final rule and farms defined as very small businesses have an additional 3 years. There is also an extended 2-year compliance period for certain proposed provisions for water quality in § 112.44 and related provisions in §§ 112.45 and 112.50 (specifically, §§ 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7)). The extended compliance dates for these specific water quality standards would then be 4 years from the effective date for small businesses and 5 years from the effective date for very small businesses.

For a more detailed description of the full regulatory flexibility options offered for this proposed rule, see the Preliminary Regulatory Impact Analysis (PRIA) (Ref. 43).

C. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement including 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 2012 Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this proposed rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on: Future costs; particular regions, communities, or industrial sectors; national productivity; economic growth; full employment; job creation; and exports.

The issues listed above are covered in detail in the cost benefit analysis of the preceding sections and in the PRIA (Ref. 43).

D. Small Business Regulatory Enforcement Fairness Act

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 U.S.-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.

IV. 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). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

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.

Title: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.

Description: Section 105 of the FDA Food Safety and Modernization Act requires that ''not later than 1 year after the date of enactment, . . . shall publish a notice of proposed rulemaking to establish 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 the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death . . .''

Description of Respondents: The proposed rule applies to farms that grow produce, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. There are 40,211 farms in the United States, the District of Columbia, and the Commonwealth of Puerto Rico, excluding sprouting operations (Ref. 44), that would be covered by the proposed rule. We estimate that there are approximately 285 sprouting operations covered by this proposed rule.

The information collection estimate for the produce safety proposed rule will change due to the number of farms that are affected by the requirements and the revised testing requirements for agricultural water. Table 2 provides the revised estimates of the recordkeeping burden associated with supplemental requirements. The information collection estimate for the produce safety proposed rule was 1,289,959 annual hours, when the number of covered farms was 40,211. Under this supplemental codified, the number of covered farms is 35,503. After accounting for the decreased recordkeeping burden due to the lower number of farms, and the increased average hourly burden due to new records that may accompany the relaxed requirement for water usage and application intervals after, we estimate that it will take farms a total of 1,197,369 hours to collect information under this supplemental notice. This represents an annual hourly savings of 92,590 hours and approximately $5.16 million. For full information on the calculation of all recordkeeping hourly burdens please refer to the original PRA (Ref. 43). Estimates of two new information collections are presented in Table 2: §§ 112.50(b)(8) and 112.50(b)(9).

Section 112.50(b)(8) of this supplemental notice requires scientific data or information farms rely on to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *E. coli,* in accordance with § 112.44(c)(2). Currently, no information is available to the Agency to estimate how many farms would choose to apply a post-harvest time interval that would require them to keep records to comply with § 112.50(b)(8). We do not expect this number to be zero annually, nor do we expect the number to be very large. We believe that farms are more likely to use the pre-harvest interval option offered in proposed § 112.44(c)(1), which would not require additional recordkeeping, where the farm applies the proposed microbial die-off rate to calculate an appropriate time interval. Based on our current understanding of operations in the produce industry, for the purposes of this analysis, it is estimated that, annually, 100 farms would choose to apply a post-harvest time interval as a result of this supplemental notice. We estimate that these farms will spend .33 hour (20 minutes) annually to obtain and maintain this documentation. Therefore, 100 records × .33 hour = 33 annual hours for farms to comply with this requirement. We acknowledge the uncertainty in these estimates. We request comment on the number of farms that would choose to apply a post-harvest time interval and the time needed to comply with this recordkeeping requirement.

Section 112.50(b)(9) of this supplemental notice requires scientific data or information you rely on to support your testing frequency for untreated surface water used for purposes that are subject to the requirements of § 112.44(a). No information is currently available that would allow us to estimate the number of farms that would be subject to this requirement. However, we expect that it would be extremely rare for a farm to use untreated surface water for activities, such as hand washing, that would be subject to the requirements of § 112.44(a). Therefore, for the purposes of this analysis, we estimate that one farm per year will engage in activity related to the requirement of § 112.50(b)(9) and that this farm will spend .33 hour (20 minutes) annually to obtain and maintain this documentation. Therefore, 1 record × .33 hour = .33 annual hours. We acknowledge the uncertainty in these estimates. We request comment on the number of farms that would use untreated surface water for purposes listed in § 112.44(a) (such as hand washing), and the time needed to comply with this recordkeeping requirement.

TABLE 2—NEW RECORDKEEPING HOURLY BURDENS

Documentation of Scientific Data to Support Time Interval Between Last Irrigation and End of Storage						
112.50(b)(8)	100	1	100	.33	33	$0
Documentation of Scientific Data to Support Testing Frequency for Untreated Surface Water Used for Purposes Subject to § 112.44(a)						
112.50(b)(9)	1	1	1	.33	.33	$0

V. Analysis of Environmental Impact

In publishing the Produce Safety proposed rule, we relied on a categorical exclusion from the need to prepare an EA or EIS under 21 CFR 25.30(j) (78 FR 3504 at 3616). However, as explained in the NOI, based on currently available information, including comments received, and upon further analysis, FDA has determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)), and therefore, an EIS is necessary for the final rule (78 FR 50358, August 19, 2013). Accordingly, FDA is in the process of preparing an EIS and, under that process, expects to provide a draft EIS for public comment prior to preparing a final EIS document and issuing the Record of Decision.

VI. Comments

Interested persons may submit either electronic comments regarding the specific issues identified for public comment in 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.*

VII. 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. These references are also available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

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List of Subjects in 21 CFR Part 112

Foods, Fruits and vegetables, Packaging and containers, Recordkeeping requirements, Safety.

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, as proposed to be added on January 16, 2013 (78 FR 3504), be further amended as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 112 continues to read as follows

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A—[Amended]

■ 2. In § 112.3, revise paragraphs (b)(1) and (b)(2) and in paragraph (c), revise the definitions for ''*Covered activity,*'' ''*Farm,*'' ''*Harvesting,*'' ''*Holding,*'' and ''*Packing*'' to read as follows:

§ 112.3 What definitions apply to this part?

* * * * *

(b) * * *

(1) *Very small business.* For the purpose of this part, your farm is a very small business if it is subject to this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $250,000.

(2) *Small business.* For the purpose of this part, your farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) * * *

* * * * *

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of ''farm'' as defined in this chapter. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

* * * * *

Farm means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes establishments that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a

distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on 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 a farm. 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) of the Federal Food, Drug, and Cosmetic 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 are examples of harvesting.

* * * * *

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), 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) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (*e.g.,* activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), 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) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 3. In § 112.4, revise the first sentence of paragraph (a) to read as follows:

§ 112.4 Who is subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a ''covered farm'' subject to this part.* * *

* * * * *

Subpart B—[Amended]

■ 4. Section 112.12, is amended by adding the phrase ''as provided in § 112.44(d) and'' at the end of paragraph (a)(1); by removing '';'' and adding it its place ''.'' at the end of paragraph (a)(2); and by removing paragraphs (a)(3) and (a)(4).

Subpart E—[Amended]

■ 5. Section 112.44, is amended by revising paragraphs (c) and (d) to read as follows:

§ 112.44 What testing is required for agricultural water, and what must I do based on the test results?

* * * * *

(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N to develop and verify the water quality profile of the water source as described in § 112.45(b)(1). Using your water quality profile as described in § 112.45(b)(1), if you find that (when applicable) the estimate of the statistical threshold value (STV) of samples exceeds 410 colony forming units (CFU) of generic *E. coli* per 100 mL of water, or if you find that the geometric mean (GM) of samples exceeds 126 CFU of generic *E. coli* per 100 mL of water (or an alternative microbial standard consistent with paragraph (d)(1) of this section), you must either:

(1) Apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (or an alternative microbial die-off rate consistent with paragraph (d)(2) of this section) to achieve a (calculated) log reduction of your geometric mean of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL, or an alternative microbial standard consistent with paragraph (d)(1) of this section;

(2) Apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your geometric mean of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL (or an alternative microbial standard consistent with paragraph (d)(1) of this section), provided you have adequate supporting scientific data and information. You may apply this time interval in addition to the time interval in accordance with paragraph (c)(1) of this section; or

(3) If options (c)(1) or (c)(2) are not selected, immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either reinspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

(d) You may establish and use alternatives to the following requirements provided you satisfy the requirements of § 112.12:

(1) Microbial quality standard established in paragraph (c) of this section; and

(2) Microbial die-off rate established in paragraph (c)(1) of this section that is used to determine the time interval between last irrigation and harvest.

■ 6. Section 112.45, is revised to read as follows:

§ 112.45 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

(1) You receive water from a public water system, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water

supply program, and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(c), you must take the following steps for each source of the untreated surface water:

(1) Conduct a baseline survey to develop a water quality profile of the agricultural water source.

(i) You must conduct a baseline survey in order to initially develop the water quality profile of your water source. You must determine the appropriate way(s) in which the water may be used based on your water quality profile in accordance with § 112.44(c)(1) through (3).

(ii) The baseline survey must be conducted over a minimum period of 2 years by calculating the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli* (*E. coli)* (colony forming units (CFU) per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. The water quality profile initially consists of the GM and STV of generic *E. coli* calculated using this data set.

(iii) You must develop a new water quality profile:

(A) At least once every 10 years by recalculating the GM and STV values using a minimum total of 20 samples collected during your most recent annual surveys (which are required under paragraph (b)(2) of this section); and

(B) When required under paragraphs (b)(2) and (b)(3) of this section.

(2) Conduct an annual survey to verify the water quality profile of your agricultural water.

(i) After the baseline survey described in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, you must test the water annually to verify your existing water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest.

(ii) If the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile and, as appropriate, modify your water use based on the new water quality profile in accordance with § 112.44(c)(1) through (3) as soon as practical and no later than the following year. To develop a new water quality profile, you must calculate new GM and STV values using either:

(A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or

(B) Your current annual survey data, combined with new data, to make up a dataset of at least 20 samples; and

(3) If you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in paragraph (b)(2) of this section (for example, if there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the quality of your water source), you must develop a new water quality profile. To develop a new water quality profile, you must calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you must modify your water use based on the new water quality profile as soon as practical and no later than the following year.

(c) If you use untreated ground water for purposes that are subject to the requirements of § 112.44, you must test the quality of each source of the water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected during a time period(s) as close as practical to harvest. If the samples tested meet the applicable microbial standard of § 112.44 (*i.e.,* no detectable generic *E. coli* per 100 mL under 112.44(a) or a geometric mean of generic *E. coli* of 126 CFU or less per 100 mL under 112.44(c), as applicable), you may test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. You must resume testing at least four times per growing season or year if any annual test fails to meet the applicable microbial standard in § 112.44.

(d) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard. You must have adequate scientific data or information to support your testing frequency.

(e) You may meet the requirements related to agricultural water testing required under paragraphs (b), (c), and (d) of this section using:

(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

■ 7. Section 112.50, is amended by adding new paragraphs (b)(8) and (b)(9) to read as follows:

§ 112.50 Under this subpart, what requirements apply regarding records?

* * * * *

(b) * * *

(8) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that is used to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *E.coli* in accordance with the provision in § 112.44(c)(2); and

(9) Scientific data or information you rely on to support your testing frequency for untreated surface water used for purposes that are subject to the requirements of § 112.44(a).

Subpart F—[Amended]

■ 8. Section 112.56 is amended by removing from paragraph (a)(1)(i) the phrase ''9 months'' and adding in its place the phrase ''Reserved''; removing from paragraph (a)(4)(i) the phrase ''45 days'' and adding in its place the phrase ''0 days''; and removing and reserving paragraph (b).

■ 9. Section 112.60 is amended by removing paragraphs (b)(1) and (b)(5) and redesignating paragraphs (b)(2), (b)(3), and (b)(4) as paragraphs (b)(1), (b)(2), and (b)(3), respectively.

Subpart I—[Amended]

■ 10. Add § 112.84 to read as follows:

§ 112.84 Does this regulation require covered farms to take actions that would constitute a ''taking'' of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the ''taking'' of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (*i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart P—[Amended]

■ 11. Section 112.182, is amended by removing '';'' and adding in its place ''.'' at the end of paragraph (c) and removing paragraphs (d) and (e).

Subpart R—[Amended]

■ 12. Section § 112.201, is revised to read as follows:

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw your qualified exemption under § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:

(1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 10 calendar days of the date of the notification, to FDA's notification; and

(3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

■ 13. Section 112.202 is revised to read as follows:

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(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.

■ 14. Add § 112.213 to read as follows:

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) shall, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved the problems with the conduct or conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–22447 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P