EPA-APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE NEW MEXICO SIP

Name of SIP provision	Applicable geographic or non-attainment area	State submittal/ effective date	EPA approval date	Explanation
* * *	*	*	*	*
New Mexico Visibility Protection Plan for Phase I, Part I of the Federal Visibility Requirements, August 8, 1986.	Statewide	08/21/86	01/27/06 [Insert *FR* page number where document begins].	
New Mexico Visibility Protection Plan for Phase I, Part II of the Federal Visibility Requirements, September 9, 1992.	Statewide	10/08/92	01/27/06 [Insert *FR* page number where document begins].	

§ 52.1636 [Removed and Reserved]

■ 3. Section 52.1636 is removed and reserved.

[FR Doc. 06–760 Filed 1–26–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 166

[EPA–HQ–OPP–2004–0038; FRL–7749–3]

RIN 2070–AD36

Pesticides; Emergency Exemption Process Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action revises the regulations governing emergency exemptions that allow unregistered uses of pesticides to address emergency pest conditions for a limited time. One change provides applicants for certain repeat exemptions a simple way to re-certify that the emergency conditions that qualified for an exemption in a previous year continue to exist. Another change revises the criteria for determining when a potential emergency condition is expected to cause a significant economic loss and revises the data requirements for documenting the loss. These revisions streamline and improve the application and review process by reducing the burden to both applicants and the Environmental Protection Agency (EPA, or ''the Agency''), allowing for potentially quicker decisions by the Agency, and providing for consistent and equitable determinations of ''significant economic loss'' as the basis for an emergency. This action also includes several minor revisions to the regulations. None of these various improvements compromise protections for human health and the environment.

DATES: This final rule is effective on March 28, 2006.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2004–0038. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*). Follow the on-line instructions. 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, 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*.

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). Potentially affected 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. 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/*. An electronic version of 40 CFR part 166 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Purpose

The primary purpose of this rulemaking is to simplify the process of applying for emergency exemptions, and allow for potentially quicker responses to emergency pest conditions, without affecting current protections for human health and the environment. This action revises the regulations at 40 CFR part 166, to make a variety of improvements to the pesticide

emergency exemption program and process. The two most significant of the revised requirements are streamlining provisions intended to reduce the burden to both applicants and the Agency and to expedite decisions on some exemption requests. The first of these revisions expressly authorizes applicants for certain repeat exemptions to re-certify that an emergency condition continues in subsequent years, and to incorporate by reference all information submitted in a previous application rather than annually re-submit complete but perhaps redundant applications.

The second change revises the approach to determining when a potential emergency condition is expected to cause a ''significant economic loss'' (SEL). In addition to reducing the application and review burden, the new economic assessment approach will result in consistent and equitable determinations of whether a significant economic loss is expected. These two streamlining approaches have been tested in limited pilot projects since 2003.

In addition, EPA is making a number of revisions to correct or update minor administrative aspects of the emergency exemption regulations. The reason for each of these minor administrative revisions falls into one of the following categories: Conformance with statutory requirements arising from the Food Quality Protection Act of 1996 (FQPA); codification of improved practices that have been voluntary but widely followed by applicants; and correction of typographical or administrative errors. Also, the Agency is adding specific language to the regulations to clarify that treatment of ''invasive species'' is a valid basis for issuing a quarantine exemption.

III. Statutory Authority

EPA regulates the use of pesticides under the authority of two federal statutes: 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 that 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 USC 346a). Section 408(l)(6) provides that where EPA grants an emergency exemption under FIFRA section 18, the Agency must establish a time-limited tolerance or exemption from the requirement of a tolerance for any residues of the pesticide chemical in food or feed.

IV. Background

A. April 2003 Notice Initiating Pilot for Two Primary Revisions now being Codified

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 pilot continued through the end of 2005, but has not been extended for 2006 as it is superceded by this final rule. The two potential improvements included in the pilot were: (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 re-submit to EPA complete new applications and, (2) a new approach to documenting an SEL that focuses on the significance of the potential loss relative to yields and/or revenues without the emergency rather than a 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 final rule, with modification. Today's final rule expands the application to all pesticides, beyond the restriction to reduced-risk pesticides under the limited terms of the pilot.

Anyone interested in the background leading up to the pilot program, or other related documents, may wish to review the announcement of the pilot, and the related documents. EPA considers the comments on the pilot program to be part of the administrative record for this rulemaking. A public docket was established for that announcement under docket ID number EPA–HQ–OPP–2002–0231. Interested parties should follow instructions under **ADDRESSES** for accessing the docket, but should use docket ID number EPA–HQ–OPP–2002–0231 to access the docket for the April 24, 2003, announcement.

B. September 2004 Proposed Rule

EPA published a proposed rule on September 3, 2004 (69 FR 53866) (FRL–7371–3). The proposed rule included proposals for the two revised practices in the pilot program, but without the limitation to reduced-risk pesticides, as well as a number of minor administrative revisions. Key public comments and Agency responses are briefly summarized in Unit V. of this document and, more completely, in a separate Response to Comments document available in the public docket.

Those interested in seeing the proposed rule, related documents, and public comments submitted may access them in the docket. A public docket was established for this rulemaking under docket ID number EPA–HQ–OPP–2004–0038. Interested parties should follow instructions under **ADDRESSES** for accessing the docket.

C. Summary of Pilot Experience

The pilot was started on April 24, 2003, and will not be extended for the 2006 growing season as it is being superceded by today's final rule. Applicability of the pilot was restricted to ''reduced-risk'' pesticides in order to limit the scope and effectively add an additional margin of safety while the new procedures were tested. Although participation in the pilot was limited, the process worked well for both applicants and EPA.

For the 2003 growing season, 16 exemptions were identified by EPA as eligible for re-certification, of which 7 submitted re-certification applications. In 2004, 12 exemptions were eligible, of which 4 applied by re-certification, while in 2005, 10 exemptions were eligible for re-certification and 6 used the process. EPA made expedited decisions on re-certification requests under the pilot in an average of 9 days in 2003, 14 days in 2004, and 8 days in 2005, counted from receipt of the request until the decision was made. Of the exemptions that were eligible but for which no re-certification was submitted, some were for pesticide uses that had obtained federal registration under FIFRA section 3 since the previous year's exemption, some were not requested at all (indicating that the

emergency ended), and the others were requested using conventional exemption requests.

The revised approach to determining an SEL applied to any new exemption request, as long as the requested chemical was designated as reduced-risk. However, for all 3 years of the pilot, EPA voluntarily conducted economic evaluations of exemption requests using both the current approach of historical 5–year data, as well as the proposed new loss-based (tiered) approach. This experience indicates that the new approach will not cause EPA to find SEL more commonly, nor expand the definition of emergency. A retrospective analysis to develop the loss-based approach, covering 2000 through 2003, showed that approximately the same number of requests would result in an SEL finding using the new, loss-based approach as actually occurred under the existing approach. The new criteria will, in most cases, reduce applicants' data burden and thereby streamline the exemption process.

V. Public Comments, EPA Responses, and Modifications for Final Rule

This unit briefly discusses the major public comments received on the proposed rule, EPA's responses to those comments, and changes made in the final rule as a result. All comments leading to modifications to the proposed revisions for the final rule are included here, as are opposing comments on the same issues, and comments opposed to proposed revisions for which modifications were not made. A more detailed, complete summary of public comments and Agency responses is available in a separate document in the public docket for this rule. That document also addresses comments and responses on the April 2003 document that announced the pilot program.

A total of 28 submissions of public comments on the proposed rule were received. A total of 41 commenters were represented by these comments, as some were submitted jointly by multiple parties. For ease of discussion and a better understanding of the sources of the various comments, commenters are grouped according to the type of organization or interest. The number of comment submissions on the proposed rule, by type of commenter are: Two by education/research groups; 3 by agriculture/food industry groups; 1 by environmental/public interest groups (joint submission by 13 groups); 12 by grower groups; 2 by pesticide industry/registrants; 1 by a private citizen; and, 10 by States (9 State lead pesticide regulatory agencies and 1 by the American Association of Pesticide Control Officials, which represents the States in pesticide regulatory matters).

Generally, all except for the environmental/public interest groups and the private citizen favored both of the two primary proposals, although a few only commented on one of the two, and some suggested modifications. The 13 environmental/public interest groups and the private citizen were opposed to both of the primary revisions, but the environmental/public interest groups also suggested some modifications to the proposals.

All changes made in the final rule relative to the proposed rule are explained in this unit, while a summary of all provisions of the final rule is in Unit VI. EPA decided to make these changes to the proposed revisions after considering public comments on the proposed rule. Each substantive comment is briefly paraphrased, followed by EPA's response to that comment. Where multiple commenters made a substantially similar comment, it is stated once, with an indication of how many made the comment and the types of organizations the commenters represent.

This unit is organized into separate sections for the two main provisions of the final rule, a section on all other aspects of the rule, and a section on miscellaneous comments not covered in the first three sections. Within each section, one or more issues raised by commenters is addressed. For each issue, all applicable comments are presented, followed by EPA's response, including the resulting modification to the proposed revision, if any, and the rationale for making the change or not.

A. Re-certification of Emergency Condition by Applicants

EPA has significantly reorganized § 166.20(b)(5) for improved clarity, but no substantive changes relative to the proposed rule are intended, except as discussed below.

1. *Commenter Issue: Allow re-certification beyond third year*—(a) *Comments requesting modification to proposal*. The proposed rule would have allowed re-certification applications only in the second and third years of an exemption for an applicant, assuming the exemption met the eligibility criteria (e.g., type of emergency condition that could reasonably be expected to continue). Many commenters stated that eligibility to use a streamlined re-certification application for repeat requests should not be limited to the second and third years of an exemption, but rather be longer or indefinite, as there is no compelling reason to limit it to 3 years. These commenters argued that re-certification is specifically and solely for the purpose of determining the existence of an emergency condition, and that EPA could still decline a valid re-certification application based on new risk information, availability of new alternative controls, or insufficient progress toward registration of the requested use.

In addition, full registration of a pesticide product often takes longer than 3 years, particularly for minor uses, even when States move expeditiously to identify the need. The commenters felt that States and affected growers should not be penalized when registration actions take more than 3 years. Commenters who supported allowing re-certification beyond the third year suggested various alternative limitations, including no limit. These general comments were made by 22 commenters (9 grower groups, 7 State lead agencies, 2 education/research groups, 2 agriculture/food industry groups, and 2 pesticide industry/registrants).

(b) *Opposing comments*. Other commenters felt that applicants should not be allowed to re-certify emergency conditions at all. They stated that repeat conditions are routine, and therefore not an emergency, as defined in the regulations. These commenters believe that repeat requests reflect poor management by growers and that repeat exemptions should be more difficult, not easier, to obtain. They contend that EPA already grants too many repeat exemptions and ignores progress-toward-registration requirements. Allowing applicants to re-certify emergency conditions would only make matters worse. These comments were made by 13 environmental/public interest groups in a joint submission, and by one private citizen.

(c) *EPA Response, including decision on re-certification limits*. EPA has carefully considered the comments summarized above concerning whether, and how long, to allow re-certification applications. The Agency is convinced not only that the re-certification process will provide the intended benefits of reduced burden and potentially quicker emergency response without negative consequences, but also that it would afford the same benefits in subsequent years as it would in the second and third years. Therefore, benefits would increase with the greater applicability of this improved process. Any specific limit to the number of years of eligibility for re-certification would be arbitrary. Therefore, in the final rule EPA has chosen to remove the applicability

restriction for re-certification that would have limited it to the second and third years.

However this modification to the proposed 40 CFR 166.20(b)(5) includes the authority for EPA to declare an exemption ineligible for re-certification at any time, on a case-by-case basis. In determining whether to end eligibility for re-certification, the Agency will consider the continued validity of the information, generally from the original application, that documents the projected losses, as well as whether any of the other information needs to be updated. If EPA decides that updating the documentation of an SEL is likely to significantly improve the projected loss estimates, or, if any other information casts doubt on whether the initial conditions still exist, then the Agency may declare the exemption ineligible for re-certification. The applicant for any exemption that is ineligible for re-certification may use a standard, full application format.

In response to comments questioning whether re-certification, or any repeat exemption requests, should be allowed at all, EPA has recognized for many years that an emergency may continue for multiple years when the emergency condition continues relative to the routine situation prior to the first occurrence of the emergency. This most commonly occurs when a pesticide, formerly relied upon by growers, becomes unavailable for use or loses effectiveness and no other effective means of pest control is available. Such a situation would generally continue until an alternative control becomes available, e.g., an effective alternative pesticide becomes registered for the use (often the chemical requested for the exemption), or an effective alternative non-chemical control becomes available.

The ability to indefinitely re-certify emergency conditions is not expected to increase the number of exemption requests submitted or the number of exemptions granted. EPA expects that when an emergency condition continues in a subsequent year, States would submit a repeat application regardless of whether a streamlined or full application were required. This rule reduces the burden in such situations. EPA believes that the reduced burden afforded by this rule would not induce applicants to make a repeat request.

Re-certification that an emergency condition continues to exist, for a previously granted exemption, would be part of a streamlined application for an emergency exemption. If the same emergency condition exists in a subsequent year that existed for the first year of an exemption, then EPA would generally again find that the emergency condition exists, regardless of whether a full application or a re-certification application were submitted. A re-certification application would simply reduce the burden on the applicant and help the Agency make the emergency determination more quickly. However, a determination by EPA that an emergency condition exists is not sufficient basis for an exemption to be approved. A re-certification application is no more likely to be approved than a full application for the same repeat request. Like a full application, a re-certification application would also be reviewed for, and could be denied owing to any of the following: New risk information; availability of new, effective alternative controls; or insufficient progress toward registration of the requested pesticide use.

Some commenters believe EPA grants too many repeat exemptions and that some exemptions are repeated for too many years. EPA would like to limit the number and length of long-running exemptions, and is pursuing new opportunities for minimizing such outcomes. Each year, EPA makes registration decisions on a large number of pesticide uses sought separately by State applicants under the emergency exemption program. For the fiscal years 2001 through 2004, EPA transitioned 313 uses to federal labels that had been requested under the section 18 exemption program, thereby precluding further repeat exemptions for those uses. These products are registered after a comprehensive analysis of the risks posed by these uses.

In addition, the Pesticide Registration Improvement Act (PRIA), enacted in early 2004, established time limits for EPA to make decisions on registration actions under section 3 of FIFRA which should further accelerate the pace of registration decision-making for all actions. Because of the emphasis within PRIA on review schedules, EPA is processing registration decisions more quickly than in the past. Pesticide uses that are requested for repeat exemptions will either gain registration more quickly than in the past, or their registration application could be not granted or denied in the same timeframe. The congressionally mandated review schedules under PRIA all become shorter and more compressed in upcoming years. For instance, the Agency's available review period for a new food use for a conventional pesticide goes from 38 months in FY 2004 to 22 months in FY 2006. Similarly, the review schedule for each type of registration action becomes shorter in later implementation years of the law. Although PRIA shortens the timeframe for registration decisions, the law also provides more resources through registrant fees and does not compromise the rigorous, comprehensive nature of the risk analysis necessary to support each registration decision. In this manner, EPA expects that each registration action will be evaluated within the context of PRIA. Under the previous priority planning scheme, certain actions did not receive priority due to resource and policy considerations. Additionally, EPA is mandated to complete re-registration of older pesticides by the end of 2006. Remaining decisions on eligibility to re-register pesticide products are also expected to affect repeat exemptions, leading to the denial of some and paving the way for the registration of others.

The Interregional Research Project No. 4 (IR-4) program is a highly successful cooperative effort and partnership of the State land grant universities, industry, the U.S. Department of Agriculture (USDA), and EPA, to address the chronic shortage of pest control options for minor crops. In many cases, the crop protection industry lacks economic incentive to pursue registrations on minor crops because of low acreage and limited sales potential. IR-4 generates and supplies research data needed by EPA in order to register compounds for use on minor crops. The IR-4 process continues to improve, and registrations for repeat exemptions are among the highest priorities in the IR-4 queue. In 1999, IR-4 initiated a streamlined project schedule of 30 months for its highest priority clearance projects. Pest management gaps associated with section 18 applications qualify for this highest priority schedule of 30 months. IR-4 is also increasingly performing research on pesticides which are presumed to pose less hazard than traditional synthetic chemicals. Over three quarters of the pesticides IR-4 evaluates and then submits for review to EPA are classified as reduced-risk materials under the Agency's programs for supporting transition to lower toxicity and sustainable means of pest management. Additionally, the review schedule under PRIA also favors and places a bias in support of submissions involving reduced-risk pesticides. For instance, the Agency's review time period under PRIA for a new use of a conventional pesticide in FY 2006 is 22 months whereas the review period for a reduced-risk pesticide in FY 2006 is 20 months. These incentives could help IR-4 and its collaborators realize a large

number of clearances. EPA anticipates that the processes discussed above will further enhance recent successes in registering repeat uses faster, as well as ensure that regulatory evaluations for any pending registration actions associated with a section 18 use will take place efficiently.

EPA has authority under § 166.32 to revoke any exemption during its active use period, if the Agency learns that the emergency no longer exists, the risks are unacceptable, the use is not effective, or users are not complying with the terms and conditions of the exemption. When necessary and appropriate, this provides another means to end long-running exemptions quickly, without waiting for an exemption to expire.

2. *Commenter Issue: Make voluntarily canceled pesticides ineligible for re-certification*—(a) *Comments requesting modification to proposal*. Some commenters felt that voluntarily canceled pesticides should be added to the list of pesticide categories for which, when requested for an exemption, the applicant is not eligible to use a re-certification application. The proposal already lists several categories of pesticides (e.g., new active ingredient, first food use, canceled pesticides) that warrant heightened review and public notice, and are therefore not eligible for re-certification. These commenters contended that EPA should not allow re-certification for voluntarily canceled pesticides. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments*. No other comments were received on the issue of pesticide categories ineligible for re-certification.

(c) *EPA Response, including decision on modification*. The proposed rule listed several categories of pesticides as ineligible for re-certification. Specifically, the existing regulations at 40 CFR 166.24(a) identify a number of situations where, upon receipt of an application for an emergency exemption, the regulatory status of a pesticide product calls for public notice and comment. EPA believes there is a legitimate need for heightened review and awareness of exemption requests with the listed regulatory statuses. Both the notice-and-comment requirements as well as the need for heightened review would preclude the benefit of an expedited review that would otherwise be expected from a re-certification application. The categories proposed as ineligible for re-certification include new pesticide active ingredients, first food uses, canceled or suspended pesticides, and pesticides that have been the subject of a Special Review. Because a pesticide that has been voluntarily canceled by its registrant may be similar to these other categories of pesticides, the Agency agrees with this comment and believes this category of pesticide uses should also be ineligible for re-certification. Therefore, the proposed 40 CFR 166.20(b)(5) is modified accordingly in the final rule. Also, EPA is expanding the provision for 40 CFR 166.24 to add this category of pesticide uses to those for which EPA will issue a Notice of Receipt. Therefore, a Notice of Receipt will be published in connection with the submission of emergency exemption uses that involve pesticide uses which have been voluntarily canceled. Therefore, while applicants may still request exemptions for a voluntarily canceled pesticide, the streamlined re-certification application process will not be allowed for such uses.

3. *Commenter Issue: Add to documentation requirements for repeat exemptions*—(a) *Comments requesting modification to proposal*. Some commenters suggested that repeat applicants should be required to document at least:

(i) What effect the exemption had on the emergency condition during the first year,

(ii) Why the exemption continues to be necessary,

(iii) That there are no feasible non-chemical alternatives, and,

(iv) That the original predictions of economic harm are legitimate. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments*. No other comments were received on the issue of modifying the documentation requirements for repeat exemption requests.

(c) *EPA Response, including decision on modification*. EPA's responses below correspond to the lettered list of the commenters' suggested documentation requirements for repeat requests:

(i) Annually, in a post-exemption report per § 166.32, and with any repeat application per § 166.20(a)(11), applicants will still be required to include a description of the effect the exemption had on the emergency condition.

(ii) A re-certification application must contain a certification that the same emergency condition previously documented continues and is the reason the exemption continues to be necessary.

(iii) EPA believes that the applicant is in a better position than the Agency to identify availability of a non-chemical alternative, i.e., cultural practice, for the specific use in their State. EPA agrees that it would be appropriate to have applicants (which are primarily State agencies) for repeat exemptions document availability and effectiveness of new non-chemical controls identified since the previous year's application, or to certify that none are known. Therefore, in the final rule EPA has added a requirement, at § 166.20(b)(5)(v)(E), that applicants certify that they are not aware of any alternative non-chemical practice that may offer a meaningful level of pest control, or else provide documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible. In situations where such effective and feasible cultural practices are available, EPA would not grant the exemption because there would not be an emergency condition, by definition.

(iv) One way to validate the reasonableness of the estimated losses would be to allow them to happen, i.e., to grow the crop under the emergency condition without use of the requested pesticide. EPA already has the discretion to grant a repeat exemption subject to the condition that some research areas be grown under the emergency condition without use of the requested pesticide, although such validation has generally not been required. Occasionally, confirmatory data, such as comparative product performance studies, are required on repeat requests. The re-certification program would not alter this practice. Furthermore, re-certification requires that other economic factors that result in a projection of an SEL (e.g. cost of alternative, crop prices) have not changed substantially, and that there is no new information about pest damage.

B. Determining and Documenting "Significant Economic Loss" (SEL)

1. *Commenter Issue: Lower quantitative thresholds for SEL, add flexibility*—(a) *Comments requesting modification to proposal*. Some commenters said that the thresholds for the three tiers for determining SEL should be lower, as the proposed thresholds require total elimination of net income to qualify. Also, EPA should be allowed flexibility to use judgement to make an SEL finding for situations not meeting any of the thresholds. Commenters argued that total elimination of annual net income is too severe a threshold, and that some lesser loss constitutes a significant economic loss. These commenters feel the three tiers should be screens to identify obvious emergencies, and that flexibility, which does not clearly exist

in the proposed rule, should be added to identify the less obvious emergencies. No commenter suggested an alternative level for any threshold, or a basis on which to develop one. This general comment was made by 17 commenters (9 grower groups, 4 State lead agencies, 2 agriculture/food industry groups, and 2 pesticide industry/registrants).

(b) *Opposing comments*. Other commenters felt that the proposed quantitative thresholds for determining SEL are already too low. They stated that the proposed tiered approach to document an SEL with the selected thresholds would unreasonably expand the definition of emergency and make it easier to find that an emergency exists. These commenters felt that the proposed method allows prohibited pesticide uses for profit. They assert that the proposed new approach together with the quantitative thresholds for the three tiers are unlawful, arbitrary and capricious, and contrary to congressional intent. This comment was made by 13 environmental/public interest groups in a joint submission.

(c) *EPA Response, including decision on modification*. After considering all comments, EPA believes that the proposed thresholds are appropriate and should not be relaxed, but that flexibility should be available to allow EPA to use judgement to make an SEL finding where projected losses are particularly difficult to quantify or other factors warrant an emergency exemption. Some commenters concluded that the proposal provided no flexibility for EPA to use judgement to determine an SEL for situations not meeting any threshold, regardless of how close to a threshold quantitative loss projections may come. To the extent that this comment reflects a concern that EPA would consider only quantitative data in determining whether the loss thresholds are met, EPA notes that it interprets the language of both the proposed and final rule to allow for consideration of estimates based on qualitative information, either alone or in addition to quantitative information, in determining whether losses under the emergency condition would exceed the thresholds for SEL. However, EPA intends to limit the use of qualitative information to document projected losses, relying on such information only in cases where credible quantitative information is not available.

In response to the concern that the quantitative loss thresholds of § 166.3(h)(1) may not apply to all pest activity primarily affecting the current growing season, EPA has expanded § 166.3(h)(2) so that EPA may use its broader criteria wherever they are more appropriate. The proposed rule provided a loss-based approach with quantitative thresholds applicable to pest activity primarily affecting the current growing season under § 166.3(h)(1), and ''for all other pest activity'' included in a provision at § 166.3(h)(2) to determine an SEL for situations where the loss-based approach does not adequately address the expected loss, similar to a provision in the existing regulations. Such losses include those not confined to the current year or those that impact capital assets rather than productive activities. This change to § 166.3(h)(2) will allow the flexibility to apply an appropriate methodology for assessing the consequences of an emergency, and help ensure that any of the widely variable situations potentially causing an SEL can be adequately addressed.

Although no commenter addressed the issue, EPA has corrected the scope of the proposed SEL definition. The SEL criteria under the proposed § 166.3(h)(1) would have applied to ''pest activity that primarily affects the current crop.'' For the final rule ''or other output'' is added after ''current crop,'' so that non-crop productive activities (e.g., dairy production) may also be assessed under the loss-based, tiered approach. For the same reason, EPA has removed the word ''crop'' from §§ 166.3(h)(1)(i) and 166.20(b)(4)(i).

As explained above, some commenters believe that the proposed thresholds for SEL are too high, arguing that these thresholds effectively require total elimination of net income to qualify. Other commenters believe that the proposed thresholds make it easier to find that an emergency exists, allowing unregistered pesticide uses for profit. Actually, the selected thresholds neither raise nor lower the standard for SEL. EPA's retrospective analysis of past exemption requests, discussed in the Economic Analysis available in the public docket for this final rule, shows that the new approach would not make SEL findings any more common and would not otherwise expand the definition of emergency. The analysis indicates that virtually the same number of requests would result in an SEL finding using the new approach as actually occurred under the current approach, although different findings (in both directions) may occur in some individual cases.

Although the new tiered approach for determining SEL maintains the same overall standard to qualify, its fixed, quantitative thresholds intentionally make the standard consistent, in contrast to the current variable standard. However, the fixed SEL standard allows an easy comparison of the quantitative thresholds to farm income statistics. It is true that, according to USDA statistics, the new thresholds for SEL are roughly equivalent to elimination of net farm income from the affected crop, if fixed costs are also considered. Because the new SEL standard is comparable to the average of the current standard, for the first time it is apparent that the current standard is approximately equivalent to elimination of net farm income. However, when the States recommended revising the approach to determining SEL, their stated reason was to establish a fixed standard that is more equitable and easier to document. EPA had extensive interaction with stakeholders during the development of this rule, but received no input saying that the existing standard for SEL was too high.

EPA acknowledges that economic terms such as ''net revenue'' and ''net farm income'' may be confusing and are not always used the same way by all parties. Although the proposed threshold for the third tier for SEL is 50% of ''net revenues,'' as defined in the preamble to the proposed rule, this is not equivalent to ''profits'' because it does not include fixed costs. For the purpose of this rule, EPA defines net revenue as gross revenue less variable operating costs. A calculation of ''profit'' would typically subtract fixed costs from this amount. In this case, ''profit'' is roughly equivalent to the gross pay of a typical salaried employee and is essentially the return to the farmer's labor and managerial skills. This is also referred to as ''net farm income.'' If typical fixed costs were included in the consideration of impacts on income, a loss of 50% of net revenues (Tier 3 threshold) would, according to USDA statistics, result in approximate elimination of net farm income. With this as the context for the SEL thresholds, EPA believes that there is no basis for concern that farmers might unduly profit from emergency exemptions.

Section 18 of FIFRA provides broad discretion for EPA to define and determine, by regulation, when an emergency exists. The Agency believes that the new approach and thresholds are not arbitrary or capricious, as they are essentially refinements to make the standard that has been used for years more uniform and equitable, without raising or lowering it. Furthermore, while this standard may seem severe to some, the standard for SEL was always intended to identify and avert true economic emergencies, and was not intended to maintain farm income at or

near a certain level. EPA believes that there should be a high standard for allowing an exemption from the requirements of registration. Even if EPA were to consider a lower standard, the Agency is not aware of a basis for selecting a lower standard that would not be arbitrary.

C. Other Regulatory Provisions

1. *Commenter Issue: Confirm efficacy and economics of non-chemical alternatives*—(a) *Comments requesting modification to proposal*. Commenters stated that EPA should use section 18 to promote Integrated Pest Management (IPM) by confirming the efficacy and economics of non-chemical alternatives for pesticide uses requested for an emergency exemption. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response, including decision on modification*. The existing § 166.20(a)(4)(ii) already requires applicants to explain why alternative practices would not provide adequate control or would not be economically or environmentally feasible. Some time after this final rule is issued, EPA plans to provide new guidance for applicants to improve the quality and consistency of information submitted on non-chemical alternatives. Although EPA supports and encourages IPM and use of risk-reducing, alternative, non-chemical controls, as evidenced by the Agency's voluntary Pesticide Environmental Stewardship Program, the Agency does not directly regulate cultural practices. For this reason and because applicants are typically State agricultural agencies, EPA believes that the applicant is in a better position than the Agency to identify availability of a non-chemical alternative practice for the specific use in their State, and to assess its effectiveness and feasibility. In this final rule, a new provision has been added at § 166.20(b)(5)(v)(E) to require that applicants using the re-certification process separately certify that they are not aware of any available chemical alternatives or reasonable non-chemical alternative practices, or if they know of any such practice that they include with the application documentation demonstrating that the chemical or practice does not provide adequate control or is not economically or environmentally feasible.

2. *Commenter Issue: Clarify or improve notification/confirmation for crisis exemptions*—(a) *Comments requesting modification to proposal*. Commenters stated that for crisis exemptions, the proposal to have applicants notify EPA and receive verbal confirmation from the Agency of no risk-based objections before using the crisis provisions needs clarification and possible revision. The proposal says that EPA will attempt to provide such confirmation as quickly as possible, and within 36 hours. Commenters stated that they may not be able to reach the appropriate EPA contact on a Friday, a weekend, or a holiday, which could delay confirmation and use of the crisis exemption until 36 hours after the beginning of the next work day. They suggest that EPA make someone available at all times, or, add a provision that notification can be made by voicemail, and a consent by default would be assumed after 36 hours if the applicant has not heard back from EPA by that time. One commenter also suggested that EPA should make exceptions to the 36–hour waiting period for EPA confirmation for some uses, including public health crises, bioterrorism attacks, and non-food uses. This comment was made by two State lead agencies.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response, including decision on modification*. The reason for this revision is to replace the current ambiguous language at 40 CFR 166.43(a), which allows for the possibility of a State or federal agency notifying EPA after beginning use of the crisis provisions. The revision will codify a process that has been widely practiced and accepted by applicants, and that has become more necessary after enactment of FQPA. FQPA expressly required that time-limited tolerances be established for emergency exemption uses that may result in residues in food. EPA maintains that it is in the best interest of all parties (including States, EPA, users of pesticides under section 18, the food processing and marketing industries, etc.) that there is some assurance before the use begins that EPA will be able to establish a ''safe'' tolerance for a pesticide to be used under a crisis exemption. Without that assurance, users run the risk of producing an adulterated crop that results in unsafe pesticide residues and would be illegal to sell. It is also important that EPA be given the opportunity to voice other objections to a use being considered for a crisis exemption. The Agency may be aware of risk issues unknown to the applicant, and has the authority to deny crisis provisions for a particular pesticide use, under § 166.41(a).

EPA is keenly aware of the time-sensitivity of emergency situations for which crisis exemptions are needed. The Agency will continue to make every effort to receive and quickly respond to notifications of intent to declare a crisis. EPA believes that the concerns raised by these commenters can be adequately addressed in the same manner that EPA has managed these issues since enactment of FQPA. It is true that EPA staff are not available at all times, such as at night or during weekends, to receive notification of a State's intent to declare a crisis. However, EPA believes that applicants generally first become aware of the need for a crisis exemption at least a few days before notifying EPA of its intent to issue a crisis exemption. If an applicant notifies the Agency of their intent to declare a crisis as soon as possible, even before they have gathered all of the necessary information, EPA should be able to provide confirmation before use of the pesticide is needed. The Agency believes that the existing confirmation process now being codified has not caused significant delays to use of crisis exemptions in the past. In fact, there have been cases where EPA staff have worked with applicants during weekends in order to provide timely confirmation, and in extraordinary circumstances EPA will continue to do this in the future. A default presumption of no EPA objection to a crisis exemption, in cases when the Agency cannot be immediately reached, would provide neither the necessary assurances for users of the pesticide, nor proper protections for human health and the environment.

EPA is not taking the commenter's suggestion that an exception to the need for EPA confirmation be made in cases of non-food uses, or public health or bioterrorism threats. For non-food uses, EPA can generally provide confirmation more quickly than for food uses, but must still be allowed the opportunity to identify other unacceptable risks. In the case of major public health threats or bioterrorism, a national emergency network and system is in place that will enable applicants to contact EPA at any time, and EPA will quickly respond. Through the National Infrastructure Protection Plan, as part of a network of federal, State, and local governments, agencies can quickly contact EPA whenever a public health threat arises, including terrorism. In such cases, the Agency expects to be able to act very quickly and at any time. For certain listed biological threats, there is an expedited process in place whereby, once notified of the emergency need for an unregistered pesticide or use, EPA would evaluate the applicant's remedial action plan and, after considering the

safety and efficacy of such use, would decide whether to issue a crisis decision.

The Agency has modified the proposed language at § 166.43(a) for the final rule, to remove references to EPA's confirmation and the 36–hour time period, as it is not appropriate in this paragraph for notification by applicants to EPA. EPA will strive to provide the confirmation as quickly as possible and within the customary 36 hours, and will attempt to match the urgency of decision-making with the urgency of the situation. This final rule does not attempt to change the timeframe in which EPA provides confirmation. The Agency's practice will continue that the 36–hour clock does not start until EPA actually receives and acknowledges the notice, and only applies to business days. The lack of a response in 36 hours should not be interpreted as approval of the crisis exemption; this final rule does not include decision by default. The language in the proposed § 166.40(c) is modified for this final rule to allow EPA to withhold confirmation due to any objection, not just risk-based objections.

D. Miscellaneous Comments

Protections for endangered species under the emergency exemption program and pest resistance management issues are discussed in Unit VIII. These are important issues that were discussed in the preamble to the proposed rule, but for which no regulatory revisions were proposed. Some comments received on these issues are addressed in Unit VIII, while other significant miscellaneous comments are included below.

1. *Commenter Issue: The section 18 pilot violates the Administrative Procedure Act*—(a) *Comment summary*. Commenters stated that the section 18 pilot violates the Administrative Procedure Act (APA) as a binding regulation without notice and comment. These commenters went on to say that EPA solicited public comment on the pilot provisions in the **Federal Register** Notice that initiated the pilot, but failed to respond to those comments. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response*. The comment that the pilot violated the APA is not relevant to the proposed or final rule and to whatever extent it might have been relevant to the pilot program, the issue is moot because EPA has ended the pilot program. EPA disagrees with the comment because the section 18 pilot program was not a binding regulation and did not require notice and comment rulemaking under section 553 of the APA. EPA believes that participants in the section 18 pilot program conformed to the requirements of the Agency's existing regulations pertaining to emergency exemption requests at 40 CFR part 166. The purpose of the pilot was to gain experience and gather information for the rulemaking on improvements to the section 18 process. The pilot was intentionally limited in scope. During the course of the pilot, less than 5% of all applications received were eligible for the pilot and utilized its provisions. No applicant was required to use the pilot. EPA is confident that the pilot's standard for an emergency finding was no higher or lower than the current standard. The risk side of the assessment and decision process was not changed for the pilot. Furthermore, an additional safety margin was essentially added to the pilot by limiting application to ''reduced-risk'' pesticides.

During development of the proposed rule, EPA carefully considered public comments received on the **Federal Register** Notice that initiated the pilot. Those comments and EPA responses are summarized in the separate response-to-comments document that also addressed comments on the proposed rule and is available in the public docket.

2. *Commenter Issue: Documentation for endangered species needs clarification*—(a) *Comment summary*. Commenters stated that documentation requirements for endangered species concerns in emergency exemption requests need clarification and further guidance. They also said that EPA, the U.S. Fish and Wildlife Service and the National Marine Fisheries Service have data on endangered species that States do not have, and these federal agencies should either provide such data, or make it readily available to States. One commenter suggested that when measures are necessary to protect endangered species, EPA should involve the State early (before decision). This comment was made by three State lead agencies and by AAPCO.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response*: EPA believes that an important aspect of assuring protections of endangered and threatened species in the implementation of the emergency exemption program is to have available good information on the potential exposure and risk of a requested use to a listed species and its habitat. Some time after promulgation of this final rule, EPA plans to issue improved guidance on what information regarding threatened and endangered species should be included with an application. EPA will continue to involve applicants in the discussion of possible mitigation measures whenever it appears that threatened or endangered species may be at risk.

VI. Final Rule Revisions to Emergency Exemption Process

While Unit V. summarizes changes in the regulatory provisions of the final rule from those in the proposed rule, Unit VI. summarizes how this final rule revises the existing regulations at 40 CFR part 166 that govern the emergency exemption process.

A. Re-certification of Emergency Condition by Applicants

1. *How the re-certification process will work*. This final rule adds a new paragraph (b)(5) to 40 CFR 166.20 that allows applicants for eligible repeat exemptions to submit streamlined ''re-certification'' applications. The re-certification application process applies only to specific exemptions, and is not available to applicants for quarantine exemptions, public health exemptions, or crisis exemptions. In addition, re-certification can only be used if the same exemption was approved for the same applicant the previous year, or use period, and meets other eligibility criteria discussed below. Subject to limitations specified in § 166.20(b)(5) and discussed below, where an emergency condition that originally qualified for an emergency exemption continues in a subsequent year, eligible applicants may re-certify that the same emergency condition continues and rely on the preceding year's submission to document the economic impact of the pest emergency. This re-certification approach allows applicants to incorporate by reference all information submitted in a previous application, instead of submitting a complete new application and supporting documentation. The re-certification of the emergency condition by the applicant combined with other information available to EPA will serve as the basis for EPA's determination as to whether an emergency condition continues to exist.

While a re-certification application may allow for speedier preparation of exemption requests and quicker determinations by EPA that an emergency condition exists, it will not result in automatic granting of an emergency exemption. In addition to an emergency finding, before granting an exemption EPA must also determine that, among other things, there are no

effective registered alternatives to the requested pesticide use, no feasible alternative practices that provide adequate control are available, the requested pesticide use will not cause unreasonable adverse effects on human health or the environment, and there has been sufficient progress towards registration of the requested use. If an effective product has been registered for the requested use since the previous exemption was approved, an emergency condition may no longer exist. If the Agency has received new risk information since approving the previous exemption, then the risk will be re-evaluated. Likewise, if the request includes any change in the conditions of use that may increase exposure, such as application rate, number of applications, type of application, pre-harvest interval, re-entry interval, total number of acres, or change in the geographic area proposed for treatment, then the risk will also be re-evaluated. EPA may determine that sufficient progress towards registration has not been made for a requested pesticide use. The risk evaluation process for repeat requests is not changed by this rule.

Not all repeat exemption requests will be eligible for re-certification. Upon approval of any specific exemption, EPA intends to make an initial assessment regarding potential eligibility for a streamlined re-certification application the following year, in the event that the applicant reapplies the next year. EPA will consider the following in determining potential 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, and therefore not be eligible for re-certification, would include a temporary supply problem of a registered product, an isolated weather event, or a sporadic pest outbreak.

2. *Whether the pesticide product, owing to its regulatory status, warrants heightened review before any additional use is approved.* EPA will rely primarily 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. The first five categories listed below are from the existing 40 CFR 166.24(a), while the sixth is a similar category, added for the final rule, as discussed in Unit V.A.2. An applicant will be ineligible to use a re-certification application when the following categories of pesticides are requested for an exemption:

(a) A new chemical;

(b) The first food use of an active ingredient;

(c) Any use of a pesticide if the pesticide has been subject to a suspension notice under section 6(c) of the Act;

(d) A pesticide which:

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

(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);

(e) A pesticide which:

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

(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;

(f) A pesticide which:

(i) Contains an active ingredient which was contained in a pesticide product that was voluntarily canceled by its registrant, and

(ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the pesticide which was voluntarily canceled by its registrant.

Furthermore, EPA may declare that an exemption that was previously eligible for re-certification is no longer eligible. In determining whether to end eligibility for re-certification, the Agency will consider the continued validity of the information, generally from the original application, that documents the projected losses, as well as whether any of the other information needs to be updated. If EPA decides that updating the documentation of an SEL is likely to significantly improve the projected loss estimates, or, if any other information casts doubt on whether the initial conditions still exist, then the Agency may declare the exemption ineligible for re-certification. The applicant for any exemption that is ineligible for re-certification may use a standard application.

In instances where EPA determines that an exemption is potentially eligible for re-certification, EPA will advise the successful applicant that, should it reapply the following year, they appear eligible to use a re-certification application. EPA anticipates that this advice will 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 appears 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 appears eligible for re-certification provided the applicant submits the specified information. Finally, EPA reserves the authority to declare an emergency exemption ineligible for re-certification where, in the Agency's sole discretion, it determines that a complete application is necessary.

An acceptable re-certification application must include not only the applicant's re-certification that the emergency condition continues, but also its certification to several other specific facts, or be accompanied by additional information. An eligible re-certification applicant will be exempted from the information requirements of § 166.20(a)(1) through (a)(10), and of the existing § 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;

(v) The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or, if any, has provided documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible.

Applicants meeting the requirements of § 166.20(b)(5), as discussed above, would not need to submit new, updated documentation that the emergency condition continues or the data elements otherwise required under 40 CFR 166.20, except that the interim

report specified in § 166.20(a)(11) would still be required where a re-certification is filed before the final report on the previous exemption is available.

2. *Rationale for new re-certification process*. Allowing applicants for eligible exemption requests to recertify 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 potentially 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 administrative step of its review of the documents supporting the exemption requests. If no pesticides that could avert the emergency have been newly registered, no new non-chemical controls have been developed, and nothing has changed to affect the assessment of risk, then re-certification of an emergency will lead to significantly shorter Agency review.

For repeat exemption requests where the emergency situation has not changed, EPA's experience with full, annual applications indicates that projected yield and revenue losses are generally comparable to those found the first year and a significant economic loss is again found. This is reasonable since applicable losses are those resulting from the emergency situation relative to the situation prior to the first occurrence of the emergency. Therefore, with the applicant's certification that the emergency condition continues and that all information in the earlier application is still accurate, reliance on the previously submitted data and other supporting information should be adequate to support an emergency finding. Re-certification only alters the process for an emergency finding, whereas determinations of acceptable risk, availability of alternative controls, and progress toward registration are not changed by this final rule. With a re-certification application, the applicant and Agency must still address these other areas necessary to approve or deny the request, just as with a full application. Furthermore, the final rule provides that EPA may declare an exemption ineligible for re-certification at any time, should the Agency decide that a full application is more appropriate. For the reasons discussed above, EPA believes that the re-certification process will provide the benefits of reduced burden and quicker emergency response, without compromising either the quality of decisions or protections for human health and the environment.

B. Determining and Documenting ''Significant Economic Loss''

1. *How determination of significant economic loss (SEL) will work*. This rule re-defines ''significant economic loss'' at 40 CFR 166.3(h). Under the new definition, the method for determining the amount of the projected loss due to the emergency condition will not change, although the calculation will be done in steps (tiers) and sometimes the later steps will be unnecessary. However, the new definition of SEL changes how EPA will determine whether the loss is considered ''significant.'' The revised approach provides standard criteria for determining the significance of the projected 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. Successive screening levels (tiers) have been chosen that permit situations that clearly qualify to be resolved quickly, with a minimum of data. Each tier has a quantitative loss threshold that generally applies 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 requires more data and involves more analysis on how the emergency affects revenues.

Tier 1: Yield Loss - Tier 1 is based on quantity loss, i.e., crop yield or other output 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 is 20% for all situations. 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 is not necessary to separately estimate economic loss, which would require detailed economic data.

Tier 2: Economic Loss as a Percentage of Gross Revenues - A quantity or yield loss that does not satisfy the threshold in Tier 1 may nonetheless cause a significant economic loss because such loss alone may not reflect all economic losses. 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 or output 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 is 20% of gross revenue for all situations. 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 quantity nor economic losses are above the thresholds in Tiers 1 and 2, EPA will compare impacts to net revenues. Net revenues are defined for the purposes of this rule as gross revenues minus operating costs. The loss threshold in Tier 3 is 50% of net revenues for all situations. Emergency conditions that fall short of the thresholds in Tiers 1 and 2 may qualify as a significant economic loss in Tier 3, particularly for enterprises with high costs of production relative to gross revenue.

Applicants should 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 appear in § 166.20(b)(4)(i). If the projected loss does not meet this threshold, applicants should determine whether their projected loss meets the Tier 2 gross revenue threshold of § 166.3(h)(1)(ii), providing additional data as noted in § 166 20(b)(4)(ii). Failing to meet that threshold, applicants should submit the data to perform the analysis necessary for the Tier 3 net revenue threshold of § 166.3(h)(1)(iii) as given in § 166.20(b)(4)(iii). The three tiers established in § 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 allows an applicant to collect data, and build a case for significant economic loss, as needed and determined by the conditions, without requiring additional data. Applicants will continue to submit data to demonstrate the emergency nature of the pest outbreak including the basis for expected losses in quantity, and sometimes quality and/or additional production costs. However, applicants no longer need to submit historical economic data demonstrating variations in revenues, although historical data may be appropriate to define the baseline, routine, or ''without emergency'' scenario. The new guidance document that EPA is issuing in conjunction with this final rule includes a description of information that EPA expects applicants to submit in order to demonstrate an SEL.

This loss-based approach is designed to capture the economic impact of pest activity as it affects the current production season, which will be sufficient for most emergency exemption applications. Although § 166.3(h)(1) applies the loss-based approach to pest activity primarily affecting the current growing season, EPA has reserved the authority to use a case-by-case approach in the new § 166.3(h)(2). Where EPA determines that the loss-based approach of § 166.3(h)(1) would not adequately describe the expected loss, for example long-term losses in orchard crops, the Agency would continue to make its significant economic loss determinations based on other criteria (i.e., a substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity) where the applicant demonstrates significant losses that would not be recognized under § 166.3(h)(1).

2. *Rationale for revised SEL approach.* The revised methodology for determining an SEL is intended to streamline the data and analytical requirements for emergency exemption requests, and allow for potentially 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 believes that the loss-based approach better and more directly permits EPA to evaluate the significance of economic losses.

An analysis of past emergency exemption requests suggests that this revised approach will not cause a significant change in the overall likelihood of an SEL finding, although findings may differ in individual cases. The results of this analysis are discussed in the Economic Analysis of the final rule, available in the public docket. The analysis shows that in many cases an SEL can be adequately demonstrated with less data and without loss of reliability or flexibility through the revised methodology. The new approach is expected to lead to savings to both applicants and EPA from reduced data and analytical burdens. Under the new procedure, applicants may elect to submit the minimum amount of data necessary to demonstrate a significant economic loss in one of three increasingly refined tiers. If the first tier is sufficient, the burden is reduced most significantly, as it identifies the most obvious emergencies with less data. The loss-based approach requires 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. 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 approach is expected to save applicants time and resources in gathering data and preparing submissions. The Agency's burden should be reduced due to the simplified approach and clear, consistent thresholds.

Because the loss-based approach in today's final rule shifts the focus from annual price variability to actual pest-related losses, it is expected to lead to more consistent and transparent 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 new, loss-based 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.

C. Specifying Invasive Species as Targets under Quarantine Exemptions

Existing regulations describe four types of emergency exemptions, one of which is a quarantine exemption. The purpose of a quarantine exemption is stated in 40 CFR 166.2(b) as follows:

> (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 necessarily 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 existing regulations, probably because it was not widely used at the time 40 CFR part 166 was promulgated. This final rule adds the term ''invasive species'' to § 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. The rule also adds, at § 166.3(k), a definition of ''invasive species'' that is derived from that used in Executive Order 13112 (64 FR 6183, February 3, 1999).

D. Updating Administrative and Communication Processes

A number of minor revisions to 40 CFR part 166 are made with this final rule to correct errors or update administrative aspects of the emergency exemption regulations, particularly in light of the fact that the Food Quality

Protection Act (FQPA), which amended FIFRA and the FFDCA, was enacted since the regulations under part 166 were last revised. Each of these revisions is made 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 are non-substantive or reflect minor changes to the regulatory requirements, but all correct, improve, or update the regulations. The corrections of typographical or administrative errors or inaccuracies are self-explanatory. The 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 existing regulations predate FQPA and therefore do not reflect this requirement. Four revisions are made to bring 40 CFR part 166 into agreement with current practices as required by the FFDCA. Inasmuch as FFDCA section 408(l)(6) applies to all food-use emergency exemptions, regardless of whether its requirements are reflected in 40 CFR part 166, these 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, this rule amends § 166.3(e) to revise the definition of ''first food use.'' The existing definition includes an explanation that no permanent tolerance or food additive regulation has been established for such a use. The word ''permanent'' is removed in the revised definition so that any tolerance would be included, and the reference to ''food additive regulation'' is removed because, owing to the FQPA amendments, EPA no longer issues food additive regulations.

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

The third revision made necessary by FQPA is to add, under § 166.40, an additional limitation to the authority of a State or federal agency to issue a crisis exemption, namely, that they 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. This revision at § 166.40(c) also stipulates that all crisis exemptions be conditioned upon EPA confirming that it has no other objection to the use of the pesticide under the crisis provisions.

The fourth change is to remove from § 166.30(b) and § 166.47 the now-superfluous requirement that EPA directly notify the U.S. Food and Drug Administration (FDA), USDA, and State health officials. The original 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. Prior to FQPA, EPA did not routinely establish tolerances for food use pesticides applied under an emergency exemption program. This notification provision served to advise other agencies of the exemption and to support field enforcement activities. Now, however, with the FQPA requirement that time-limited tolerances be established in accordance with FFDCA section 408(l)(6), such levels are published in the **Federal Register**, along with detailed background regarding safety of these tolerances, as well as incorporated into 40 CFR part 180. Therefore, EPA considers providing separate notification to the other regulatory organizations (FDA, USDA, and State health officials) on an individual basis redundant to the **Federal Register** notice and incorporation of the regulatory decision in the appropriate section of 40 CFR part 180.

Several revisions are made in this final rule to codify minor improvements to the process that have been identified since the existing 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 § 166.20, ''Application for a specific, quarantine, or public health exemption,'' paragraph (a)(2)(i)(A) is revised so that an application must include a copy of the EPA-approved label for each specific pesticide product requested, instead of the existing requirement to include the registration number and name of the product. This will facilitate the review of applications.

Next, under § 166.20(a)(3), the final rule adds a new item, and revises several of the others, to specify that the conditions of use requested in an application must include the maximum number of applications, the period of time for which the use is proposed, and 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 in the past where it was not apparent from the application, EPA had to contact the applicant to obtain the information. Expressly requiring this information in § 166.20(a)(3) will expedite review of applications and allow tolerances to be established in an orderly fashion.

Additionally, this rule revises § 166.20(a)(9) 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 repeat 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. This final rule revises § 166.24(a)(6)(i) and § 166.25(b)(2)(ii) to relax this presumption for repeat emergency exemption applications for uses being supported by 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. In many cases, 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, a somewhat slower rate of progress towards registration is reasonable for emergency exemptions for uses being supported by the IR-4 program. Accordingly, this rule

revises § 166.24(a)(7)(i) and § 166.25(b)(2)(ii) 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 other, typically commercial, parties. For uses supported by parties other than IR-4, the 3-year presumption in the existing regulations remains in effect.

This rule revises § 166.30(a)(1) to reflect that EPA will not process incomplete applications, and that action on such submissions will be halted until required additional information is submitted.

The rule clarifies § 166.32(b) to ensure that applicants submit interim use reports for exemptions when requesting a repeated emergency exemption prior to the due date of the final report.

This rule also clarifies the authority of an applicant to issue a crisis exemption by specifying in § 166.40(a) that crisis exemptions are to be used only for unpredictable emergency conditions. This change is strictly for purposes of clarification, as the term ''unpredictable'' already appears in the introductory language of § 166.40, and does not represent any intention by EPA to change the criteria for crisis exemptions. This rule also adds a paragraph (c) under § 166.40, so that the state's authority to exercise the crisis exemption is stayed pending verbal confirmation by EPA that a tolerance can be established in a timely manner and that the Agency has no other objections.

This final rule also revises § 166.43(a)(1) 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. Section 166.43(a)(1) is revised to require advance notification for crisis exemptions by applicants. This replaces 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 will continue to provide the necessary verbal confirmations as quickly as possible, thereby often allowing use of the crisis exemption in less than 36 hours. This final rule does not attempt to change the customary 36–hour timeframe for Agency response to notification. 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. EPA believes that these requests can be reviewed in a timely manner through the appropriate use of OPP resources.

To clarify necessary information for a crisis exemption, this rule revises § 166.43(b)(1) and (b)(4), 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 the 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, this rule revises § 166.49(a)(1) through (a)(4) and deletes § 166.49(a)(5), to clarify information requirements, such as applicant, product used, site treated, and contact information.

VII. Implementation of Final Rule

This final rule becomes effective March 28, 2006. Applicants submitting exemption requests that are received by the Agency after publication of the final rule, but before the effective date, will have the option of using the revised approaches for re-certification or documenting an SEL, or using the outgoing application method and approach. Applications received by EPA after the effective date will be processed under the approach described in today's final rule. However, applicants for exemptions eligible to use a streamlined re-certification request may still submit a full application, even after the effective date. EPA recognizes that persons who have previously obtained emergency exemptions have not yet been advised whether those emergency exemptions are eligible for the re-certification program. The Agency will use submissions received in fiscal year 2005 as the baseline year for evaluating whether emergency exemptions are eligible for the new re-certification program. As soon as possible, and before the effective date of this final rule, EPA intends to share with applicants and post on its web page a list of candidate exemptions that appear to Agency reviewers to be eligible for the re-certification program. Applicants that believe an exemption is eligible for re-certification may submit a re-certification application prior to EPA's release of the eligibility list. However, upon receipt, the Agency must agree that it was eligible for re-certification in order to process the request in that fashion.

Applications that have already been received by EPA as of today's publication date, January 27, 2006, will be processed and reviewed in the context of the existing framework and authorities, unless the applicant submits a replacement request under the provisions of the final rule. The section 18 pilot program is terminated as a result of the promulgation of this final rule.

Mindful that this national program has many stakeholders, EPA plans to provide training on how this final rule affects the application, review, and approval process for emergency exemptions. EPA intends to hold public meetings and develop information materials to help applicants comply with this final rule and help others understand its new provisions. A guidance document concerning the re-certification process and the new, loss-based approach for determining and documenting an SEL is being issued in conjunction with this final rule. EPA plans to issue new guidance on other aspects of the final rule, or revised guidance on other areas, in the future as it is needed and available.

VIII. Related Issues and Emergency Exemption Program Context

A. Pest Resistance Management

The April 24, 2003 **Federal Register** Notice, that initiated the pilot to test the re-certification and revised SEL processes, indicated that EPA was considering addressing pest resistance management (RM) in this rulemaking. However, after carefully considering public comments on that Notice and re-considering the possibility of emergency exemptions for the purpose of resistance management, EPA decided not to include such a change in the proposed rule. Additional comments on this issue were received in response to the proposed rule and considered by the Agency. EPA believes that section 18 is an inappropriate avenue for addressing the worthy goal of managing pest resistance, for several reasons.

Some who commented on the proposed rule also stated that exemptions for the purpose of RM should be allowed. Some commenters said that although the recently enacted Pesticide Registration Improvement Act (PRIA) may help bring more RM tools to

market sooner, it will not be sufficient to address the lack of RM tools, particularly for minor crops. While these commenters recognize the need to prevent abuse of RM exemptions, and the difficulty in developing clear criteria for approval of an exemption for RM, they believe that there is ample middle ground between liberally allowing RM exemptions and allowing no such exemptions. This general comment was made by 19 commenters (nine grower groups, four State lead agencies, two education/research groups, two agriculture/food industry groups, and two pesticide industry/ registrants).

Virtually all commenters that addressed RM agree with EPA that any potentially successful approach for RM exemptions would be proactive, allowing exemptions before resistance has occurred for a particular use in the field. Most also agree that predicting and documenting a case of resistance would be highly variable and complex. The Agency believes that the burden to applicants of preparing a request for an RM exemption that included such documentation would be substantially higher than the burden of preparing other requests. EPA believes such costly and complex burden is contrary to the purpose of this rulemaking. Likewise, the burden to EPA of reviewing and deciding on such a request would be high, diverting resources from other priorities. EPA feels that such a burden is not the best use of Agency resources, and that other means of dealing with RM would be both more efficient and more appropriate. Furthermore, a need for an RM tool to address a future problem arguably does not fit within a conventional interpretation of ''emergency.''

EPA understands the importance of pest resistance management and continues to explore how to best use its regulatory and non-regulatory authorities to support and facilitate effective RM. The Agency believes that RM capabilities will be improved through a multi-faceted approach involving incorporating RM considerations into pesticide labeling (i.e., Pesticide Registration Notice 2001–5), registering more pesticides for minor crops, resistance management education programs, crop management and stewardship programs, further crop grouping for tolerance setting, and outreach efforts with stakeholders. Under PRIA, EPA is making more timely decisions and accelerating the registration of many products expected to be useful for RM. EPA's process for classifying a pesticide product as ''reduced-risk'' considers RM as an important factor. New products that would address significant RM needs would reach the market sooner, thereby providing a strong incentive to registrants to incorporate RM in their registration submissions. Also, the IR-4 process has continued to improve in recent years, identifying priority pesticide needs for minor crops and facilitating quicker registrations, including many useful RM tools.

B. Endangered Species Considerations

The existing emergency exemption regulations include information requirements for applicants and review requirements for EPA concerning threatened and endangered species. In the proposed rule, EPA did not propose to revise these requirements. However, a discussion of plans for improving the process for ensuring that pesticides used under emergency exemptions do not affect threatened and endangered species was included in the preamble. One comment submission on the proposed rule claimed that EPA's section 18 activities routinely violate the Endangered Species Act (ESA). These commenters said that the streamlining proposals would make matters worse. The commenters said that EPA does not list a single example of consultation with the U.S. Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (NMFS) in the course of a section 18 review. They also cite a recent letter from FWS to EPA Region 2 stating that the section 18 process insufficiently addresses EPA's consultation obligations under ESA. This comment was made by 13 environmental/public interest groups in a joint submission, and no other comments were received on this issue.

EPA disagrees that this final rule in any way lessens protections for threatened and endangered species. As noted, the regulatory provisions regarding submission and consideration of information relating to listed species have not been altered by the rule nor have EPA's obligations under the ESA been altered. EPA also disagrees that its plans for improving its processes will make matters worse. Indeed, EPA plans, as discussed in the proposal, explain that the Agency and FWS and NMFS (the Services) have developed mechanisms to provide increased and more expeditious scrutiny to these issues than the Agency has in the past.

The Services, in collaboration with EPA and USDA, have developed a counterpart regulation (50 CFR part 402), that would make the process of consultation about EPA actions involving pesticides - including any necessary consultations for emergency exemptions under section 18 - 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. The Services agreed 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 section 7 of the ESA and implementing regulations.'' (69 FR at 47735).

EPA looks closely at potential ecological risks of pesticide use in connection with decisions on requests for emergency exemptions. As a result of the Services' acceptance of the Agency's ecological risk assessment process, the Agency intends to provide new guidance and to work closely with applicants for emergency exemptions, to improve the information submitted concerning threatened and endangered species and possible effects on them of the requested use. EPA anticipates that these measures will 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. As EPA develops this new guidance, EPA will look for opportunities to enhance consideration of these impacts in its emergency exemption decision process, including any need to consult with FWS and NMFS.

C. Improving Transparency in Decisions

One of the ongoing challenges for EPA in relation to the emergency exemption program is to ensure that State agencies and interested stakeholders have useful, accurate, and timely information on the status of applications they are interested in as well as other key information that could help clarify pesticide use directions and facilitate observance of necessary safety restrictions that have been placed on the exempted use pattern. Along these lines, EPA is striving to upgrade the quality of the information available to States, pesticides users, extension agents and other key stakeholders under the section 18 program and also to enhance the transparency of this program in general. One activity that the Agency has developed in this area is a searchable section 18 data system that is supported on the Office of Pesticide Programs' web page. This data system, located at *http://cfpub1.epa.gov/oppref/section18/search.cfm* permits basic queries of

submissions and overall status information for emergency exemption applications. EPA also publishes information notices in the **Federal Register** in accordance with 40 CFR 166.30. These are retrospective summaries of the section 18 activity sorted and presented on the basis of the requesting agency.

EPA is also exploring other means of providing useful status and regulatory information for emergency exemptions that involve pest management concerns of national significance. For instance, in connection with the response to the newly identified select agent that causes the plant disease soybean rust, EPA has developed a special web page (*http://www.epa.gov/oppfod01/cb/csb_page/updates/soybean_rust.htm*) that provides the public with a comprehensive listing of all of the products that have claims for control of the soybean rust pathogen. Soybean rust is a serious disease of soybean crops and has been identified as a select agent under the Agricultural Bioterrorism Control Act. Due to the national scope of the soybean industry, there has been significant interest on the part of the public in learning which pesticides have regulatory clearances for this pest. Finally, EPA is exploring another initiative for sharing information on the section 18 program more extensively. Specifically, EPA is investigating ways to post more comprehensively its decision documents under this program. Section 18 decision letters are public documents which the Agency transmits to the requesting state agency. However, certain stakeholders have requested copies of these materials directly. To this end, EPA has plans for posting its decision documents under section 18 on the Agency's web page.

IX. FIFRA Review Requirements

In accordance with FIFRA section 25(a), this final 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 final rule, and no comments were received from any of the congressional committees or USDA.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this final rule is not a ''significant regulatory action'' under section 3(f) of the Executive Order.

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

This action is not expected to cause any significant adverse economic impacts. There are no direct impacts on local governments or small entities, because this action directly affects only Federal and State agencies that petition EPA for section 18 use authorization, neither of which qualify as a small entity under the Regulatory Flexibility Act (RFA). The only substantive impacts expected are burden reductions to applicants 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 final rule, based on predicted future applications affected by the regulatory revisions, EPA estimates the annual combined savings for applicants and EPA of around $1.5 million; nearly $1.2 million from re-certification, and over $0.3 million from changing to the loss-based method of determining SEL.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden that would require additional approval by OMB under the Paperwork Reduction Act (PRA), 44 USC 3501 *et seq*. This 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).

The annual respondent burden for the collection of information currently approved by OMB is estimated to average 99 hours per application. 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 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 number assigned to this final rule (No. 2070–0032) will be listed in 40 CFR part 9.

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 rulemaking 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 final 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 final rule only applies to Federal and State government agencies, the only entities that can petition the EPA under FIFRA section 18. As such, this action will not impact local or tribal governments or the private sector, and will not significantly or uniquely affect small governments. In addition, as described in Unit X.A., this final rule is expected to result in an overall reduction of existing costs for applicants and EPA of around $1.5 million. Accordingly, this rule is not subject to the requirements of sections 202 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 final 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 final 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 final rule. In the spirit of the Order, and consistent with EPA policy to promote communications between the Agency and State governments, EPA specifically solicited comment from State officials on the proposed rule.

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 final 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 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 final rule.

G. Executive Order 13211

This final 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 X.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 final rule because this action is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866 (see Unit X.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, sampling procedures) that are developed or adopted by voluntary consensus standards bodies. This final rule does not impose any technical standards that would require EPA to consider any voluntary consensus standards.

J. Executive Order 12898

This final 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.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report that includes a copy of the rule to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 166

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 13, 2006.

Stephen L. Johnson,

Administrator.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 166—[AMENDED]

■ 1. The authority citation for part 166 continues 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 or other output, one or more of the following:

(i) 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 any pest activity where EPA determines that the criteria in paragraph

(h)(1) would not adequately describe the expected loss, 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* means the Interregional Research Project No. 4, a cooperative effort of the state land grant universities, the U.S. Department of Agriculture 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 requested; 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) 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 may submit re-certification applications relying on previously submitted information to satisfy the information requirements of paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this section, where all of the following conditions are met:

(i) An exemption was granted for the same pesticide at the same site to the same applicant the previous year;

(ii) The emergency condition could reasonably be expected to continue for longer than 1 year;

(iii) EPA has not declared the use ineligible for re-certification;

(iv) The use is not subject to public notice pursuant to § 166.24(a)(1) through (a)(6);

(v) The applicant certifies that all of the following are true:

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

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

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

(D) 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;

(E) The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or has provided documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible.

* * * * *

■ 5. Section 166.24 is amended by revising the introductory text of paragraph (a), redesignating paragraphs (a)(6) and (a)(7) as paragraphs (a)(7) and (a)(8) respectively, adding a new paragraph (a)(6), and revising newly redesignated paragraph (a)(7)(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) The application proposes use of a pesticide which:

(i) Was voluntarily canceled under section 6(f) of the Act, and

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was voluntarily canceled under section 6(f);

(7) * * *

(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 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 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 in advance of utilization of the crisis provisions.

* * * * *

(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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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0515; FRL–7757–2]

Sorbitol Octanoate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical sorbitol octanoate on all food commodities when applied/used in accordance with label directions. AVA Chemical Ventures, L. L. C. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sorbitol octanoate.

DATES: This regulation is effective January 27, 2006. Objections and requests for hearings must be received on or before March 28, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0515. All documents in the docket are listed on the www.regulations.gov website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the online instructions.) 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.