

potential agenda topics that your tribe would like to see addressed at the conference. EPA will forward all suggestions to the selected tribal host. EPA also encourages you to attend the conference regardless of whether you are interested in hosting the event.

#### List of Subjects

Environmental protection, Indian tribes.

Dated: April 16, 2003.

**Stephen L. Johnson,**

*Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*

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#### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0231; FRL-7293-6]

RIN 2070-AD36

#### Pesticides; Emergency Exemption Process Revisions Pilot and Request for Comment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to issue emergency exemptions to States and Federal agencies, allowing them to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. EPA is announcing and seeking comment on a limited pilot program initiated by this Notice. The pilot is limited to exemption applications for which the requested chemical is a pesticide previously identified by EPA as a reduced-risk pesticide. Under this limited pilot, EPA will allow applicants for certain exemptions to re-certify that the emergency conditions which initially qualified for an exemption continue to exist in the second and third years, and will allow for a new tiered approach to be used for documenting a "significant economic loss." This limited pilot is the result of extensive stakeholder involvement and an effort to streamline the emergency exemption process. EPA is also seeking comment on another potential improvement to the emergency exemption program that would provide exemptions for certain pest resistance management purposes. EPA is considering these improvements to the emergency exemption program in an effort to reduce the burden to both applicants and EPA, allow for quicker

decisions by the Agency, and facilitate resistance management, while maintaining health and safety requirements. EPA currently intends to publish a proposed rule in 2003 that will propose several potential improvements to the emergency exemption regulations. EPA will consider any available information from this pilot as it proceeds with rulemaking.

**DATES:** Comments, identified by the Docket ID No. OPP-2002-0231, must be received on or before June 23, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION** section.

#### FOR FURTHER INFORMATION CONTACT:

Joseph Hogue, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-9072; fax number: 703-305-5884; e-mail address: [hogue.joe@epa.gov](mailto:hogue.joe@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a Federal, State, or Territorial government agency that petitions EPA for section 18 use authorization. Regulated categories and entities may include, but are not limited to:

- Federal Government (NAICS Code 9241), *i.e.*, Federal agencies that petition EPA for section 18 use authorization.
- State or Territorial governments (NAICS Code 9241), *i.e.*, States, as defined in FIFRA section 2(aa), that petition EPA for section 18 use authorization.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed above could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the summary of the applicability provisions as found in Unit III.B. of this Notice. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed in the **FOR FURTHER INFORMATION CONTACT** section.

##### B. How Can I Get Copies of this Notice and Other Related Information?

1. **Docket.** EPA has established an official public docket for this action under Docket ID No. OPP-2002-0231. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 703-305-5805.

2. **Electronic access.** You may access this **Federal Register** Notice electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA

intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

#### *C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the

comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in Docket ID No. OPP-2002-0231. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention Docket ID No. OPP-2002-0231. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Mail Code: 7502C, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OPP-2002-0231.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm.

119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, Attention Docket ID No. OPP-2002-0231. Such deliveries are only accepted during the Docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

## **II. Purpose of this Notice**

This Notice announces the implementation of and seeks public comment on a limited pilot starting with the 2003 growing season. The pilot involves two potential process improvements to the emergency exemption program that are the result of an effort to streamline the emergency exemption process. EPA is taking this action after extensive stakeholder involvement (see Unit IV.). The pilot is limited to exemption applications for which the requested chemical is a pesticide previously identified by EPA as a reduced-risk pesticide. Under the limited pilot, EPA will allow applicants for certain exemptions to re-certify (and incorporate a previous application's information by reference) that the emergency conditions which initially qualified for an exemption continue to exist in the second and third years, and will allow for a new tiered approach to be used for documenting a "significant economic loss." EPA is also seeking

comment on another potential change being considered for the emergency exemption program, *i.e.*, whether to allow exemptions for pest resistance management purposes.

EPA is considering these improvements to the emergency exemption program regulations in 40 CFR part 166 in an effort to reduce the burden to both applicants and EPA, allow for quicker decisions by the Agency, and facilitate pest resistance management, while maintaining health and safety requirements. EPA currently intends to publish a proposed rule in 2003 that will propose several potential improvements to the emergency exemption regulations. EPA will consider any available information from this pilot as it proceeds with rulemaking.

The potential revisions to the emergency exemption process described in this Notice arose from an effort to evaluate the emergency exemption regulations at 40 CFR part 166, begun in 1995. As part of that effort, in November 1996, the Agency hosted a Section 18 Stakeholders Workshop to discuss possible improvements to the Agency's emergency exemption process and receive stakeholder input. The improvements discussed at the workshop, and those included in this Notice, directly affect only applicants for emergency exemptions. States are the primary applicants for emergency exemptions, although Federal agencies may also apply.

Recommendations from the Association of American Pest Control Officials (AAPCO) Section 18 Task Force, representing the States, are the general basis for EPA's plan announced by this Notice. AAPCO originally provided EPA with recommendations following the 1996 workshop and recently submitted a revised, shortened list of three recommendations. This Notice begins to address those three recommendations. EPA has carefully refined each recommendation in an effort to address concerns expressed by other stakeholders. In refining those recommendations, the Agency attempted to maximize the streamlining benefits while making sure it can still carry out its health and safety responsibilities. A discussion of the evaluation process leading up to this Notice, including stakeholder input and recommendations, is in Unit IV.

After receiving comment on this Notice or near the end of the first year under the pilot, EPA plans to again consult the Pesticide Program Dialogue Committee (PPDC) on the potential improvements discussed in this Notice. At that time, the Agency, applicants for

emergency exemptions, and many others will be able to share and discuss their experiences concerning the pilot provisions. The diverse group of stakeholders represented at PPDC meetings provides an excellent source of feedback to the Agency. Input from the PPDC will be carefully considered, along with public comments received in response to this Notice, public comments on the proposed rule expected in 2003, and experience from the pilot, when deciding what will be included in the final rule.

The following is a summary of the statutory and regulatory framework of the Emergency Exemption Program, a description of the extensive stakeholder involvement that forms the basis for the limited pilot and this request for comment, a detailed description of the limited pilot, and the Agency's request for comment.

### III. Existing Statutory and Regulatory Framework

#### A. Statutory Provisions--FIFRA Section 18

Section 18 of FIFRA gives the Administrator of EPA broad authority to exempt any Federal or State agency from any provision of FIFRA if the Administrator determines that emergency conditions exist which require such exemption.

#### B. Regulatory Provisions--40 CFR Part 166

Regulations governing such FIFRA section 18 emergency exemptions are codified in 40 CFR part 166. Generally, these regulations allow a Federal or State agency to apply for an exemption to allow a use of a pesticide that is not registered when such use is necessary to alleviate an emergency condition. A State, as defined by FIFRA section 2(aa), means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands and American Samoa. The regulations set forth information requirements, procedures, and standards for EPA's approval or denial of such exemptions.

Federal and State agencies may apply to EPA for a section 18 emergency exemption from FIFRA due to a public health emergency, a quarantine emergency, or a "specific" emergency. Most exemptions from FIFRA requested or granted under section 18 fall under the category of "specific exemptions." Typical justifications for specific exemptions include, but are not limited to, the expansion of the range of a pest; the cancellation or removal from the market of a previously registered and

effective pesticide product; and the development of resistance in pests to a registered product, or loss of efficacy of available products for any reason. Additionally, an emergency situation is generally considered to exist when no other viable (chemical or non-chemical) means of control exist, and where the emergency situation will cause significant economic losses to affected individuals if the exemption is not granted.

When a Federal or State agency applies to EPA under section 18, it must submit a request in writing that documents the emergency situation, the pesticide proposed for the use, the target pest, the crop, the rate and number of applications to be made, the geographical region where the pesticide would be applied, and a discussion of risks which may be posed to human health or to the environment as a result of the pesticide use (40 CFR 166.20). EPA conducts an expedited review of the request, verifying the existence of the emergency, assessing risks posed to human health through food, drinking water, and residential exposure, assessing risks posed to farmworkers and other handlers of the pesticide, assessing any adverse effects on non-target organisms (including Federally listed endangered species), and assessing the potential for contamination of ground water and surface water. If an application for the requested use has been made in previous years, EPA does an assessment of the progress toward registration for the use of the requested chemical on the requested crop, and considers this status in the final determination to grant or deny the exemption. If EPA concludes that the situation is an emergency, and that the use of the pesticide under the exemption will be consistent with the standards of the Food Quality Protection Act (FQPA) and 40 CFR part 166, then EPA may authorize the pesticide to be used under section 18.

Section 18 pesticide uses for specific and public health exemptions can be authorized for periods not to exceed 1 year; uses under quarantine exemptions can be authorized for up to 3 years. Since actions taken under section 18 are intended to address a time-specific crisis or emergency need for temporary relief, most section 18 exemptions are specific exemptions which are granted for just one growing season. Such actions should not, therefore, be viewed as an alternative to registering the use(s) needed for longer periods. If the situation addressed with the section 18 exemption persists, or is expected to persist, affected entities must take the proper steps to amend the existing

registration or seek a new registration to address that future need.

#### **IV. Background and Summary of Stakeholder Feedback**

##### *A. 1996 Section 18 Workshop to Streamline Emergency Exemption Process*

In 1995, as part of an effort to streamline regulations, the Agency began a process to evaluate the emergency exemption regulations at 40 CFR part 166, and to formulate recommended changes to the operating procedures. As part of that effort, in November 1996, the Agency hosted a Section 18 Stakeholders Workshop to discuss possible regulatory changes to the Agency's section 18 process and receive stakeholder input. Participants of that meeting included representatives from State agencies responsible for pesticide oversight, chemical companies, and environmental and public interest groups. Participants voiced their concerns and identified suggestions for improving the emergency exemption process.

Although EPA scheduled the section 18 workshop prior to passage of the FQPA, in August 1996, the workshop was held shortly after the law was enacted. Because FQPA included new requirements affecting emergency exemptions, and was just 3 months old at the time of the workshop, the new law was of great interest to participants. Stakeholders at the workshop were deeply concerned that the new requirements of FQPA would hurt both the Agency's review time and approval rate for exemption requests, as well as increase the burden on applicants (primarily States) for information and documentation. Several of the recommendations raised in the workshop addressed these three concerns.

##### *B. NASDA/AAPCO Initial Recommendations to EPA for Improvements*

Subsequent to the November 1996 Section 18 Stakeholders Workshop, the National Association of State Departments of Agriculture (NASDA) and the Association of American Pest Control Officials (AAPCO) jointly sent a letter to EPA to provide recommendations for changes to the emergency exemption process. The letter referred to recommendations contained in a series of NASDA Proposed Resolutions. A copy of that letter and the Proposed Resolutions are available in the public docket for this Notice. The NASDA/AAPCO recommendations, which generally

summarized issues raised at the workshop, were:

1. Seek changes to current regulations which will allow EPA the flexibility to base decisions on crop yield as opposed to crop value (or profit loss) in situations where that is a better indicator of pest damage.

2. Provide States general guidance regarding the appropriate documentation of an "urgent, non-routine situation" and allow States to certify that the "urgent, non-routine situation" exists based on the guidance.

3. Implement a performance audit program to ensure compliance with the guidance and give States justification to resist pressure to certify an "urgent, non-routine situation" when it does not exist.

4. Delegate to the States authority to reissue the section 18 exemption for a second or third year, based on the State's confirmation/certification that the basis for an emergency continues to exist.

5. Actively support and coordinate regional section 18 requests.

6. Enter into discussions with the States to establish reasonable monitoring criteria and approaches for wildlife and endangered species.

7. Support specific exemptions for resistance management where there is documented scientific evidence of resistance to currently registered pesticides or where valid research demonstrates that a dynamic process of resistance is developing.

8. Amend 40 CFR 166.2 to include "reduced risk" as an acceptable basis for granting a section 18 exemption. The definition of "reduced risk," and the requirements for this request should allow States the ability to request a section 18 to allow for a pesticide use that will result in a lower potential for an adverse impact on human health or any other non-target species, including but not limited to, pest predators, pollinators, endangered species, and other organisms of special concern. Requests should be limited to only those situations where the "reduced risk" request will not result in additional risk to any aspect of the environment. Such requests should only be permitted where the proposed use is highly effective so that the potential for an increase in pesticide applications is extremely low.

The NASDA Proposed Resolutions also included recommendations concerning the establishment of time-limited tolerances for residues in food of pesticides used under emergency exemptions. Tolerances for pesticide uses under section 18 have already been addressed separately by EPA, as FQPA

required that the Agency publish a regulation to put in place a process for that purpose. Therefore, the NASDA/AAPCO recommendations concerning tolerances are not included in this discussion.

##### *C. The Food Quality Protection Act and Evolution of the Emergency Exemption Program*

FQPA included new requirements affecting emergency exemptions, as stated above. FQPA set a new safety standard, and, for the first time required time-limited tolerances for pesticide residues in food resulting from pesticide use under emergency exemptions. As a result of FQPA, each emergency exemption request must be evaluated based on the potential risk to human health and the environment, including the aggregate risk to the public from ingestion of treated food, pesticide residues in drinking water, and exposure to the pesticide in and around the home and other non-occupational settings.

Processing time for emergency exemption requests (days from receipt of request to decision) increased significantly in 1997, the first year after FQPA, as EPA developed methodology to implement section 18 under the new law. Due to the urgent nature of emergency exemption requests, the Agency worked very hard to streamline the process. Average processing time decreased to pre-FQPA rates in 1998, and has decreased each year since then. The average processing time for exemption requests reached an all-time low of 44 days in 2000, for the first time surpassing the Agency's goal of 50 days, and decreased again to 34 days in 2001.

The approval rate for exemption requests is similar to pre-FQPA levels. The number of exemption requests has increased sharply since 1996, as have the number of exemptions granted. EPA believes the burden on applicants to request any individual emergency exemption has not increased since the recommendations were made, and in some cases it has decreased. The Agency has worked hard to be flexible with applicants, to make full use of existing data, and to minimize documentation requirements where appropriate, with particular attention to issues raised in the NASDA/AAPCO recommendations. Although FQPA did not appreciably increase applicant burden in preparing any specific emergency exemption request, the Agency is always interested in improving and streamlining its processes.

#### *D. Stakeholder Feedback and EPA Response Since Workshop and Initial Recommendations*

Since the Section 18 Stakeholders Workshop in 1996 and receipt of the NASDA/AAPCO recommendations, EPA has worked closely with stakeholders to develop the best approach to address the recommendations. Adoption of any of the recommendations would primarily affect applicants for emergency exemptions. Because only States, U.S. territories, and Federal agencies can apply for emergency exemptions, EPA has had the rare opportunity to work very closely with a large percentage of the parties affected by a procedural change to gain valuable, ongoing feedback during the effort to develop the potential improvements discussed in this Notice.

After the initial NASDA/AAPCO recommendations were submitted, a workgroup consisting of EPA staff and several representatives of State agencies responsible for pesticide oversight met regularly to develop specific options to address each of the recommendations. During this time and subsequently, the Agency looked for ways to improve the process and further expedite decisions on requests. EPA reviewed the NASDA/AAPCO recommendations, and the options developed by the workgroup, to determine what could be accomplished through non-regulatory internal process improvements. These efforts paid off in repeatedly shortened average review times for emergency exemption requests.

Due to the significant improvements in the emergency exemption process and program during the several years following the original NASDA/AAPCO recommendations, the needs of the States changed. The AAPCO Section 18 Task Force has reviewed the past set of recommendations and recently provided updated, final State recommendations for improving the emergency exemption program (see Unit IV.E.). Each of the original eight recommendations has either been intentionally excluded by AAPCO in their final three recommendations, or is being addressed in this Notice. AAPCO's letter with the final recommendations acknowledged that, based on several years of experience with the section 18 process under FQPA, they no longer suggested that EPA pursue the other initial recommendations. The initial recommendations numbered 1, 4, and 7 (see Unit IV.B.) are addressed in this Notice. The second and third of the initial recommendations were designed to be implemented together, and were

essentially another option for the fourth, which AAPCO ultimately favored. EPA does encourage and help to coordinate regional emergency exemption requests involving multiple States, which was the fifth recommendation. Concerning recommendation number six, EPA is continuing to work with States to develop monitoring criteria for wildlife and endangered species in the context of pesticide registration. While the eighth recommendation, to allow exemptions based on reduced risk, has not been adopted, EPA does take reduced risk benefits into account as a factor in decisions.

EPA also solicited public comments on the original NASDA/AAPCO recommendations to improve the emergency exemption process, in the preamble to the proposed rule titled "Tolerances for Pesticide Emergency Exemptions" (64 FR 29823, June 3, 1999) (FRL-5750-1). The Agency only received comments on the listed recommendations from four parties. Two of the commenters were State departments of agriculture. Both States generally agreed with all the recommendations, but in particular supported the three revisions addressed in this Notice. One State offered refinements to several of the recommendations.

The other two commenters were public interest groups. Both groups opposed all of the recommendations. However, EPA believes that the operational revisions to the process being piloted have been refined in such a way as to address most of the concerns stated in their comments. One group noted that the current emergency exemption regulations are the result of negotiated rulemaking, a process which included a balanced representation of interests, but that the Section 18 Stakeholders Workshop, which culminated in the NASDA/AAPCO recommendations was not an adequately open process. EPA believes the workshop included participants from a wide array of interests, as representatives from State agencies responsible for pesticide oversight, chemical companies, and environmental and public interest groups attended. Also, the Agency's plan to undertake notice-and-comment rulemaking procedures before adopting any final changes to the section 18 process will again allow all interested parties to participate in the development of the potential changes.

In May 2002, EPA presented its general plan concerning the three revisions to the emergency exemption process included in this Notice to the PPDC. The PPDC provides a forum for

a diverse group of stakeholders to provide feedback to EPA on various pesticide regulatory, policy, and program implementation issues. A wide array of stakeholders provided comments at the May meeting, which EPA has considered in refining the pilot and proposed revisions in this Notice. A transcript of the presentation and discussion at the May PPDC meeting is in the public docket for this Notice.

#### *E. Final Recommendations by AAPCO Section 18 Task Force*

AAPCO provided EPA with their updated recommendations for improving the emergency exemption process:

##### *1. Multi-year section 18 exemptions.*

EPA should delegate authority to the States to reissue section 18 exemptions for a second or third year, based on the State's confirmation that the basis for an emergency situation continues to exist.

##### *2. Resistance management.*

EPA should support specific exemptions for pest resistance management where there is documented scientific evidence of resistance to currently registered pesticides or where valid research demonstrates that resistance is developing.

##### *3. Criteria for significant economic loss.*

EPA should base decisions on crop yield rather than crop value (or profit loss) in situations where crop yield is a better indicator of pest damage.

These are three of the eight recommendations originally submitted to the Agency in 1997. These updated recommendations were provided to EPA by AAPCO, verbally at the May 2002 PPDC meeting, and again in a letter in September 2002, from the president of AAPCO. A copy of that letter is available in the public docket for this Notice. The three potential revisions discussed in this Notice would essentially address these three recommendations, albeit with modifications based on input from other stakeholders. Each of the initial eight recommendations has either been dropped by AAPCO in their final recommendations, or is being addressed in this Notice.

#### **V. Limited Pilot of Potential Process Improvements Beginning with the 2003 Growing Season**

This limited pilot was developed after long and careful consideration of input by stakeholders. EPA believes that the changes being piloted will significantly benefit both applicants for pesticide emergency exemptions and the Agency. These benefits are expected to accrue without any increase in risk to human health or the environment. The pilot

will also provide valuable information that will aid the Agency in developing and completing regulatory revisions related to these process improvements, which the Agency currently expects to propose in 2003.

*A. Which Emergency Exemptions will be Included in the Pilot?*

The pilot will be limited to emergency exemption applications for which the requested product is a pesticide previously identified by EPA as a reduced-risk pesticide, as discussed below. The pilot will only involve specific exemptions, and does not affect public health or quarantine exemptions. The pilot will begin with emergency exemptions for the 2003 growing season. As such, EPA will consider the two process improvements when it reviews eligible applications for emergency exemption for the 2003 growing season, including those applications that are currently pending final decision on and any applications received after April 16, 2003. The Agency recognizes that those applications currently under review by EPA that are eligible for the pilot, are not likely to include information that addresses the two improvements described in this Notice. In such cases, the Agency intends to work with the applicants to apply the pilot provisions where appropriate and desired by the applicant. It should be noted that at no time during the pilot is any applicant required to use the pilot provisions, even if eligible. Any applicant which chooses to forgo the pilot and use the established application process may do so.

EPA chose to focus the pilot on reduced-risk pesticides, a specific set of pesticide products which includes conventional pesticides which were registered under EPA's Reduced-Risk Pesticide Initiative, plus biological pesticides registered through the Biopesticides and Pollution Prevention Division (BPPD). The goal of the Reduced-Risk Pesticide Initiative and BPPD is to encourage the development, registration, and use of lower-risk pesticide products which would result in reduced risks to human health and the environment when compared to existing alternatives. A detailed description of reduced-risk pesticides may be found in Pesticide Regulation Notice 97-3, which is available in the public docket for this Notice. The reduced-risk determination for conventional pesticides is made by EPA for each use of a pesticide, particularly when compared to existing registered alternatives for that use. However, for use in implementation of the revised

practices under the pilot in this Notice, any active ingredient which is contained in at least one product registered under the Reduced-Risk Initiative, plus any biological pesticide, will be considered a reduced-risk active ingredient. Any product containing one or more of these active ingredients and no others will be eligible, while any product containing any other active ingredient will not be eligible for exemption under the pilot.

EPA has prepared a list of all reduced-risk active ingredients, as defined above, so that applicants and others may easily determine which emergency exemption requests may be eligible for consideration under the pilot for the revised approach for documentation of significant economic loss. The new economic loss approach under the pilot may be applied to any exemption request for a reduced-risk pesticide on this list. However, in order for exemptions to be eligible for re-certification of an emergency under the pilot, in addition to the restriction to reduced-risk pesticides, they must also meet the other criteria for candidacy for re-certification set forth in Unit V.B.1. Therefore, the Agency has prepared a second list of existing (*i.e.*, granted for use in 2002) exemptions that are eligible for re-certification. EPA has also prepared a guidance document for implementation of the revised practices under the pilot, which is intended to further aid applicants in preparing applications. The two lists for determining eligibility of exemptions under the pilot are appendices to the guidance document, which will be sent to the States and included in the public docket for this Notice.

*B. What Process Improvements are Being Piloted?*

Two potential improvements to the emergency exemption program will be tested through this limited pilot.

1. *Re-certification of emergency condition by applicants*—i. *What is our current practice?* EPA authorizes emergency exemptions (except quarantine exemptions) for no longer than 1 year. However, depending on the nature of the non-routine condition which caused the emergency, some exemptions may subsequently be granted again, 1 year at a time. Currently, EPA conducts a full review of an application for the first year of an exemption, to determine whether an emergency condition exists, to ensure the use will not result in unreasonable adverse effects to man or the environment, and, if the use will result in pesticide residues in food or feed, to make a safety finding consistent with

section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Applicants may submit an application for a subsequent year, in which case the Agency must again confirm the emergency condition and acceptability of the risk. For requests after the first year, the applicant again submits information to support the emergency finding, and EPA reevaluates the situation to determine, relative to the first year, whether: (1) The emergency condition has changed; (2) any alternative products have been newly registered for the use, or other effective pest control techniques are now available; (3) any changes have occurred in the status of the chemical's risk assessment; and (4) the requested use pattern has changed.

ii. *How will re-certification work under the pilot?* The first potential improvement that is part of the pilot will allow applicants for certain exemptions to re-certify in the application that the emergency conditions which initially qualified for an exemption continue to exist in the second and third years. Under the pilot, this re-certification by the applicant will serve as the basis for EPA's determination that an emergency condition continues to exist. An acceptable application which re-certifies the emergency will incorporate by reference all information submitted in a previous application or applications to document the initial emergency condition for which an exemption was granted previously. Eligible applications in years two and three may consist only of applicants' re-certification of the emergency condition, incorporation by reference of supporting materials, and specification of the pesticide application practices that growers would observe. Applicants would not need to submit new documentation that the emergency condition continues or the additional data elements generally required under 40 CFR 166.20.

EPA will apply specific criteria to determine whether an exemption request will be eligible for re-certification of the emergency condition by the applicant. All of the following criteria need to apply in order for EPA to consider an exemption as a candidate for re-certification of an emergency under the pilot:

1. EPA granted the same exemption the previous year, and it is the second or third year of the request by that applicant. The Agency determined that the situation the previous year satisfied requirements for an emergency condition (40 CFR 166.3(d)). A complete application will be required the first year of an exemption for a particular

applicant, in order to establish the existence of the emergency. Re-certifications will not be accepted as the basis for an emergency after 3 years of an exemption to an applicant.

2. The emergency situation can reasonably be expected to continue for longer than 1 year. Examples of these include situations where a registered product relied upon by growers becomes permanently unavailable; expansion of a pest's range; and, documented loss of efficacy of a registered product. Situations which would not be expected to continue would include a temporary supply problem of a registered product; an isolated weather event; and a sporadic pest outbreak.

3. The exemption is not for a new chemical, a first food use, or for a chemical under Special Review. An exemption that is for a product containing an active ingredient which has never been contained in a product registered as a pesticide under section 3 of FIFRA, or has never been registered for a food use, has officially been placed under Special Review by the Agency, or has been the subject of a Notice of Intent to Cancel under FIFRA section 6, would not be considered for candidacy for re-certification of the emergency.

4. The requested pesticide is registered for another use and has been designated as "reduced-risk" by EPA for one or more uses. The reduced risk program is explained in PR Notice 97-3. This program offers pesticide manufacturers incentives for developing registration applications for pesticides which are less risky than the alternatives for a given pest problem. A committee of EPA scientists evaluates and selects pesticides and uses which are considered to be reduced risk.

Under the pilot, EPA will accept re-certifications of emergency conditions for exemptions which satisfy the eligibility criteria described above. It may not be clear to applicants whether some exemptions are eligible for re-certification. Since eligibility determinations must be made by the Agency, EPA has developed a list of emergency exemptions granted for use in 2002 that appear to be candidates for re-certification for the 2003 growing season. This list (included in the guidance document available in the public docket) is intended to help avoid an applicant's assumption that an exemption is eligible for re-certification of the emergency, when in fact it is not. EPA will attempt to include all appropriate candidates on this list. However, applicants may contact the Agency to request an eligibility determination for exemptions they

believe satisfy the criteria but which are not on the list.

For applications which are eligible and include a proper re-certification of the emergency condition, EPA will continue to assess whether the requested use poses a risk to human health or the environment that exceeds statutory and regulatory standards. If the risks posed by the requested use are determined to be unacceptable, the exemption request will be denied. However, when the emergency condition and requested use in an eligible year are the same as in the initial year of the exemption, EPA will only re-evaluate the situation to determine, relative to the first year, whether: (1) Any alternative products have been newly registered for the use; (2) any changes have occurred in the status of the chemical's risk assessment; and (3) the requested use pattern has changed. If an effective product has been registered for the requested use since the previous exemption was granted, then an emergency condition no longer exists. If the Agency has received new risk information since granting the previous exemption, then the risk will be re-evaluated. Likewise, if the request includes any change in the use pattern which may increase exposure (application rate, number of applications, type of application, pre-harvest interval, re-entry interval, total number of acres, and all other directions for use) then the risk will also be re-evaluated.

For eligible requests with applicant certification of a continuing emergency, if the three remaining review factors (product registrations, risk assessment status, and requested use pattern) have not changed, the Agency's review time is expected to be significantly reduced. In such cases, applicants are expected to benefit by expedited decisions, in addition to the reduced burden due to the certification of the emergency. Applicants will be permitted to modify the use pattern for the emergency program in an application in which they re-certify the emergency. However, EPA will need to determine whether, and how, such changes impact exposure and risk to human health or the environment. Therefore, these changes may undercut the ability of applicants to receive an expedited Agency decision. If the use pattern is the same as in the first year, applicants may include a separate certification that their requested use pattern has not changed in the re-certification year, and incorporate by reference all use pattern specifications submitted in a previous application or applications. This certification of an unchanged use

pattern will aid in expediting the Agency's decision.

If the Agency determines that there has been insufficient progress towards registration of the requested chemical on the requested crop, a request could be denied, consistent with current regulations and practice, regardless of eligibility for re-certification. Progress toward registration is determined for a pesticide-crop combination, whereas the year-count (first, second, third, etc.) in the eligibility cycle for re-certification would be determined separately for each applicant, and could often differ among applicants in a given year. Lack of progress towards registration would generally not cause denials during the first 3 years of exemptions for a chemical-crop combination. However, since some applicants may apply for the first time, in a year subsequent to the first request for a chemical-crop combination by another applicant, lack of progress towards registration could potentially interrupt the eligibility cycle for some applicants.

EPA is sensitive to emergency exemption requests being repeated for a number of years and requires that steps be taken to obtain a registration for the emergency use. Under this pilot for re-certifiable emergencies, EPA will not allow re-certification of emergencies for exemptions that have been granted for more than 3 years.

iii. *Why pilot this potential improvement?* Allowing applicants to re-certify the existence of an ongoing emergency condition for certain eligible exemption requests is expected to reduce the burden to both applicants and EPA as well as allow for quicker decisions. When an applicant certifies the continuation of the emergency condition and incorporates previously submitted materials by reference, a complete new application sufficient to characterize the situation in accordance with 40 CFR 166.20 will not be required. This will save applicants time and effort in gathering data and preparing their submissions. The Agency will save time and resources by not having to annually repeat the analyses that support the applicable requests. If no pesticides which can avert the emergency have been newly registered, and nothing has changed to affect the assessment of risk, then re-certification of an emergency will lead to significantly shorter Agency review, saving valuable time for those affected by the emergency.

EPA's experience indicates that emergency situations which continue after the initial year generally cause comparable losses in succeeding years. Therefore, with the certification of a



continuing emergency, the economic data and other supporting information required by 40 CFR part 166 would be unnecessary.

The limited focus of the pilot on reduced-risk pesticides will significantly reduce the number of exemptions potentially affected under the pilot. Nevertheless, the Agency expects the pilot to provide valuable experience. Any available information from the pilot will be considered along with public comments in forming a better proposed rule that EPA currently intends to issue in 2003 and aid in the development of final improvements to the emergency exemption program.

2. *Tiered approach for documentation of "significant economic loss"*—i. *What is our current practice?* EPA determines whether the loss from an emergency would result in net cash returns (gross revenue less operating expenses) below the historical variation in net cash returns. Applicants are required to submit economic information necessary to make this determination, when available. In addition to information used to estimate the amount of the anticipated yield and profit losses, annual data for 5 years of average yields, prices, and production costs are submitted by applicants and analyzed by EPA to establish profit variability.

ii. *How will the tiered approach to determining significant economic loss be used under the pilot?* A large majority of emergency exemptions are granted because they meet the regulatory criteria for an emergency condition that affected growers will suffer a "significant economic loss" due to an urgent, non-routine situation if the requested exemption is not granted. This second potential improvement that is part of the pilot will allow applicants to develop the significant economic loss documentation necessary to support many specific exemption requests through a less burdensome economic methodology.

This tiered approach is based on an analysis of data found in a random selection of past requests for emergency exemptions submitted by States, including requests that were denied. The analysis shows that in many cases significant economic loss can be demonstrated in a more flexible manner without loss of reliability. The analysis of past section 18 requests suggests that the current approach is often unnecessarily burdensome in terms of information requirements. This new approach under the pilot will often reduce the burden to applicants relative to the current approach, while maintaining the level of approvals of current regulations. The tiered approach

is intended to require less data from applicants in cases where the same conclusion of a significant economic loss would be made with the additional data and analysis.

Current regulations (40 CFR 166.20(b)) list certain information which must be included, as appropriate, in an application for a specific exemption:

(b) *Information required for a specific exemption.* An application for a specific exemption shall provide all of the following information, as appropriate, concerning the nature of the emergency:

(4) A discussion of the anticipated significant economic loss, together with data and other information supporting the discussion, which addresses all of the following:

(i) Historical net and gross revenues for the site;

(ii) The estimated net and gross revenues for the site without the use of the proposed pesticide; and

(iii) The estimated net and gross revenues for the site with use of the proposed pesticide.

The regulations state that all of the above information must be included "as appropriate." EPA exercises judgement based on experience, in determining when something less, or different, is appropriate. For example, under the current approach the Agency typically considers 5 years of annual data on historical net and gross revenues to be appropriate, although the regulations do not prescribe 5 years. However, in some cases, such as a very minor or new crop for which less data are available, this requirement is not considered appropriate if the applicant substitutes other credible information. Therefore, EPA believes that the pilot approach will allow applicants to focus their applications on the most "appropriate" information for determining whether or not a significant economic loss will occur.

Because the analysis of past exemption requests, on which the pilot approach is based, demonstrates that the likelihood of approval of some requests is not significantly changed by the pilot tiered approach, EPA believes that the requirement of those data in those cases is not appropriate. However, even when annual historical data are not required, applicants would generally continue to utilize historical data under the pilot approach, albeit in a different way. Each tier requires a quantitative threshold to be met, which is a certain percentage of a baseline of either crop yield, gross revenues, or net revenues. The best approach to determine the baseline in most cases is to use the average of historical data, including yield and price data.

Whereas the existing method generally requires detailed historical data, with the new approach the analytical burden for determining significant economic loss will be divided into three successive tiers. If the pest situation does not appear likely to result in a significant economic loss based on the first tier analysis, it could qualify based on further analysis in succeeding tiers. Each additional tier would require more data and involve more analysis on how the emergency affects profitability. For a loss to be considered economically significant, it must exceed a threshold. Each tier has a quantitative threshold that will generally apply to all eligible emergency exemption applications. Where conditions do not neatly fit into the tiered approach, for example long-term losses in orchard crops, the Agency may make a finding of significant economic loss based on other criteria, such as changes in the net present value of an orchard, if these losses are demonstrated by the State.

*Tier 1--Yield Loss.* Tier 1 is based on crop yield loss. If the projected yield loss due to the emergency condition is sufficiently large, EPA will conclude that a significant economic loss will occur, due to the magnitude of the expected revenue loss. The yield loss threshold in Tier 1 will be 20% for all crops. This threshold is set at a sufficiently high level such that a loss which exceeds the threshold will also meet the thresholds in Tiers 2 and 3, if the additional economic data were submitted and analyzed. Therefore, for such large yield losses it will not be appropriate or necessary to separately estimate economic loss, which requires detailed economic data.

*Tier 2--Economic Loss as a Percentage of Gross Revenues.* A yield loss which does not satisfy the threshold in Tier 1 could also lead to a significant economic loss because yield loss may not capture all economic losses. In addition to yield losses there may be other impacts that affect economic loss, including quality losses and changes in production costs, such as pest control costs and harvesting costs. For situations with yield losses that do not meet the significant economic loss criterion for Tier 1, EPA will evaluate estimates of economic loss as a percent of gross revenue in Tier 2, to determine if the loss meets that threshold for a significant economic loss. The economic loss threshold in Tier 2 will be 20% of gross revenue for all crops. Again, this threshold in Tier 2 is set with the intention that losses exceeding the threshold also meet the threshold in Tier 3, if it were analyzed.



*Tier 3--Economic Loss as a Percentage of Net Revenues.* Because typical profit margins (net cash revenues as a percentage of gross revenues) vary among crops, EPA will consider impacts on net cash revenues in Tier 3 if neither yield or economic losses are above the required thresholds in Tiers 1 and 2. Specifically, Tier 3 will measure economic loss as a percent of net cash revenues. The loss threshold in Tier 3 will be 50% of net cash revenues for all crops during the pilot. Some emergency conditions which fall short of the thresholds in Tiers 1 and 2 may qualify as a significant economic loss in Tier 3, particularly for crops with narrow profit margins. Even if economic loss seems small in comparison to gross revenues, the situation could still be determined to be a significant economic loss if the profit margin is narrow.

For those emergency exemptions in which significant economic loss is a qualifying factor, applicants will determine which tier their situation is expected to qualify under, specify that tier in their request, and submit the data necessary for analysis under that tier. The three tiers are designed such that when an emergency condition qualifies for significant economic loss under a lower tier, data for higher tiers is not required, and the burden and cost are reduced. Each successive tier builds upon the previous one. That is, the information required for estimating a lower tier is also necessary in estimating each higher tier. This will allow an applicant to collect data, and build a case for significant economic loss, as needed and determined by the conditions.

iii. *Why pilot this potential improvement?* This new methodology for determining a significant economic loss is intended to streamline the data and analytical requirements for emergency exemption requests. In addition, the methodology is designed to be more flexible than the existing procedure for determining a significant economic loss. Specifically, the Agency believes this approach makes a better comparison between the emergency situation and what would exist without the emergency, rather than a comparison with the past. An analysis of past section 18 requests suggests that this new approach will not cause a significant change in the overall likelihood of a significant economic loss finding, although findings may differ in individual cases. Further, it is expected to lead to considerable savings to both applicants and EPA from reduced data and analytical burdens. Under the pilot procedure, applicants may elect to submit the minimum amount of data

necessary to demonstrate a significant economic loss in one of three increasingly refined tiers. If the first tier is sufficient, the burden is reduced most significantly. Even in the highest tier, the burden may be reduced relative to the old approach as the analysis focuses on the current year rather than historical data. Like re-certification of emergencies, this will save applicants time and resources in gathering data and preparing submissions. The Agency's burden will be reduced due to streamlined reviews.

As with re-certification of emergencies, the Agency expects the pilot to provide useful experience with the tiered approach for documentation of significant economic loss. That experience will be considered along with public comments to assist in the planned rulemaking process for improving the emergency exemption regulations. The Agency will analyze the selected threshold levels during the pilot period to confirm that they are appropriate, and also use any helpful information supplied in public comments. EPA will also scrutinize the approach of using a uniform threshold level in each tier for all crops, and consider whether different levels for various crop groups would be more appropriate.

## VI. Request for Comment

### A. Comment Sought on Improvements Being Piloted

The Agency seeks comment on the potential changes included in the limited pilot described in Unit V., and on how those provisions should be implemented through a future rulemaking. EPA currently intends to publish a proposed rule in 2003 that will propose several potential improvements to the emergency exemption regulations. EPA will consider any available information from this pilot as it proceeds with rulemaking.

If the re-certification process is fully implemented through rulemaking, the eligibility criteria established in that rulemaking would become final, and may differ from the criteria under the pilot. The Agency expects that after such a final rule, whenever EPA granted an exemption, and classified it as a candidate for re-certification, it would also include in the approval letter the number of years of candidacy remaining at that time (*i.e.*, 1 or 2 years). This notification in the approval letter of candidacy for the following year will not occur during the pilot, as the criteria under the pilot are not final. Instead, EPA will prepare a list of candidate

exemptions (see Unit V.A.) for each year that the pilot is in effect.

The scope of the pilot is purposely limited to reduced-risk pesticides in order to significantly reduce the number of exemptions potentially affected, while still benefiting from the experience of the potential improvements to inform the rulemaking process. However, EPA does not anticipate that the improvements being piloted should be limited to reduced-risk pesticides in a final rule.

### B. Comment Sought on Consideration of Resistance Management Exemptions

Although not included in the limited pilot described in this Notice, the Agency is considering another potential improvement to the emergency exemption program, *i.e.*, whether to allow exemptions for pest resistance management purposes. This potential improvement was not included in the pilot due to uncertainty and complexity of issues with respect to the appropriate requirements for scope and degree of resistance development, as well as level and type of documentation. To aid the Agency in developing this potential improvement for inclusion in the proposed rule that is currently expected in 2003, the Agency specifically seeks comment on this additional potential improvement to the emergency exemption program that would allow exemptions for resistance management under specific criteria where pest resistance to registered pesticides is developing or has developed.

1. *What is our current practice?* Exemptions are only authorized for resistance management in cases where documented pest resistance to the registered pesticide has already developed and use of the registered pesticide is expected to result in significant economic losses. Under current regulations, if there is at least one available registered pesticide that is effective enough to prevent significant economic losses, then the situation is generally not found to be an emergency regardless of whether or not the alternative is considered to be vulnerable to the development of resistance by the target pest.

2. *How might resistance management exemptions work?* Some emergencies are the result of the development of pest resistance to a registered pesticide that is essential for the management of a pest which, unchecked, can cause significant economic loss. The optimal time to respond to this emergency would be early enough to prevent or retard the development of widespread resistance. Timely action in granting the emergency use of another pesticide could increase

the useful life of the essential registered pesticide and ultimately limit the need for more emergency exemptions. The potential improvement would take a more preventive approach to resistance management.

Under such an approach, EPA could review applications and look for all four of the following criteria before approving an emergency exemption request for resistance management:

i. Pest resistance is developing or has developed to the registered pesticide product. Claims that a pest is developing or has developed resistance to a pesticide should be documented by scientific evidence. The applicant would submit the best readily available information which supports their case. Because acceptable techniques for verifying resistance vary considerably for the numerous crop-pest-pesticide combinations, EPA determinations on sufficiency of documentation would be made on a case-by-case, weight-of-the-evidence basis. Resistance development would be documented through field studies, references to field studies, or loss of ability to control the pest in the field and confirmed to be due to pest resistance in commercial plantings or other actual use conditions such as in greenhouses.

Typically, documentation of a decrease in susceptibility to a pesticide would involve collections of pest samples from fields suspected of containing high frequencies of resistant pests, and laboratory bioassay would be conducted to estimate the frequency of resistant individuals and the degree of resistance. Field tests would be conducted to assess the degree to which the laboratory resistant bioassay reflects loss of efficacy under typical treatment conditions in the field. Because resistance developed or measured under laboratory or other non-field conditions may not accurately reflect conditions in normal use situations, the applicant would need to demonstrate that the data presented can substitute for field conditions. That is, the laboratory bioassay must have relevance to the field such that individuals shown to be resistant in the laboratory bioassay actually do contribute to a substantial loss of efficacy under the treatment conditions of the field. The data should reflect numerous susceptibility estimates within single locations and multiple locations to confirm resistance and account for within-field variability. The geographic extent of resistant populations should be described.

The applicant could present evidence on previously reported resistance incidences that are substantially similar to the pest situation under

consideration, as well as a rationale for why resistance is anticipated.

Applicable situations include those where resistance has been documented, either in the U.S. or outside the U.S., for the same pest species or related pest species, similar pesticide use patterns, and comparable climatic conditions. Documentation of comparable situations should also include evidence that the loss of efficacy was not due to misapplication, weather, or other effects not due to resistance. Documented field failures due to pest resistance outside the U.S. and/or laboratory or non-commercial greenhouse experiments could also be included to substantiate resistance in the same or closely related pest species. However, evidence should be presented to justify the use of related pest species, since even closely related pest species may have a different genetic potential to develop resistance.

Information should be provided on the genetic, biological (biotic and behavioral), and operational (chemical and application technology) characteristics that influenced the selection of resistance. Evidence should be provided that indicates the typical number and frequency of pesticide applications, and rate of application used, and host, and why the target pest is likely to develop or has developed resistance at the requested and/or reported site(s), country, county, State, or region. The applicant must also discuss what has been done to manage resistance to the existing registered alternatives and why the requested pesticide is essential to managing pest resistance. This information is important for understanding the basis of resistance and choosing appropriate strategies to manage it.

ii. The registered chemical to which resistance is developing is considered essential for the management of the pest(s) in the particular crop. The pesticide to which resistance is developing should be a registered pesticide which serves as the standard treatment, is critical for obtaining control of the emergency pest, and for which suitable registered alternatives are lacking. If the registered pesticide is used only rarely, the likelihood of resistance developing is generally greatly reduced. Applicants would be asked to document that the pest is one which occurs regularly in the subject crop and State, and is capable of causing a significant economic loss (see Unit V.B.) if no effective control were available. This criterion would ensure that, while addressing resistance proactively by preventing future emergency conditions before they occur, the scope of these exemptions would

not include those for which an actual emergency would never occur.

iii. The request is for only one chemical, which is in a different class, or has a different mode of action, from the registered chemical to which resistance is developing. Applicants would be asked to provide evidence to demonstrate that the requested chemical has a different mode/mechanism of action, metabolic effect, behavioral response, target enzyme, or target life stage from the available effective registered pesticides. Evidence should also be presented regarding whether the requested pesticide may result in unintended pesticide exposure in non-target pests, if available. Pesticide Registration Notice 2001-5, available in the public docket for this Notice and on the Internet at [http://www.epa.gov/opppmsd1/PR\\_Notices/pr2001-5.pdf](http://www.epa.gov/opppmsd1/PR_Notices/pr2001-5.pdf), describes the Agency's voluntary policy toward resistance management based on mode of action. The Appendices of that document provide the mode of action classification of all of the available registered active ingredients for insecticides, miticides, acaricides, fungicides, bactericides, and herbicides for agricultural uses.

iv. The applicant has a credible approach to managing the development of resistance using both the requested chemical and the chemical to which resistance is developing. The applicant would be asked to include various pest management strategies to reduce selection pressure to not only the requested pesticide, but also the registered alternatives that still may have utility. When available, the applicant should also include supplemental control measures for reducing selection pressure, especially those of a non-chemical nature (e.g., biocontrol, scouting, cultural practices, crop rotation, and use of a pest forecasting system). Management tactics might also include biological and ecological factors that influence pest migration, dispersion, or overwintering, for example. Management strategies should consider all useful information on the stability and inheritance of resistance (cross- and multiple resistance) and relevant information on pest ecology, biology, and toxicology.

3. *Why is this potential improvement being considered?* EPA believes that granting emergency exemptions on the basis of resistance management is a proactive approach for addressing the development of resistance in its early stages, thereby preventing significant economic losses before they occur. Availability of an additional pesticide for resistance management may reduce the likelihood of the common scenario

of increasing frequency and rate of application of a single available pesticide with decreasing effectiveness. Therefore, a decrease in risk to man and the environment is expected to accompany the economic benefit to pesticide users.

4. *Are there particular questions to consider in preparing comments?* The Agency is looking for specific comments on the types of data or documentation to demonstrate resistance and the proposed approach for this type of emergency exemption. In order to help focus public comments on the resistance management proposal, the following questions and issues are offered for consideration and comment:

i. There is likely to be some delay in confirming resistance in the field once it is suspected.

Given this circumstance, what level of documentation would be appropriate through laboratory, greenhouse, or field studies either in county, State, region, inside or outside the U.S.?

ii. How should noted resistance in related pest species be used to aid a request?

iii. How many years of field data and how many geographic locations would one need to establish a reasonable case for pest resistance?

iv. Comments are requested on the documentation of cross-resistance potential.

v. Should emergency exemptions for resistance management be limited to requests for chemicals in a different class, or with a different mode of action, than the chemical to which resistance is developing?

vi. What evidence should be provided to demonstrate the likely effectiveness of proposed management strategies to manage resistance?

#### *C. General Considerations for Commenters*

As you prepare comments for submission to EPA, you may find the following suggestions helpful:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the Notice or collection activity.
7. Make sure to submit your comments by the deadline in this Notice.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

#### **List of Subjects**

Environmental protection, Pesticides, Emergency exemptions.

Dated: April 16, 2003.

**Stephen L. Johnson,**

*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

[FR Doc. 03-10169 Filed 4-23-03; 8:45 am]

**BILLING CODE 6560-50-S**

### **FEDERAL MARITIME COMMISSION**

#### **Notice of Agreement(s) Filed**

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

*Agreement No.:* 011835-001.

*Title:* CMA CGM/CNAN Space Charter Pooling and Cooperative Working Agreement.

*Parties:* CMA CGM Societe Nationale de Transports Maritimes-CNAN.

*Synopsis:* The proposed agreement modification would permit the parties to include in their revenue pool freights received from the carriage of containers on deck.

By Order of the Federal Maritime Commission.

Dated: April 21, 2003.

**Bryant L. VanBrakle,**

*Secretary.*

[FR Doc. 03-10174 Filed 4-23-03; 8:45 am]

**BILLING CODE 6730-01-P**

### **FEDERAL RESERVE SYSTEM**

#### **Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes

and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 19, 2003.

**A. Federal Reserve Bank of Dallas**  
(W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *AIM Bancshares, Inc.*, Levelland, Texas; to become a bank holding company by acquiring 68.47 percent of the voting shares of The First National Bank of Littlefield, Littlefield, Texas.

Board of Governors of the Federal Reserve System, April 18, 2003.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 03-10077 Filed 4-23-03; 8:45 am]

**BILLING CODE 6210-01-S**

### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Centers for Disease Control and Prevention**

[Program Announcement 03045]

#### **Sexually Transmitted Disease (STD) Prevention Program Communication Network; Notice of Availability of Funds**

Application Deadline: June 23, 2003.