

**Register** as a final regulation, taxpayers may rely on any reasonable interpretation of section 2651(e). For this purpose, these proposed regulations are treated as a reasonable interpretation of the statute.

**Deborah M. Nolan,**

*Acting Deputy Commissioner for Services and Enforcement.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 166

[OPP-2004-0038; FRL-7371-3]

RIN 2070-AD36

### Pesticides; Emergency Exemption Process Revisions

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing several revisions to its regulations governing emergency exemptions that allow unregistered uses of pesticides to address emergency pest conditions for a limited time. The first significant change would allow applicants for certain repeat exemptions a simple way to re-certify that the emergency conditions that initially qualified for an exemption continue to exist in the second and third years. The second significant proposal would re-define significant economic loss and adjust the data requirements for documenting the loss. These proposed revisions would streamline and improve the application and review process by reducing the burden to both applicants and the EPA, allowing for quicker decisions by the Agency, and providing for more consistently equitable determinations of "significant economic loss" as the basis for an emergency. These two proposals are currently being employed in limited pilot programs. In addition, EPA is proposing several minor revisions to the regulations to clarify that quarantine exemptions may be used for control of invasive species, and to update or revise certain administrative aspects of the regulations. All of these proposed revisions can be accomplished without compromising protections for human health and the environment.

**DATES:** Comments must be received on or before November 2, 2004.

**ADDRESSES:** Submit your comments, identified by docket ID number OPP-2004-0038, by one of the following methods:

*Federal eRulemaking Portal:* <http://www.regulations.gov/>. Follow the on-line instructions for submitting comments.

*Agency Web Site:* <http://www.epa.gov/edocket/>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

*E-mail:* [opp-docket@epa.gov](mailto:opp-docket@epa.gov).

*Mail:* Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

*Hand Delivery:* Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to docket ID number OPP-2004-0038. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.epa.gov/edocket/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the federal regulations.gov websites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information

about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL-7181-7). For additional instructions on submitting comments, go to Unit I.C. of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

#### 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 20460-0001; 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 an emergency use authorization under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 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 in this unit 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 proposed rule. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 166 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

#### *C. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at

your estimate in sufficient detail to allow for it to be reproduced.

- vi. Provide specific examples to illustrate your concerns, and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

#### **II. Purpose**

The primary purpose of this notice of proposed rulemaking is to simplify the process of applying for emergency exemptions, and allow for quicker responses to emergency pest conditions, without affecting current protections for human health and the environment. This document proposes several revisions to the regulations at 40 CFR part 166, in an effort to make a variety of improvements to the pesticide emergency exemption program and process. The two most significant of the revised practices being proposed are streamlining provisions intended to reduce the burden to both applicants and the Agency, and expedite decisions on exemption requests. The first of these revisions would expressly authorize applicants for certain repeat exemptions to re-certify that an emergency condition continues in the second and third years, and to incorporate by reference all information submitted in a previous application rather than annually submit complete applications. The second revision would pertain to the determination of "significant economic loss," shifting the emphasis from the historical profit variability to the potential loss relative to yields and/or revenues without the emergency, and establishing a tiered analysis that will in many cases substantially reduce applicants' data burden related to substantiating the significance of losses. Each of these revisions would streamline the application and review process for emergency exemptions. In addition, the proposed economic assessment approach would directly result in more consistently equitable determinations of whether a significant economic loss is expected than does the current approach. These two streamlining proposals are currently being employed in limited pilot projects.

EPA also intends to achieve several other objectives in this proposed rule. First, revisions are proposed to correct or update several minor administrative aspects of the emergency exemption regulations, which have not been revised since 1986. The reason for each of these minor administrative revisions

falls into one of the following categories: Correction of typographical or administrative errors; conformance with requirements of the Food Quality Protection Act of 1996 (FQPA); and codification of improved practices that have been voluntarily but widely followed by applicants. Second, the Agency is proposing to add specific language to the regulations to clarify that treatment of "invasive species" is a valid basis for issuing a quarantine exemption. Third, this proposed rule includes a discussion of how the Agency protects endangered and threatened species, and ensures compliance with the Endangered Species Act, through its implementation of the emergency exemption program. No regulatory proposals are included relative to endangered species measures. Finally, this proposed rule informs the public that EPA has revised its tentative plan to include in this proposed rule a proposal to allow exemptions for the purpose of pest resistance management. An explanation of why resistance management exemptions are not being proposed at this time, and a discussion of what alternative plans the Agency has for addressing resistance management, are included.

The Agency encourages interested parties to submit comments on any of the proposed regulatory revisions by following the instructions under **ADDRESSES**. Commenters should explain any modifications they suggest for the proposed revisions, along with their rationale. EPA would like applicants for emergency exemptions to submit comments concerning their experience with the pilot for the two streamlining provisions being proposed. Applicants who have participated in the pilot are asked to submit comments explaining the pros and cons of the revised practices. Applicants who were eligible for, but elected not to participate in, the pilot are asked to submit comments explaining why they did not participate. Units V. and VI. outline the specific revisions being proposed, but also include discussion asking potential commenters to consider alternative approaches for particular aspects of the proposal. In addition to inviting public comments on this proposed rule, EPA plans to consult the Pesticide Program Dialogue Committee (PPDC) on these proposed revisions, as it has prior to initiating the pilot for the streamlining proposals. Input from the public comments received in response to this proposed rule, and experience from the pilot will be carefully considered, when deciding whether to modify these proposed revisions for the final rule.

### III. Statutory and Regulatory Framework

#### A. Statutory Authority

EPA regulates the use of pesticides under the authority of two federal statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).

FIFRA provides the basis for regulation, sale, distribution and use of pesticides in the United States. FIFRA generally prohibits the sale and distribution of any pesticide product, unless it has been registered by EPA in accordance with section 3. (7 U.S.C. 136a.). 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 an exemption. (7 U.S.C. 136p). Under section 2(aa) of FIFRA, the term "State" is defined to include a "State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and America Samoa." (7 U.S.C. 136(aa)).

Section 408 of FFDCA authorizes EPA to set maximum residue levels, or tolerances, for pesticides used in or on foods or animal feed, or to exempt a pesticide from the requirement of a tolerance, if warranted. (21 U.S.C. 346a).

#### B. Existing Regulatory Provisions

Regulations governing FIFRA section 18 emergency exemptions are codified in 40 CFR part 166. Generally, these regulations set forth information requirements, procedures, and standards for EPA's approval or denial of a request from a Federal or State agency for an exemption to allow a use of a pesticide that is not registered when such use is necessary to alleviate an emergency condition.

Federal and State agencies may apply for an emergency exemption due to a public health emergency, a quarantine emergency, or a "specific" emergency. Most emergency exemptions requested or approved fall under the category of "specific exemptions" and are requested in order to avert an economic emergency for an agricultural activity. 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 approved.

A Federal or State agency must submit an emergency exemption 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 that may be posed to human health or to the environment as a result of the pesticide use (40 CFR 166.20). EPA reviews 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 also 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 approve 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 section 18 and 40 CFR part 166, and, for food uses, section 408 of FFDCA, then EPA may authorize emergency use of the pesticide.

Use under specific and public health exemptions can be authorized for periods not to exceed 1 year, and uses under quarantine exemptions can be authorized for up to 3 years (40 CFR 166.28). Public health exemptions are for the control of pests that will cause a significant risk to human health, while quarantine exemptions are intended to control the introduction or spread of pests that are new or not known to be widely prevalent or distributed within and throughout the United States and its territories. Emergency exemptions should not 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

#### A. April 2003 Notice Initiating Pilot for Two Revisions Now Being Proposed

EPA published a Notice in the **Federal Register** on April 24, 2003 (68 FR 20145) (FRL-7293-6), announcing the initiation of a limited pilot program to test two potential improvements to the emergency exemption process. The two potential improvements currently being piloted are: (1) Allowing applicants for certain repeat exemptions to re-certify that the emergency condition still exists in the second and third years, and to incorporate by reference all information submitted in a previous application rather than annually submit complete new applications and, (2) a new approach to documenting a significant economic loss that focuses on the significance of the potential loss relative to yields and/or revenues without the emergency rather than comparison to historical profit variation. The April 2003 Notice also discussed whether exemptions for the purpose of pest resistance management might be allowed. Finally, the Notice solicited public comment on all three potential changes, and announced EPA's plan to issue a proposed rule addressing them. The two revised practices included in the pilot are also included in this proposed rule, without the restriction to reduced-risk pesticides that limits the scope of the pilot.

Anyone interested in the background leading up to the pilot program, or other related documents, may wish to review the **Federal Register** Notice announcing the pilot, and the related documents. A public docket was established for that Notice under docket ID number OPP-2002-0231. Interested parties should follow instructions under **ADDRESSES** for accessing the docket, but use docket ID number OPP-2002-0231 to access the docket for the April 24, 2003 Notice.

#### B. Summary of Early Pilot Experience

The pilot program is limited to requests for a specific set of "reduced-risk" pesticides, which significantly limits the number of potentially eligible exemption requests. The summary of participation in the pilot focuses on the 2003 growing season, since the 2004 season was still underway at this time.

The first part of the pilot allowed applicants for eligible repeat exemptions to re-certify the existence of their emergency condition. The re-certification pilot involves exemptions that meet all of the following eligibility criteria: (1) EPA approved the same exemption the previous year, and it is the second or third year of the request

by that applicant, (2) the emergency situation can reasonably be expected to continue for longer than 1 year, (3) the exemption is not for a new chemical, a first food use, or for a chemical under Special Review, and (4) the exemption is for a chemical previously identified by EPA as reduced-risk. For the 2003 growing season, 16 exemptions were identified by EPA as eligible for re-certification and the list was made available to States and the public. Of the 16 exemptions eligible to repeat by re-certification, 7 submitted applications using re-certification. Of the nine exemptions that were eligible but for which no re-certification was submitted, three were for pesticide uses that had obtained federal registration under FIFRA section 3 since the 2002 exemption; three were not requested at all in 2003; and the remaining three were requested using conventional emergency exemption requests. In the seven instances of a re-certification, EPA staff was able to make expedited decisions with an average of 9 days from receipt of the request until the decision was made.

The second part of the pilot, for the loss-based approach for determining a significant economic loss, is limited only by the restriction to reduced-risk pesticides. Unlike the re-certification part of the pilot, there is no specific list of eligible exemptions, only eligible pesticide active ingredients to be requested. Therefore, there is no fixed number of eligible exemptions for the loss-based economic approach. EPA did not receive any submissions using the loss-based approach for determining a significant economic loss under the terms of the pilot during the 2003 growing season, although we have already received some in 2004. For the past year, the Agency has routinely prepared side-by-side assessments that evaluate the data under the traditional method, as well as the loss-based approach outlined in the pilot, to gain a better understanding and compare the ways of measuring whether pest situations represent emergencies. The loss-based approach is considered to measure more accurately the significance of losses associated directly with the pest problem, and is less influenced by other factors such as market fluctuations. In addition, cursory assessments of available past submissions have been done using the loss-based approach.

Both of these proposed revisions offer a cost saving and reduce the burden on States as well as on EPA. The Agency expects that the level of participation in both areas of the pilot will increase as the level of familiarity and

understanding among State agencies increases. Efforts to facilitate the understanding and use of the pilot initiatives are currently underway.

#### V. Proposed Revisions to Emergency Exemption Process

The two revisions discussed below are currently being employed in limited pilot programs that were initiated by a **Federal Register** Notice in April 2003. A guidance document was prepared for use by applicants to participate in the pilot programs. After reviewing this Unit V., interested parties may find it useful to review that guidance document for the Agency's detailed plans for implementation of these revisions. A final guidance document will be made available when a final rule is published. In the meantime, the guidance document for the pilot would be particularly helpful in understanding what information would be required to be submitted by applicants under the proposed revisions. The pilot guidance document for the 2004 growing season is available in the public docket. Interested parties should follow instructions under **ADDRESSES**.

##### A. Re-certification of Emergency Condition by Applicants

1. *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 that caused the emergency, some exemptions may subsequently be approved 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 human health 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).

If the emergency condition continues in subsequent years, applicants may submit a similar application, 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, with a full application, including updated economic data. For these repeat requests 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; (4) the requested conditions of use have changed; and (5) the pesticide for the requested use has made sufficient progress towards registration.

2. *How would re-certification work under the proposed approach?* This proposed revision would reduce the burden on applicants who seek re-approval of certain emergency exemptions in subsequent years. EPA proposes to add a new paragraph (b)(5) to 40 CFR 166.20, which would allow applicants for eligible repeat exemptions to submit applications that rely on the preceding year's submission to document the economic impact of the pest emergency. This re-certification approach would allow applicants to incorporate by reference all information submitted in a previous application, instead of submitting a complete re-application and supporting documentation. The re-certification of the emergency condition by the applicant combined with the materials already in EPA's files would serve as the basis for EPA's determination as to whether an emergency condition continues to exist.

Upon approval of any emergency exemption, EPA would make an upfront, separate, additional determination regarding eligibility for a streamlined re-certification application the following year, in the event that the applicant reapplies the next year. Eligibility for a re-certification application would not determine whether an emergency exemption application could be approved. Rather eligibility would affect the information that should be submitted in the application. EPA would consider several factors in determining eligibility to use a streamlined re-certification application:

1. *Whether the emergency situation could reasonably be expected to continue for longer than 1 year.* An emergency situation could reasonably be expected to continue where, for example, a registered product relied upon by growers becomes permanently unavailable, a pest expands its range, or a registered product ceases to be effective against a pest. Situations that would not be expected to continue would include a temporary supply problem of a registered product, an isolated weather event, or a sporadic pest outbreak.

2. *Whether an emergency exemption has been approved more than twice for the same pesticide at the same site.* EPA recognizes that some emergency situations can continue for more than 1 year, however, pesticide registration

pursuant to FIFRA section 3 is the appropriate long-term response, rather than the section 18 emergency exemption. According to the regulations and EPA policy, a failure to request registration of a use requested under section 18 for more than 3 years may indicate that adequate progress toward registration is not being made. Therefore, EPA carefully examines all exemption submissions submitted for more than 3 years.

3. *Whether the pesticide product, owing to its regulatory status, warrants heightened review before any additional use is approved.* EPA will rely on the same criteria used in the existing regulations at 40 CFR 166.24(a), which identifies a number of different situations where, upon receipt of an application for an emergency exemption, the regulatory status of a pesticide product calls for public notice and comment:

(1) The application proposes use of a new chemical.

(2) The application proposes the first food use of an active ingredient.

(3) The application proposes any use of a pesticide if the pesticide has been subject to a suspension notice under section 6(c) of the Act.

(4) The application proposes use of a pesticide which:

(i) Was the subject of a notice under section 6(b) of the Act and was subsequently canceled.

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was the subject of the notice under section 6(b).

(5) The application proposes use of a pesticide which:

(i) Contains an active ingredient which is or has been the subject of a Special Review.

(ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the pesticide which is or has been the subject of the Special Review.

In instances where EPA determines that the emergency situation could reasonably be expected to continue, where an emergency exemption has been approved not more than twice for the same pesticide at the same site, and where the pesticide product's regulatory status does not warrant heightened review, EPA would notify the successful applicant that, should it re-apply the following year, it is eligible to use a re-certification application. EPA anticipates that this notification would be included in the notice of approval of the current year's application. However, if an exemption is not classified as a candidate for re-certification in the approval notice, and an applicant believes that subsequent information

would make it eligible, the applicant may contact the Agency to request an eligibility determination. In some instances, EPA may determine that an emergency condition exists, and that the exemption is eligible for a re-certification application the following year, yet conclude that additional information should be gathered in order to support approval in future years. In such instances, EPA may indicate in the approval notice that the exemption is eligible for re-certification upon submission of the specified information.

Under the proposed rule, an eligible re-certification applicant would be exempted from the information requirements of 40 CFR 166.20(a)(1) through (a)(10), and of the existing 40 CFR 166.20(b), where the applicant certifies that:

(i) The emergency condition described in the preceding year's application continues to exist.

(ii) Except as expressly identified, all information submitted in the preceding year's application is still accurate.

(iii) Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year.

(iv) Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied.

Applicants meeting the above requirements would not need to submit new, updated documentation that the emergency condition continues or the additional data elements generally required under 40 CFR 166.20, except that the interim report specified in 40 CFR 166.20(a)(11) would still be required where a re-certification is filed before the final report on the previous exemption is available.

Eligibility for re-certifying the emergency condition would not determine whether an emergency exemption application could be approved. For applications that are eligible and include a proper re-certification of the emergency condition, EPA would again determine 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 would be denied unless the risks could be mitigated. Where an application re-certifies that the emergency condition and requested use are the same as in the initial year of the exemption, EPA would 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; (3) the requested conditions of use have changed; and, (4) the pesticide for the requested use has made sufficient progress towards registration. If an effective product has been registered for the requested use since the previous exemption was approved, then an emergency condition may no longer exist. If the Agency has received new risk information since approving the previous exemption, then the risk would be re-evaluated. Likewise, if the request includes any change in the conditions of use that 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 would also be re-evaluated. Because some applicants may start their 3-year re-certification period in later years than others, it is possible that EPA may determine that sufficient progress towards registration has not been made for a pesticide requested by an applicant eligible for re-certification.

For eligible requests where the applicant has certified a continuing emergency, if the three remaining review factors (product registrations, risk assessment status, and requested conditions of use) 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 would be permitted to modify the conditions of the emergency use in an application in which they re-certify the emergency. However, EPA would need to determine whether, and how, such changes impact exposure and risk to human health or the environment. Therefore, such changes may undercut the Agency's ability to make an expedited decision. If the conditions of use are the same as the conditions of use in the exemption approved by EPA in the previous year, applicants may include a separate certification that their requested conditions of use have not changed, and incorporate by reference all conditions of use submitted in a previous application or applications. This certification that the conditions of use are unchanged would 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 submitting a re-

certification application. Registrant progress toward registration is determined for a pesticide-crop combination, whereas the year-count (first, second, third) in the eligibility cycle for re-certification would be determined separately for each State/Federal applicant, and could often differ among section 18 applicants in a given year. Lack of progress towards registration would 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.

It is EPA's view that section 18 applies to non-routine conditions, and thus the Agency does not expect to re-approve emergency exemptions indefinitely. Under this proposal EPA would not allow submission of re-certification applications where exemptions have been previously granted for 3 or more years. As provided in 40 CFR 166.25(b)(2)(ii), an applicant for an emergency exemption for a use that has been subject to an emergency exemption in 3 previous years will be required to demonstrate reasonable progress towards registering the product for the use, as part of a full application.

3. *Why propose this change?* Allowing applicants for certain eligible exemption requests to re-certify the existence of an ongoing emergency condition and to incorporate by reference all information submitted in a previous application 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 each step of its review of the documents supporting the exemption requests. If no pesticides that could 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.

EPA's experience indicates that emergency situations that continue after the initial year generally are projected to cause comparable yield losses in succeeding years. Therefore, with the

certification of a continuing emergency, reliance on the previously submitted data and other supporting information should be adequate to support a decision to approve or deny an emergency exemption application.

#### *B. Determining and Documenting "Significant Economic Loss"*

1. *What is our current practice?* In determining whether a pest emergency is likely to result in "significant economic loss," EPA ordinarily compares the affected growers' projected per-acre "profits" (gross revenue less expenses, where expenses have often been poorly defined) for the affected crop, based on anticipated yield losses, to the historical variation in their "profits" for that crop in that region. Applicants are required under 40 CFR 166.20(b)(4) to submit economic information necessary to make this determination. In addition to information used to estimate the amount of the anticipated yield and profit losses, EPA generally asks for annual data for 5 years of average yields, prices, and production costs to establish profit variability.

Under the current approach, EPA and applicants estimate expected net revenues under the emergency conditions and compare them to the variation in annual profitability during the previous 5 years. If the expected net revenues under the emergency are less than the smallest net revenues of the previous 5 years, then the Agency would typically conclude that a significant economic loss will occur. Some crops have very wide fluctuations in net revenues (that in many cases are the result of market forces entirely unrelated to pest pressure). For such crops, growers may experience a large economic loss due to non-routine pest-related conditions, without a significant economic loss finding by EPA under strict adherence to the current approach. Other crops may have very little variation in historical net revenues, which could lead to a very small economic loss being found significant under the current approach.

2. *How would the proposed approach work?* This second proposed improvement would focus EPA's analysis on the economic impact of the pest emergency relative to yields and/or revenues without the pest emergency, rather than comparing it to historical profit variation for the crop and region. Moreover, the new approach would allow applicants to document economic losses with a less burdensome methodology where appropriate.

The proposed loss-based approach would use the existing methodology to

calculate the economic consequences of an unusual pest outbreak, although the calculation would be done in steps (tiers) and sometimes the later steps would be unnecessary. States would still have to submit data to demonstrate the emergency nature of the outbreak including the expected losses in quantity, and sometimes quality and/or additional production costs. However, the proposed approach would impose standard criteria for determining the significance of that loss, rather than comparing losses to past variations in revenue or profit. The goal of the criteria is to compare losses to farm or firm income in the absence of the emergency in a manner that can be easily and consistently measured. Further, successive screening levels (tiers) have been chosen that will permit situations that clearly qualify to be resolved quickly, with a minimum of data. Each tier has a quantitative threshold that would generally apply to all eligible emergency exemption applications. If the pest situation does not appear likely to result in a significant economic loss based on the first tier analysis, it might qualify based on further analysis in succeeding tiers. Each additional tier would require more data and involve more analysis on how the emergency affects revenues. Where conditions do not neatly fit into the tiered approach, for example long-term losses in orchard crops, the Agency would make its significant economic loss determinations based on other criteria, such as changes in the net present value of an orchard, if these losses are demonstrated by the applicant.

*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 would conclude that a significant economic loss will occur, due to the magnitude of the expected revenue loss. The yield loss threshold in Tier 1 would be 20% for all crops. This threshold is set at a sufficiently high level such that a loss that exceeded the threshold would 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 would not be necessary to separately estimate economic loss, which would require detailed economic data.

*Tier 2: Economic loss as a percentage of gross revenues.* A yield loss that does not satisfy the threshold in Tier 1 may nonetheless cause a significant economic loss because yield loss alone may not reflect all economic losses. In addition to yield losses, there may be other impacts that contribute to economic loss. Quality losses may result

in reductions in prices received and/or there may be 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 would 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 would be 20% of gross revenue for all crops. Again, this threshold in Tier 2 is set with the intention that losses exceeding the threshold would also meet the threshold in Tier 3, if the additional Tier 3 analysis were performed.

*Tier 3: Economic loss as a percentage of net revenues.* If neither yield or economic losses were above the required thresholds in Tiers 1 and 2, EPA would compare impacts to net revenues. Net revenues are defined for the purposes of this proposed rule as gross revenues minus operating costs. The loss threshold in Tier 3 would be 50% of net revenues for all crops. Some emergency conditions that would 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 (net revenues as a percentage of gross revenues). Even if economic loss seems small in comparison to gross revenues, the situation could still be a significant economic loss if the profit margin is narrow.

EPA selected the sizes of the proposed thresholds (20%, 20%, and 50%) based on average farm income and production expenses in the U.S., and an analysis of past requests showing what results the proposed method would provide with various thresholds. Data on farm income in "USDA Agricultural Statistics, 2003" shows that net farm income averages about 20% of gross revenue. Therefore, an economic loss of 20% of gross revenue would be sufficient to eliminate net farm income. A yield loss of 20% results in economic loss of 20% or higher. Also, since average net farm income is a little less than 50% of net revenue, an economic loss that is 50% of net revenue would be sufficient to eliminate net farm income. The analysis of past requests indicated that the average and median economic losses that qualified as a significant economic loss were about 18% and 15% of gross revenue, respectively. Since the first 2 tiers are screening thresholds, these thresholds were rounded up to 20% to be a little more stringent, with the intention that if a request did not pass Tiers 1 or 2, it could qualify with Tier 3. The analysis of past requests also

showed that the median economic loss that qualified as a significant economic loss was about 51% of net revenue. The analysis also showed that these thresholds collectively result in about the same overall likelihood of an application qualifying for a significant economic loss. That is, approximately the same total number of emergency requests that qualified for a significant economic loss using the current approach would qualify using the proposed loss-based approach, although there would be some differences in individual cases.

The regulatory revisions in this proposed rule include the quantitative thresholds for the three tiers, presented above, as this is EPA's preferred approach. Commenters are asked to consider whether the actual thresholds should be included in the revised regulations, or whether more flexibility should be preserved to refine that aspect of the proposed approach in the future. Commenters should also consider whether the levels of the proposed thresholds are appropriate, and if not, what the levels should be and why.

For specific emergency exemptions (the only ones in which significant economic loss is a qualifying factor), EPA anticipates that applicants would first determine whether their projected loss meets the Tier 1 yield loss threshold of 40 CFR 166.3(h)(1)(i), analytically the least burdensome criterion. The associated data requirements are proposed in 40 CFR 166.20(b)(4)(i). If the projected loss does not meet this threshold, EPA expects that applicants would determine whether their projected loss meets the Tier 2 gross revenue threshold of 40 CFR 166.3(h)(1)(ii), providing additional data as noted in 40 CFR 166.20(b)(4)(ii). Failing to meet that threshold, applicants would submit the data to perform the analysis necessary for the Tier 3 net revenue threshold of 40 CFR 166.3(h)(1)(iii) as given in 40 CFR 166.20(b)(4)(iii). The three tiers established in 40 CFR 166.3(h)(1)(i), (ii) and (iii) are designed such that when an emergency condition qualifies for significant economic loss under a lower tier, data for higher tiers are not required, and the burden and cost of preparing the emergency exemption application 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 would allow an applicant to collect data, and build a case for significant economic loss, as needed and determined by the conditions, without requiring additional unnecessary data.

This loss-based approach is designed to capture the economic impact of pest activity as it affects the current growing season, which will be sufficient for most emergency exemption applications. Although the loss-based approach appears in a proposed revision to the definition of significant economic loss at 40 CFR 166.3(h)(1), EPA is not attempting to revise the approach for other types of losses, at the proposed 40 CFR 166.3(h)(2). Where losses affect more than the current growing season, for example long-term losses in orchard crops, the Agency would continue to make its significant economic loss determinations based on other criteria, such as changes in the net present value of an orchard, if these losses are demonstrated by the applicant. In situations where the simple methods of the loss-based approach would not adequately reflect the likely extent of the economic loss, EPA would still attempt to determine, on a case-by-case basis, whether the pest emergency is likely to result in a substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

*3. Why propose this change?* This proposed methodology for determining a significant economic loss is intended to streamline the data and analytical requirements for emergency exemption requests, and allow for quicker decisions by EPA. In addition, the methodology is designed to reflect more accurately the significance of an anticipated economic loss. Specifically, this approach makes a more direct comparison between the losses anticipated owing to the emergency situation and the yield and/or revenues without the pest emergency, rather than a comparison to the historical range of profit variability. Year-to-year profit variability often reflects market forces entirely unrelated to pest pressure. Although EPA has attempted to make allowances for crops' differing profit variability when determining the economic significance of losses under the current approach, EPA now believes that the loss-based approach better and more directly permits EPA to evaluate the significance of economic losses.

An analysis of past section 18 requests suggests that this proposed approach would 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 savings to both applicants and EPA from reduced data and analytical burdens. Under the proposed procedure, applicants could 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 current approach as the analysis focuses on the current year rather than historical data. Like re-certification of emergencies, this would save applicants time and resources in gathering data and preparing submissions. The Agency's burden would be reduced due to streamlined reviews.

An analysis of available past requests for emergency exemptions submitted by States, including requests for which significant losses were not found, shows that in many cases significant economic loss can be adequately demonstrated in a more flexible manner without loss of reliability through the proposed methodology. The loss-based approach would require less data from applicants in cases that qualify under Tier 1, where the same conclusion of a significant economic loss would be made with the additional data and analysis under the higher tiers.

Because the proposed approach shifts the focus from annual price variability to actual pest-related losses, while still considering typical net revenues for the crop and State, it leads to more consistently accurate findings of the significance of economic losses. Under the current approach, producers of crops that have very wide fluctuations in net revenues, even if due to price variability, may experience a large economic loss due to non-routine pest-related conditions, without a significant economic loss finding by EPA under strict adherence to the current approach. Other crops and cases may have very little variation in historical net revenues, which could lead to a small economic loss being found significant under the current approach. Again, the proposed approach is designed so that it would not cause a significant change in the overall likelihood of a significant economic loss finding, but it may change the findings in individual cases so that determinations of significance are more accurate, appropriate and equitable.

Current regulations list certain information that must be included, as appropriate, in an application for a specific exemption: 40 CFR 166.20(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 existing regulations state that all of the above information must be included "as appropriate." EPA recognizes that each pest emergency has individual characteristics, and exercises judgement based on experience, in determining what information 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, and has suggested in guidance materials that applicants submit revenue data for the preceding 5 years. However, in some cases, such as a very minor or new crop for which less data are available, the Agency may rely on other credible information. Further, EPA does not compare the emergency situation to the situation with the proposed pesticide, but to the situation without the emergency. Therefore, EPA believes that the proposed approach would 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 proposed approach is based, demonstrates that the likelihood of approval of some requests is not significantly changed by the loss-based approach, EPA believes that the current requirement of those additional data in those cases can be improved. However, even when annual historical data are not required, applicants would sometimes continue to utilize historical data under the proposed approach, albeit in a different way. This is because each tier requires a quantitative threshold to be met, that is a certain percentage of a baseline of either crop yield, gross revenues, or net revenues. The best approach to determine the baseline in some cases may be to use the average of historical data, including yield and price data.

## VI. Proposed Minor Updates and Revisions

### A. Specifying Invasive Species as Targets under Quarantine Exemptions

Current regulations describe four types of exemptions, one of which is a quarantine exemption. The purpose of a

quarantine exemption is stated in the regulations as follows:

40 CFR 166.2(b) Quarantine exemption

A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.

Quarantine exemptions are not directly for the purpose of, or approved on the basis of, averting a significant economic loss, although they may ultimately help prevent large economic losses. In addition to being for the control of pests that are not widely prevalent or distributed in the U.S., quarantine exemptions are intended to control recently-introduced, non-native species. In recent years such species have come to be commonly known as "invasive species." Because of the potentially widespread and devastating impacts of invasive species to ecosystems, the environment, and the economy, the challenge of preventing their introduction, and when necessary controlling them, has garnered increasing attention in recent years. Although invasive species implicitly fall within the scope of quarantine exemptions, the now widely-recognized term does not appear in the regulations, probably because it was not widely used at the time 40 CFR part 166 was promulgated. EPA is proposing to add the term "invasive species" to 40 CFR 166.2(b) and to 166.3(d)(3)(i), to clarify that the intent of making quarantine exemptions available includes the control of invasive species. EPA also proposes to add, at 40 CFR 166.3(k), a definition of "invasive species" that is derived from that used in Executive Order 13112 (64 FR 6183, February 3, 1999).

### B. Updating Administrative and Communication Processes

A number of minor revisions to 40 CFR part 166 are being proposed to correct errors or update administrative aspects of the emergency exemption regulations, particularly in light of the fact that FQPA was enacted since the regulations under part 166 were last revised. Each of these revisions is being proposed for one of the following reasons: (1) To correct typographical or administrative errors or inaccuracies, (2) to bring the regulations into agreement with current requirements put in place by the FQPA, or (3) to reflect improvements to the process that have been identified since 40 CFR part 166 was last revised, and that have been voluntarily practiced by applicants. Each of these revisions would be non-substantive or reflect minor changes to



the regulatory requirements, but all would correct, improve, or update the regulations. The corrections of typographical or administrative errors or inaccuracies are self-explanatory. The proposed revisions for the other reasons are discussed below.

Under FFDCA section 408(l)(6), as amended by FQPA, EPA is required to establish time-limited tolerances, or exemptions from the requirement of a tolerance, for pesticide residues in food or feed resulting from uses under emergency exemptions. The current regulations predate FQPA and therefore do not reflect this requirement. Four revisions are being proposed to bring 40 CFR part 166 into agreement with current practices as required by the FFDCA. Inasmuch as section 408(l)(6) applies to all food-use emergency exemptions, regardless of whether its requirements are reflected in 40 CFR part 166, these proposed changes to 40 CFR part 166 do not substantively change the applicable law. For ease of discussion, below, "tolerance" is used to refer to a tolerance or exemption from the requirement of a tolerance.

First, EPA proposes to amend 40 CFR 166.3(e) to revise the definition of "first food use," which reads "The term *first food use* refers to the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no permanent tolerance, exemption from the requirement of a tolerance, or food additive regulation for residues of the pesticide on any food has been established for the pesticide under section 408(d) or (e) or 409 of the Federal Food, Drug, and Cosmetic Act." EPA is proposing to change this definition by removing the word "permanent," so that the establishment of any tolerance, including a time-limited tolerance, would be considered when determining whether a use was the first food use, and by removing the reference to "food additive regulation," because, owing to the FQPA amendments, EPA no longer issues food additive regulations.

Second, under 40 CFR 166.25, *Agency review*, the regulations state that the review enables EPA to make a determination with respect to several items, including in 40 CFR 166.25(a)(2) the level of residues in or on all food resulting from the proposed use. The proposed revision would add to this list the establishment of a time-limited tolerance for such residues, where necessary.

The third proposed revision made necessary by FQPA is to add, under 40 CFR 166.40, an additional limitation to the authority of a State to issue a crisis

exemption, namely, that a State may issue a crisis exemption for a food use only where a tolerance or exemption is already in effect, or where EPA has provided verbal confirmation that a time-limited tolerance for the proposed use can be established in a timely manner. It is in the best interests of applicants and potential users of the pesticide under the crisis exemption that there is some assurance that an exemption can be established in a timely manner before use of the pesticide begins. EPA also proposes that all crisis exemptions be conditioned upon EPA confirming that it has no other risk-based objection to the use of the pesticide under the crisis provisions.

The fourth proposed change, which arises because EPA now establishes formal tolerances under FQPA, is to remove the requirement under 40 CFR 166.30(b) and 40 CFR 166.47 to directly notify the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the State health officials. The purpose of this requirement was to notify these agencies of levels of pesticides that may occur in food and feed items as a result of an emergency exemption use. However, with the requirement that time-limited tolerances be established in accordance with FFDCA section 408(l)(6), such levels are published in the **Federal Register**, as well as the 40 CFR part 180, and detailed background is given regarding safety of these tolerances. Therefore, notifying the other regulatory organizations (FDA, USDA, and State health officials) on an individual basis is considered redundant to the **Federal Register** notice and incorporation of the regulatory decision in the appropriate section of 40 CFR part 180.

Several proposed revisions are to codify minor improvements to the process that have been identified since the current regulations became effective. Applicants have been generally following these practices, in most cases for several years, and EPA believes that the public will generally agree that these are improvements to the regulatory requirements. First, under 40 CFR 166.20, *Application for a specific, quarantine, or public health exemption*, EPA is proposing to revise 40 CFR 166.20(a)(2)(i)(A) so that an application must include a copy of the registered label(s) if a specific pesticide product(s) is/are requested, instead of the current requirement to include the registration number and name of the product. This is practical because emergency exemption requests are generally for pesticide products that are already

registered for other uses, but not for the requested use.

Next, under 40 CFR 166.20(a)(3), EPA is proposing to add a new item and revise several of the others, to specify that the conditions of use in an application must state the maximum number of applications, the period of time for which the use is proposed, and to specify the earliest possible harvest dates of the treated crop. Such information is clearly necessary for both risk assessment and tolerance setting, and in those rare occasions where it is not apparent from the application, EPA must contact the applicant to obtain the information. Expressly requiring this information in 40 CFR 166.20(a)(3) would expedite review of applications and allow tolerances to be established in a timely fashion.

Additionally, EPA is proposing that 40 CFR 166.20(a)(9) be revised to specify that in addition to the registrant or manufacturer being notified of the application submission, the application must also include a statement of support from the registrant or manufacturer, and the expectation that supplies of the requested material will be adequate to meet the needs under the proposed emergency use.

The existing regulations establish a measure of whether adequate progress toward the registration of a requested use is being made. Existing regulations suggest that the lack of a request for registration, within 3 years of an emergency exemption first being requested for the use, suggests that adequate progress is not being made. EPA proposes to revise 40 CFR 166.24(a)(6)(i) and 40 CFR 166.25(b)(2)(ii) to relax this presumption for repeat emergency exemption applications for uses being supported by the Interregional Research Project No. 4 (IR-4). The IR-4 program is a cooperative effort of the state land grant universities, USDA and EPA, to address the chronic shortage of pest control options for minor crops. Generally, the crop protection industry lacks economic incentive to pursue registrations on minor crops because of low acreage. IR-4 generates and supplies research data needed by EPA in order to register compounds for use on minor crops. Owing to the limited pest control options available for minor use crops, the significance of the need evidenced by IR-4 action, and the limits on IR-4 resources, EPA believes that a somewhat slower rate of progress towards registration should be accepted for emergency exemptions for uses being supported by the IR-4 program. Accordingly, EPA is proposing that 40 CFR 166.24(a)(6)(i) and 40 CFR

166.25(b)(2)(ii) be revised so that the presumption against adequate progress toward registration of repeat emergency exemptions for uses being supported by the IR-4 program would begin after 5 years, 2 years more than allowed for uses supported by the registrant. For such major crop uses, the 3-year presumption in the current regulations would remain in effect.

EPA is proposing that 40 CFR 166.30(a)(1) be revised to reflect that EPA will not process incomplete applications, and that action on such submissions will be halted until required additional information is submitted.

EPA is proposing to clarify 40 CFR 166.32(b) to ensure that applicants submit interim use reports for exemptions if requesting a repeated emergency exemption prior to the due date of the final report.

EPA proposes clarifying the authority of an applicant to issue a crisis exemption by specifying in 40 CFR 166.40(a) that crisis exemptions are to be used only for unpredictable emergency conditions. This proposed change is strictly for purposes of clarification, as the term "unpredictable" already appears in the introductory language of 40 CFR 166.40, and does not represent any intention by EPA to change the circumstances that are acceptable for crisis exemptions.

EPA is proposing that 40 CFR 166.43(a)(1) be revised to improve the notification process for crisis exemptions, reflect the standard practice of the state agencies, and provide for advance notice so that EPA may make a determination of whether a tolerance may be supported in accordance with FFDCA section 408 requirements. EPA is proposing that 40 CFR 166.43(a)(1) be revised to require advance notification for crisis exemptions by applicants. The state's authority to exercise the crisis exemption would be stayed for up to 36 hours pending verbal confirmation by EPA that a tolerance can be established in a timely manner and that the Agency has no other risk-based objections. This would replace the currently ambiguous requirement that notification must be made at least 36 hours in advance, or no later than 24 hours after the decision of a State to avail itself of a crisis exemption. Notification after the crisis has been declared does not allow EPA to evaluate whether a crisis use can be supported with a section 408 safety finding, or whether other potential risks are unacceptable, before use of the pesticide begins. In any case, EPA would continue to provide the necessary verbal confirmations as

quickly as possible, thereby often allowing use of the crisis exemption in less than 36 hours. The Agency recognizes that speed is important for all crisis exemptions, and that certain situations may be particularly urgent, including, but not necessarily limited to, national security threats and some requests under USDA's Animal and Plant Health Inspection Service quarantine program.

To clarify necessary information for a crisis exemption, EPA is proposing that 40 CFR 166.43(b)(1) and (b)(4), be revised to specify submission of the registered label(s) for the pesticide product(s) proposed for crisis use, as well as proposed use directions specific to the crisis use, and the timeframe for anticipated use, including end date.

To bring the reporting requirements for crisis exemption requests into agreement with those for specific, quarantine, and public health exemption requests, EPA is proposing that 40 CFR 166.49(a)(1) through (a)(4) be revised and 40 CFR 166.49(a)(5) deleted, to clarify information requirements, such as applicant, product used, site treated, and contact information.

## VII. EPA Plans for Resistance Management and Endangered Species Considerations

### A. Revised Plans for Addressing Resistance Management

The EPA-USDA Committee to Advise on Reassessment and Transition (CARAT) is a diverse group of stakeholders formed to make recommendations to EPA and USDA regarding strategic approaches for pest management planning, transition to safer pesticides for agriculture, and tolerance reassessment for pesticides. In October 2003, CARAT provided draft recommendations, including one that "EPA and USDA need to recognize that any transition program has to consider efficacy, economics, resistance management, and impact on non-targets." EPA agrees with the CARAT on the importance of resistance management and is exploring how to use its regulatory and non-regulatory initiatives to support and facilitate effective resistance management.

Although the April 2003 **Federal Register** Notice indicated that EPA was considering addressing resistance management in this proposed rule, EPA now plans to pursue opportunities to address pest resistance management as it implements the Pesticide Registration Improvement Act (PRIA) enacted January 23, 2004. This Act requires the Agency to establish a registration

service fee system for applications for pesticide registration and amended registration. Under this new system, fees will be charged for new applications for registration received on or after the effective date of the statute (March 23, 2004) and EPA is required to make a decision on the application within prescribed decision timeframes. Under PRIA, EPA will eliminate its backlog of registration actions and make more timely decisions. This will accelerate the registration of many products that will be beneficial to resistance management, including reduced risk products. EPA's reduced risk process considers resistance management as an important factor. New products that would address significant resistance management needs would reach the market sooner, thereby providing a strong incentive to registrants to incorporate resistance management in their registration submissions.

In addition, EPA will continue to promote the implementation of its voluntary resistance management labeling guidelines based on rotation of mode of action described in Pesticide Registration Notice 2001-5 (PR Notice 2001-5). These guidelines are part of a North American Free Trade Agreement (NAFTA) effort to harmonize resistance management guidelines. The Agency supports incorporating resistance management considerations into pesticide labeling (i.e., PR Notice 2001-5), resistance management education programs, crop management and stewardship programs, and outreach efforts with stakeholders. EPA will continue working with stakeholder groups on sustainable resistance management strategies that protect human health and the environment including the various Resistance Action Committees (RACs), registrants, consultants, academia, USDA, States, and public interest groups.

### B. Protections for Endangered Species

Like all federal agencies, EPA must comply with the requirements of the Endangered Species Act (ESA), which requires that an agency ensure, in consultation with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (jointly referred to as "the Services"), that its actions are not likely to jeopardize the continued existence of threatened or endangered (listed) species or destroy or adversely modify their critical habitat. This requirement applies, among others, to EPA actions approving emergency exemptions under FIFRA section 18. Under current ESA consultation regulations, an agency must consult with FWS and NMFS if an

action “may affect” a listed species or its critical habitat.

FWS and NMFS, in collaboration with EPA and USDA, have developed a counterpart regulation (69 FR 48115, August 6, 2004), that would make the process of consultation about EPA actions involving pesticides more efficient, effective, and timely, thereby strengthening the protections for endangered and threatened species. As part of the work supporting the counterpart rule, the Services and EPA reviewed the Agency’s approach to the assessment of potential risks to listed species resulting from pesticide use. A January 26, 2004, letter from the Services to EPA includes a quote stating that EPA’s approach to ecological risk assessment “will produce effects determinations that reliably assess the effects of pesticides on . . . listed species and critical habitat pursuant to the ESA and implementing regulations.” That letter is in the public docket for this proposed rule, and interested parties may access it by following the instructions under **ADDRESSES**.

As a result of the Services’ review of the Agency’s ecological risk assessment methodology, EPA intends to look more closely at potential risks of pesticide use in connection with decisions on requests for emergency exemptions. EPA currently requires, under 40 CFR 166.20(a)(7), information to be included in applications for emergency exemption that addresses potential risks of the requested use to endangered and threatened species. Although EPA, under existing requirements, routinely considers the impacts of emergency exemptions on endangered and threatened species, the Agency seeks to improve the guidance it gives to applicants concerning data on endangered and threatened species. EPA will need to rely on States and federal agencies to supply information as part of their requests for emergency exemptions that will enable EPA to assess the potential impacts on listed species and critical habitat of pesticide use under the proposed exemption. EPA also plans to work with the Association of American Pest Control Officials (AAPCO) and with individual States, as the primary applicants for emergency exemptions, to improve the quality of their submissions as they try to frame the potential impact of a requested pesticide use on endangered and threatened species. EPA believes these measures fall within existing requirements but should increase the availability of essential information needed to make a timely and substantive determination of the potential impact to endangered and

threatened species. EPA also plans through its reevaluation, to refocus and possibly increase consideration of these impacts in its decision process for exemption requests, including any need to consult with USFWS and NMFS.

#### VIII. FIFRA Review Requirements

In accordance with FIFRA section 25(a), this proposed rule was submitted to the FIFRA Science Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The SAP has waived its review of this proposed rule, and no comments were received from any of the Congressional Committees or USDA.

#### IX. Statutory and Executive Order Reviews

##### A. Executive Order 12866

Pursuant to Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has designated this proposed rule as a “significant regulatory action” under section 3(f) of the Executive Order because it may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. This action was therefore submitted to OMB for review under this Executive Order, and any changes to this document made at the suggestion of OMB have been documented in the public docket for this rulemaking.

In addition, EPA has prepared an economic analysis of the potential regulatory impacts of this proposed action on those affected, which is contained in a document entitled *Economic Analysis of the Proposed Pesticides Emergency Exemption Process Revisions*. A copy of this Economic Analysis is available in the public docket for this action and is briefly summarized here.

EPA is considering these improvements in an effort to reduce the burden to both the applicants and EPA, and to allow for quicker decisions by the Agency, while maintaining health and safety requirements. As such, this proposed action is not expected to cause any significant adverse economic impacts if implemented as proposed. This proposed action would only potentially affect Federal, State, or Territorial government agencies that can petition EPA for an emergency use authorization under FIFRA section 18. It would therefore have no direct impacts on local governments, small entities, pesticide producers or on government entities that may be registrants of pesticide products, and would have no

direct impacts on any other sector of the economy.

The only significant impacts expected would be burden reductions to States and Federal agencies in the application process for emergency exemptions, and to EPA in the review process, as well as quicker responses to emergency conditions. As detailed in the economic analysis prepared for this proposed rule, based on predicted future applications affected by the proposed revisions, EPA estimates the annual combined savings for applicants and EPA of around \$0.94 million, a little over \$0.6 million from re-certification, and about \$0.33 million from changing to the loss-based method of determining significant economic loss.

##### B. Paperwork Reduction Act

This action does not impose any new information collection burden that would require additional approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* This proposed rule is expected to reduce the existing burden that is approved under OMB Control No. 2070–0032 (EPA ICR No. 596), which covers the information collection activities contained in the existing regulations at 40 CFR part 166, and under the pilot program announced April 23, 2003 (68 FR 20145). A copy of the OMB approved Information Collection Request (ICR) has been placed in the public docket for this rulemaking, and the Agency’s estimated burden reduction is presented in the economic analysis that has been prepared for this proposed rule.

Under the PRA, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations in 40 CFR, after appearing in the preamble of the final rule, are listed in

40 CFR part 9 and included on any related collection instrument (e.g., form or survey).

Submit any comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, along with your comments on the proposed rule. The Agency will consider any comments related to the information collection requirements contained in this proposed rule as it develops a final rule. Any changes to the burden estimate for the ICR will be effectuated with the final rule.

### C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this proposed rule will not have a significant adverse economic impact on a substantial number of small entities. This action will only directly impact State and Federal agencies, neither of which qualify as a small entity under the RFA. This proposed rule does not have any direct adverse impacts on small businesses, small non-profit organizations, or small local governments. Section 18 only applies to Federal and State governments.

### D. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. This proposed rule only applies to Federal and State government agencies, the only entities that can petition the EPA under FIFRA section 18. As described in Unit IX.A., this proposed rule is expected to result in an overall reduction of existing costs for applicants and EPA of around \$0.94 million. As such, this action will not impact local or tribal governments or the private sector, and will not significantly or uniquely affect small governments. Accordingly, this rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

### E. Executive Order 13132

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule does not have "federalism implications," because it will not have substantial direct effects

on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. As indicated above, this proposed rule is expected to reduce burden on Federal and State government agencies that petition EPA under FIFRA section 18, and on EPA in processing the applications. Thus, Executive Order 13132 does not apply to this proposed rule. In the spirit of the Order, and consistent with EPA policy to promote communications between the Agency and State governments, EPA has specifically solicited comment from State officials.

### F. Executive Order 13175

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has determined that this proposed rule does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. As indicated above, this proposed rule only applies to State and Federal government agencies. FIFRA section 18 does not apply to tribal governments. Thus, Executive Order 13175 does not apply to this proposed rule.

### G. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not designated as an "economically significant" regulatory action as defined by Executive Order 12866 (see Unit XI.A.), nor is it likely to have any significant adverse effect on the supply, distribution, or use of energy.

### H. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) does not apply to this proposed rule because this action is not designated as an "economically significant" regulatory action as defined by Executive Order 12866 (see Unit XI.A.), nor does it establish an environmental standard, or otherwise have a disproportionate effect on children.

### I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, and sampling procedures) that are developed or adopted by voluntary consensus standards bodies. This proposed rule does not impose any technical standards that would require EPA to consider any voluntary consensus standards.

### J. Executive Order 12898

This proposed rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has not considered environmental justice-related issues.

### List of Subjects in 40 CFR Part 166

Environmental protection, Emergency exemptions, Pesticides and pests.

Dated: August 25, 2004.

**Michael O. Leavitt,**  
Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

### PART 166—[AMENDED]

1. The authority citation for part 166 would continue to read as follows:

**Authority:** 7 U.S.C. 136–136y.

2. Section 166.2 is amended by revising paragraph (b) to read as follows:

#### § 166.2 Types of exemptions.

\* \* \* \* \*

(b) *Quarantine exemption.* A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest that is an invasive species, or is otherwise new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.

\* \* \* \* \*

3. Section 166.3 is amended by revising paragraphs (a), (d)(3)(i), (e), (h), and adding paragraphs (k) and (l) to read as follows:

§ 166.3 Definitions.

\* \* \* \* \*

(a) The term *the Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*

\* \* \* \* \*

- (d) \* \* \*
(3) \* \* \*

(i) Involves the introduction or dissemination of an invasive species or a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or

\* \* \* \* \*

(e) The term *first food use* refers to the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no tolerance or exemption from the requirement of a tolerance for residues of the pesticide on any food has been established for the pesticide under section 408(b)(2) and (c)(2) of the Federal Food, Drug, and Cosmetic Act.

\* \* \* \* \*

(h) The term *significant economic loss* means that, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:

(1) For pest activity that primarily affects the current crop, one or more of the following:

- (i) Crop yield loss greater than or equal to 20%;
(ii) Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues;
(iii) Economic loss, including revenue losses and cost increases, greater than or equal to 50% of net revenues;

(2) For all other pest activity, substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

\* \* \* \* \*

(k) The term *invasive species* means, with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health.

(l) The term *IR-4 program* refers to the Interregional Research Project No. 4, which is a cooperative effort of the state land grant universities, the U.S. Department of Agriculture (USDA) and EPA, to address the chronic shortage of pest control options for minor crops, which are generally of too small an acreage to provide economic incentive

for registration by the crop protection industry.

4. Section 166.20 is amended by revising paragraphs (a)(2)(i)(A), (a)(3), (a)(9), (b)(4), and adding paragraph (b)(5) to read as follows:

§ 166.20 Application for a specific, quarantine, or public health exemption.

- (a) \* \* \*
(2) \* \* \*
(i) \* \* \*

(A) A copy of the label(s) if a specific product(s) is/are requested; or the formulation(s) requested if a specific product is not desired; and

\* \* \* \* \*

(3) *Description of the proposed use.* The application shall identify all of the following:

- (i) Sites to be treated, including their locations within the State;
(ii) The method of application;
(iii) The rate of application in terms of active ingredient and product;
(iv) The maximum number of applications;
(v) The total acreage or other appropriate unit proposed to be treated;
(vi) The total amount of pesticide proposed to be used in terms of both active ingredient and product;
(vii) All applicable restrictions and requirements concerning the proposed use which may not appear on labeling;
(viii) The duration of the proposed use; and
(ix) Earliest possible harvest dates.

\* \* \* \* \*

(9) *Acknowledgment by registrant.* The application shall contain a statement by the registrants of all pesticide products proposed for use acknowledging that a request has been made to the Agency for use of the pesticide under this section. This acknowledgment shall include a statement of support for the requested use, including the expected availability of adequate quantities of the requested product under the use scenario proposed by the applicant(s); and the status of the registration in regard to the requested use including appropriate petition numbers, or of the registrant's intentions regarding the registration of the use.

\* \* \* \* \*

- (b) \* \* \*

(4) A discussion of the anticipated significant economic loss, together with data and other information supporting the discussion, that addresses one or more of the following, as appropriate:

- (i) Crop yield or utilized yield reasonably anticipated in the absence of the emergency and expected losses in quantity due to the emergency;

(ii) The information in paragraph (b)(4)(i) of this section plus prices reasonably anticipated in the absence of the emergency and changes in prices and/or production costs due to the emergency;

(iii) The information in paragraph (b)(4)(ii) of this section plus operating costs reasonably anticipated in the absence of the emergency;

(iv) Any other information explaining the economic consequences of the emergency.

(5) *Re-certification of an emergency condition.* Applicants for specific exemptions for which the emergency condition could reasonably be expected to continue for longer than 1 year, and for which the exemption was granted for the same pesticide at the same site to the same applicant the previous year, but no more than twice, may submit less information by basing such application on previously submitted information. For applications for such exemptions, except for applications subject to public notice pursuant to § 166.24(a)(1) through (a)(5), the information requirements of paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this section, shall not apply where the applicant certifies that all of the following are true:

- (i) The emergency condition described in the preceding year's application continues to exist;
(ii) Except as expressly identified, all information submitted in the preceding year's application is still accurate;
(iii) Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year;
(iv) Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied.

\* \* \* \* \*

5. Section 166.24 is amended by revising the introductory text of paragraph (a) and (a)(6)(i) to read as follows:

§ 166.24 Public notice of receipt of application and opportunity for public comment.

(a) *Publication requirement.* The Administrator shall issue a notice of receipt in the **Federal Register** for a specific, quarantine, or public health exemption and request public comment when any one of the following criteria is met:

\* \* \* \* \*

- (6) \* \* \*

(i) An emergency exemption has been requested or approved for that use in

any 3 previous years, or any 5 previous years if the use is supported by the IR-4 program, and

\* \* \* \* \*

6. Section 166.25 is amended by revising paragraphs (a)(2), (a)(4), and (b)(2)(ii) to read as follows:

**§ 166.25 Agency review.**

(a) \* \* \*

(2) The Agency's ability and intention to establish a time-limited tolerance(s) or exemption(s) from the requirement of a tolerance for any pesticide residues resulting from the authorized use, identifying the level of permissible residues in or on food or feed resulting from the proposed use;

\* \* \* \* \*

(4) The potential risks to human health, endangered or threatened species, beneficial organisms, and the environment from the proposed use.

(b) \* \* \*

(2) \* \* \*

(ii) The progress which has been made toward registration of the proposed use, if a repeated specific or public health exemption is sought. It shall be presumed that if a complete application for registration of a use, which has been under a specific or public health exemption for any 3 previous years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not been submitted, reasonable progress towards registration has not been made.

7. Section 166.30 is amended by revising paragraph (a)(1), removing paragraph (b), and redesignating existing paragraph (c) as paragraph (b).

**§ 166.30 Notice of Agency decision.**

(a) \* \* \*

(1) *Incomplete applications.* The Agency may discontinue the processing of any application that does not address all of the requirements of § 166.20 until such time the additional information is submitted by the applicant.

\* \* \* \* \*

8. Section 166.32 is amended by revising the introductory text of paragraph (b) to read as follows:

**§ 166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health exemptions.**

\* \* \* \* \*

(b) *Interim and final reports.* A final report summarizing the results of pesticide use under any specific, quarantine, or public health exemption must be submitted to the Agency within 6 months from the expiration of the exemption unless otherwise specified by the Agency. For quarantine exemptions granted for longer than 1 year, interim reports must be submitted annually. When an application for renewal of the exemption is submitted before the expiration of the exemption or before submission of the final report, an interim report must be submitted with the application. The information in interim and final reports shall include all of the following:

\* \* \* \* \*

9. Section 166.40 is amended by revising paragraph (a), removing the period at the end of paragraph (b) and adding a semi-colon and the word "and" at the end of paragraph (b), and adding paragraph (c) to read as follows:

**§ 166.40 Authorization.**

\* \* \* \* \*

(a) An unpredictable emergency condition exists;

\* \* \* \* \*

(c) EPA has provided verbal confirmation that, for food uses, a tolerance or exemption from the requirement of a tolerance can be established in a timely manner, responsive to the projected timeframe of use of the chemical and harvest of the commodity, and that, for any use, the Agency has no other risk-based objection.

10. Section 166.43 is amended by revising paragraphs (a)(1) and (b) to read as follows:

**§ 166.43 Notice to EPA and registrants or basic manufacturers.**

(a) \* \* \* (1) The State or Federal Agency issuing the crisis exemption must notify the Administrator, and receive verbal confirmation from EPA required in § 166.40(c), in advance of

utilization of the crisis provisions. EPA will attempt to provide such confirmation as quickly as possible, but shall notify the applicant of its determination within 36 hours.

\* \* \* \* \*

(b) *Contents of notice.* Information required to be provided in notices shall include all of the following:

(1) The name of the product and active ingredient authorized for use, along with the common name and CAS number if available, including a copy of the EPA registered label and use directions appropriate to the authorized use;

(2) The site on which the pesticide is to be used or is being used;

(3) The use pattern;

(4) The date on which the pesticide use is to begin and the date when the use will end;

(5) An estimate of the level of residues of the pesticide expected to result from use under the crisis exemption;

(6) Earliest anticipated harvest date of the treated commodity;

(7) Description of the emergency situation; and

(8) Any other pertinent information available at the time.

**§ 166.47—[Removed]**

11. Section 166.47 is removed.

12. Section 166.49 is amended by revising paragraph (a) to read as follows:

**§ 166.49 Public notice of crisis exemptions.**

(a) *Periodic notices.* At least quarterly, the Administrator shall issue a notice in the **Federal Register** announcing issuance of crisis exemptions. The notice shall contain all of the following:

(1) The name of the applicant;

(2) The pesticide authorized for use;

(3) The crop or site to be treated; and

(4) The name, address, and telephone number of a person in the Agency who can provide further information.

\* \* \* \* \*

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