



**U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES (OPPTS)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460**

**OMB REVIEW UNDER EXECUTIVE ORDER 12866
DOCUMENTATION OF CHANGES MADE DURING OMB REVIEW**

Title of Action: Pesticides; Emergency Exemption Process Revisions; Proposed Rule

Docket #: OPP-2004-0039

FRL#: 7371-3

RIN #: 2070-AD36

This action was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866, which is entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). According to section 6(a)(3)(E) of the Executive Order, whenever the Agency makes publicly available a regulatory action that was reviewed under Executive Order 12866, the Agency is also required to:

- (1) Make available to the public a copy of the information that was provided to OMB's Office of Information and Regulatory Affairs (OIRA) for review under to the Executive Order, i.e., the text of the draft regulatory action and, if applicable, an assessment of the potential costs and benefits; as well as additional information required for those actions that are determined to be economically significant under section 3(f) of the Executive Order (see section 6(a)(3)(B) & (C));
- (2) Identify for the public any substantive changes between the draft submitted to OMB and the action that was subsequently issued, using a method that is complete, clear and simple; and
- (3) Identify for the public those substantive changes made at the suggestion or recommendation of OIRA.

For this regulatory action, substantive changes at the suggestion of OMB

[Please check the appropriate box.]

G were *[include in the docket the information identified in items 1-3 below]*

O were not *[need only include in the docket the information identified under item 1 below]*

made to the regulatory action reviewed under Executive Order 12866.

Accordingly, the Agency has included the following information in the public docket for this regulatory action

[Please check the appropriate box.]:

- (1) A copy of the information that was provided to OIRA for review under to the Executive Order;
- (2) Using one of the following methods, documentation of any substantive changes that were made to the draft regulatory text that was submitted to OIRA, when compared with what subsequently published:
 - G** A copy of the draft regulatory action submitted, with redline and strikeout to show the substantive changes that were made;
 - G** A document that identifies the substantive changes that were made, with page and paragraph references to the draft regulatory action that was submitted; or
 - G** Other (please describe):
- (3) Substantive changes made at the suggestion or recommendation of OMB, if any, are identified:
 - G** Through attributions to OMB in the redline and strikeout version or other document identifying the changes;
 - G** Other (please describe):

If you have any questions about the regulatory action or this documentation, please call the contact:

Name: Joe Hogue

E- Mail: hogue.joe@epa.gov

Phone: 703-308-9072

INSTRUCTIONS FOR REQUESTING OMB REVIEW UNDER EXECUTIVE ORDER 12866

GENERAL

Please make sure to answer all questions and have the appropriate officials sign the form.

1. Agency/Subagency

Provide the name of the agency or subagency originating the request. For most Cabinet-level agencies, a subagency designation is also necessary. For non-Cabinet agencies, the subagency designation is generally unnecessary.

EXAMPLE

1. Agency/Subagency originating request:
Department of the Interior
National Park Service
or
Office of Personnel Management

2. Regulation Identifier Number (RIN)

The RIN is the means by which rules are linked across the Unified Agenda of Federal Regulations (Agenda), the Regulatory Plan, and Executive Order 12866.

RINs are assigned to items in the Agenda by the Regulatory Information Service Center (Center). For E.O. 12866 submissions that have not appeared in the Agenda, the agency must obtain a RIN from the Center. The RIN is a prerequisite to the regulatory action being logged in at OIRA.

EXAMPLE

2. Regulation Identifier Number (RIN)
1024-AA12

3. Title

Please provide a brief title that describes, as specifically as you can, the subject of this rulemaking. Avoid using general headings or the title of the CFR part for your rulemaking. To the extent possible, you should keep the title the same as in the Agenda. Also, you should use the same title for all stages of a rulemaking.

4. Stages of Development

Check the stage of development for this action.

Check "Prerule" when the action submitted for review seeks to determine whether or how to initiate rulemaking. Examples include ANPRMs and reviews of existing regulations.

Check "Proposed Rule" when the action submitted will be published in the Proposed Rules section of the Federal Register (for example, an NPRM).

Check "Interim Final Rule" when the action submitted will be published in the Rules and Regulations section of the Federal Register with an Action caption of Interim Rule or Interim Final Rule.

Check "Final Rule" when the action submitted will be published in the Rules and Regulations section of the Federal Register and there have been material changes in the facts and circumstances upon which the previous action was based.

Check "Final Rule - No material change" when the action submitted is associated with a previous request (for example, an NPRM) and there has been no material change in the facts and circumstances upon which the previous action was based.

Check "Notice" when the action submitted will be published in the Notices section of the Federal Register.

Check "Other" when the action does not meet the criteria of any of the above categories. (Indicate on the line provided what type of action you are submitting; for example, a policy statement.)

5. Legal Deadline for This Submission

The deadline is for the regulatory action in this submission only and not for any future or past action in this rulemaking proceeding.

a) Indicate whether the action submitted is subject to any specific legal deadline. For example, if this submissions for an NPRM

and the Final Rule Stage has a deadline, check No. If this submission is for the Final Rule, check Yes.

b) If 5a is Yes, provide the month, day, and year of the deadline for this action (whether past or future).

c) If 5a is Yes, indicate whether the deadline is statutory of judicial.

6. Economically Significant

Check Yes if the action submitted will likely have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health and safety, or State, local, or tribal governments or communities. (Section 3(f)(1) of E.O. 12866.)

7. Agency Contact

Provide the name and telephone number of the agency person best able to answer questions regarding the content of this submission.

EO 12866 Review Draft (05/20/2004)

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 166

[OPP-2004-0039; FRL-XXXX-X]

RIN 2070-AD36

Pesticides; Emergency Exemption Process Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

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

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by Docket ID No. OPP-2004-0039, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- Agency Web Site: <http://www.epa.gov/edocket>. EDOCKET, EPA’s electronic public docket and comment system, is EPA’s preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- E-mail: opp-docket@epa.gov.
- Mail: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- Hand Delivery: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. OPP-2004-0039. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.epa.gov/edocket>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the federal regulations.gov websites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102). For additional instructions on submitting comments, go to Unit I.B. of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Joseph Hogue, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-308-9072; fax number: 703-305-5884; e-mail address: hogue.joe@epa.gov.

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

73 agency that petitions EPA for an emergency use authorization under section 18 of the Federal Insecticide,
74 Fungicide and Rodenticide Act (FIFRA). Regulated categories and entities may include, but are not limited
75 to:

- 76 • Federal Government (NAICS Code 9241), i.e., Federal Agencies that petition EPA for section 18
77 use authorization.
- 78 • State or Territorial governments (NAICS Code 9241), i.e., States, as defined in FIFRA section
79 2(aa), that petition EPA for section 18 use authorization.

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

88 *B. What Should I Consider as I Prepare My Comments for EPA?*

89 1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov
90 or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in
91 a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then
92 identify electronically within the disk or CD ROM the specific information that is claimed as CBI). In
93 addition to one complete version of the comment that includes information claimed as CBI, a copy of the
94 comment that does not contain the information claimed as CBI must be submitted for inclusion in the public
95 docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40
96 CFR part 2.

97 2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- 98 • Identify the rulemaking by docket number and other identifying information (subject heading,
99 Federal Register date and page number).
- 100 • Follow directions - The agency may ask you to respond to specific questions or organize comments
101 by referencing a Code of Federal Regulations (CFR) part or section number.
- 102 • Explain why you agree or disagree; suggest alternatives and substitute language for your requested
103 changes.
- 104 • Describe any assumptions and provide any technical information and/or data that you used.
- 105 • If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient
106 detail to allow for it to be reproduced.
- 107 • Provide specific examples to illustrate your concerns, and suggest alternatives.
- 108 • Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- 109 • Make sure to submit your comments by the comment period deadline identified.

110 **II. Purpose**

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

128 EPA also intends to achieve several other objectives in this Notice. First, revisions are proposed to
129 correct or update several minor administrative aspects of the emergency exemption regulations, which have
130 not been revised since 1986. The reason for each of these minor administrative revisions falls into one of
131 the following categories: correction of typographical or administrative errors; conformance with
132 requirements of the Food Quality Protection Act of 1996 (FQPA); and codification of improved practices
133 that have been voluntarily but widely followed by applicants. Second, the Agency is proposing to add
134 specific language to the regulations to clarify that treatment of “invasive species” is a valid basis for issuing a
135 quarantine exemption. Third, this notice includes a discussion of how the Agency protects endangered and
136 threatened species, and ensures compliance with the Endangered Species Act, through its implementation
137 of the emergency exemption program. No regulatory proposals are included relative to endangered species
138 measures. Finally, this Notice informs the public that EPA has revised its tentative plan to include in this
139 proposed rule a proposal to allow exemptions for the purpose of pest resistance management. An
140 explanation of why resistance management exemptions are not being proposed at this time, and a discussion
141 of what alternative plans the Agency has for addressing resistance management, are included.

142 The Agency encourages interested parties to submit comments on any of the proposed regulatory
143 revisions by following the instructions in Unit I.C. of this Notice. Commenters should explain any
144 modifications they suggest for the proposed revisions, along with their rationale. EPA would like applicants
145 for emergency exemptions to submit comments concerning their experience with the pilot for the two
146 streamlining provisions being proposed. Applicants who have participated in the pilot are asked to submit
147 comments explaining the pros and cons of the revised practices. Applicants who were eligible for, but
148 elected not to participate in, the pilot are asked to submit comments explaining why they did not participate.
149 Units V. and VI. of this document outline the specific revisions being proposed, but also include discussion
150 asking potential commenters to consider alternative approaches for particular aspects of the proposal. In

151 addition to inviting public comments on this proposed rule, EPA plans to consult the Pesticide Program
152 Dialogue Committee (PPDC) on these proposed revisions, as it has prior to initiating the pilot for the
153 streamlining proposals. Input from the public comments received in response to this proposed rule, and
154 experience from the pilot will be carefully considered, when deciding whether to modify these proposed
155 revisions for the final rule.

156 **III. Statutory and Regulatory Framework**

157 *A. Statutory Authority*

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

161 FIFRA provides the basis for regulation, sale, distribution and use of pesticides in the United States.
162 FIFRA generally prohibits the sale and distribution of any pesticide product, unless it has been registered by
163 EPA in accordance with section 3. (7 USC 136a.). Section 18 of FIFRA gives the Administrator of EPA
164 broad authority to exempt any Federal or State agency from any provision of FIFRA if the Administrator
165 determines that emergency conditions exist which require such an exemption. (7 USC 136p). Under
166 section 2(aa) of FIFRA, the term “State” is defined to include a “State, the District of Columbia, the
167 Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and
168 America Samoa.” (7 USC 136(aa)).

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

172 *B. Existing Regulatory Provisions*

173 Regulations governing FIFRA section 18 emergency exemptions are codified in 40 CFR part 166.
174 Part 166 was last revised in 1986. Generally, these regulations set forth information requirements,
175 procedures, and standards for EPA's approval or denial of a request from a Federal or State agency for an
176 exemption to allow a use of a pesticide that is not registered when such use is necessary to alleviate an
177 emergency condition.

178 Federal and State agencies may apply for an emergency exemption due to a public health
179 emergency, a quarantine emergency, or a “specific” emergency. Most emergency exemptions requested or
180 approved fall under the category of “specific exemptions” and are requested in order to avert an economic
181 emergency for an agricultural activity. Typical justifications for specific exemptions include, but are not
182 limited to, the expansion of the range of a pest; the cancellation or removal from the market of a previously
183 registered and effective pesticide product; and the development of resistance in pests to a registered
184 product, or loss of efficacy of available products for any reason. Additionally, an emergency situation is
185 generally considered to exist when no other viable (chemical or non-chemical) means of control exist, and
186 where the emergency situation will cause significant economic losses to affected individuals if the exemption

187 is not approved.

188 A Federal or State agency must submit an emergency exemption request in writing that documents
189 the emergency situation, the pesticide proposed for the use, the target pest, the crop, the rate and number
190 of applications to be made, the geographical region where the pesticide would be applied, and a discussion
191 of risks that may be posed to human health or to the environment as a result of the pesticide use (40 CFR
192 166.20). EPA reviews the request, verifying the existence of the emergency, assessing risks posed to
193 human health through food, drinking water, and residential exposure, assessing risks posed to farmworkers
194 and other handlers of the pesticide, assessing any adverse effects on non-target organisms (including
195 Federally listed endangered species), and assessing the potential for contamination of ground and surface
196 water. If an application for the requested use has been made in previous years, EPA also does an
197 assessment of the progress toward registration for the use of the requested chemical on the requested crop,
198 and considers this status in the final determination to approve or deny the exemption. If EPA concludes
199 that the situation is an emergency, and that the use of the pesticide under the exemption will be consistent
200 with the standards of section 18 and 40 CFR part 166, and, for food uses, section 408 of FFDCA, then
201 EPA may authorize emergency use of the pesticide.

202 Use under specific and public health exemptions can be authorized for periods not to exceed 1
203 year, and uses under quarantine exemptions can be authorized for up to 3 years (40 CFR §166.28). Public
204 health exemptions are for the control of pests that will cause a significant risk to human health, while
205 quarantine exemptions are intended to control the introduction or spread of pests that are new or not
206 known to be widely prevalent or distributed within and throughout the United States and its territories.
207 Emergency exemptions should not be viewed as an alternative to registering the use(s) needed for longer
208 periods. If the situation addressed with the section 18 exemption persists, or is expected to persist, affected
209 entities must take the proper steps to amend the existing registration or seek a new registration to address
210 that future need.

211 **IV. Background**

212 *A. April, 2003, Notice Initiating Pilot for Two Revisions now being Proposed*

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

226 Anyone interested in the background leading up to the pilot program, or other related documents,
227 may wish to review the Federal Register Notice announcing the pilot, and the related documents. A public
228 docket was established for that Notice under docket number OPP-2002-0231. Interested parties should
229 follow instructions in Unit I.B. of this document for accessing the docket, but use docket number OPP-
230 2002-0231 for the April 24, 2003, Notice.

231 *B. Summary of Early Pilot Experience*

232 The limited pilot program testing the two potential improvements that are proposed in this
233 rulemaking was initiated with the publication of a Federal Register Notice on April 24, 2003. Both parts of
234 the pilot are limited to requests for a specific set of “reduced-risk” pesticides, which significantly limits the
235 number of potentially eligible exemption requests.

236 The first part of the pilot allowed applicants for eligible repeat exemptions to re-certify the existence
237 of their emergency condition. The re-certification pilot involves exemptions that meet all of the following
238 eligibility criteria: (1) EPA approved the same exemption the previous year, and it is the second or third
239 year of the request by that applicant, (2) the emergency situation can reasonably be expected to continue
240 for longer than one year, (3) the exemption is not for a new chemical, a first food use, or for a chemical
241 under Special Review, and (4) the exemption is for a chemical previously identified by EPA as reduced-
242 risk. For the 2003 growing season, 16 exemptions were identified by EPA as eligible for re-certification
243 and the list was made available to States and the public. Of the 16 exemptions eligible to repeat by re-
244 certification, seven submitted applications using re-certification. Of the nine exemptions that were eligible
245 but for which no re-certification was submitted, three were for pesticide uses that had obtained federal
246 registration under FIFRA section 3 since the 2002 exemption; three were not requested at all in 2003; and
247 the remaining three were requested using conventional emergency exemption requests. In the seven
248 instances of a re-certification, EPA staff was able to make expedited decisions with an average of 9 days
249 from receipt of the request until the decision was made.

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

261 Both of these proposed revisions offer a cost saving and reduce the burden on States as well as on
262 EPA. The Agency expects that the level of participation in both areas of the pilot will increase as the level
263 of familiarity and understanding among state agencies increases. Efforts to facilitate the understanding and
264 use of the pilot initiatives are currently underway. Rulemaking would expand the scope of the pilot, by

265 eliminating the eligibility restriction to reduced-risk pesticides, thereby making more opportunities for
266 efficiencies.

267 **V. Proposed Revisions to Emergency Exemption Process**

268 The two revisions discussed below are currently being employed in limited pilot programs that were
269 initiated by a Federal Register Notice in April, 2003. A guidance document was prepared for use by
270 applicants to participate in the pilot programs. After reviewing this Unit V., interested parties may find it
271 useful to review that guidance document for the Agency's detailed plans for implementation of these
272 revisions. A final guidance document will be made available when a final rule is published. In the meantime,
273 the guidance document for the pilot would be particularly helpful in understanding what information would
274 be required to be submitted by applicants under the proposed revisions. The pilot guidance document is
275 available in the public docket that was established for the Federal Register Notice announcing the pilot
276 program. Interested parties should follow instructions in Unit I.B. of this document for accessing the
277 docket, but use docket number OPP-2002-0231 for the April 24, 2003, Notice.

278 *A. Re-certification of Emergency Condition by Applicants*

279 *1. What is our current practice?*

280 EPA authorizes emergency exemptions (except quarantine exemptions) for no longer than one year.
281 However, depending on the nature of the non-routine condition that caused the emergency, some
282 exemptions may subsequently be approved again, one year at a time. Currently, EPA conducts a full
283 review of an application for the first year of an exemption, to determine whether an emergency condition
284 exists, to ensure the use will not result in unreasonable adverse effects to human health or the environment,
285 and, if the use will result in pesticide residues in food or feed, to make a safety finding consistent with
286 section 408 of the Federal Food Drug and Cosmetic Act (FFDCA).

287 If the emergency condition continues in subsequent years applicants may submit a similar
288 application, in which case the Agency must again confirm the emergency condition and acceptability of the
289 risk. For requests after the first year, the applicant again submits information to support the emergency
290 finding, with a full application, including updated economic data. For these repeat requests EPA
291 reevaluates the situation to determine, relative to the first year, whether: 1) the emergency condition has
292 changed; 2) any alternative products have been newly registered for the use, or other effective pest control
293 techniques are now available; 3) any changes have occurred in the status of the chemical's risk assessment;
294 4) the requested conditions of use have changed; and, 5) the pesticide for the requested use has made
295 sufficient progress towards registration.

296 *2. How would re-certification work under the proposed approach?*

297 This proposed revision would reduce the burden on applicants who seek re-approval of certain
298 emergency exemptions in subsequent years. EPA proposes to add a new paragraph (b)(5) to 40 CFR
299 166.20, which would allow applicants for eligible repeat exemptions to submit applications that rely on the
300 preceding year's submission to document the economic impact of the pest emergency. This re-certification

301 approach would allow applicants to incorporate by reference all information submitted in a previous
302 application, instead of submitting a complete re-application and supporting documentation. The re-
303 certification of the emergency condition by the applicant combined with the materials already in EPA's files
304 would serve as the basis for EPA's determination as to whether an emergency condition continues to exist.

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

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

316 2. Whether an emergency exemption has been approved more than twice for the same pesticide at the
317 same site. EPA recognizes that some emergency situations can continue for more than one year, however,
318 pesticide registration pursuant to FIFRA section 3 is the appropriate long-term response, rather than the
319 section 18 emergency exemption. According to the regulations and EPA policy, a failure to request
320 registration of a use requested under section 18 for more than 3 years may indicate that adequate progress
321 toward registration is not being made. Therefore, EPA carefully examines all exemption submissions
322 submitted for more than 3 years.

323 3. Whether the pesticide product, owing to its regulatory status, warrants heightened review before any
324 additional use is approved. EPA will rely on the same criteria used in the existing regulations at 40 CFR
325 166.24(a), which identifies a number of different situations where, upon receipt of an application for an
326 emergency exemption, the regulatory status of a pesticide product calls for public notice and comment:

- 327 (1) The application proposes use of a new chemical;
- 328 (2) The application proposes the first food use of an active ingredient;
- 329 (3) The application proposes any use of a pesticide if the pesticide has been subject to a suspension
330 notice under section 6(c) of the Act;
- 331 (4) The application proposes use of a pesticide which:
- 332 (i) Was the subject of a notice under section 6(b) of the Act and was subsequently
333 cancelled, and
- 334 (ii) Is intended for a use that poses a risk similar to the risk posed by any use of the
335 pesticide which was the subject of the notice under section 6(b);
- 336 (5) The application proposes use of a pesticide which:
- 337 (i) Contains an active ingredient which is or has been the subject of a Special Review, and
338 (ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the
339 pesticide which is or has been the subject of the Special Review;

340 In instances where EPA determines that the emergency situation could reasonably be expected to
341 continue, where an emergency exemption has been approved not more than twice for the same pesticide at
342 the same site, and where the pesticide product's regulatory status does not warrant heightened review,
343 EPA would notify the successful applicant that, should it reapply the following year, it is eligible to use a re-
344 certification application. EPA anticipates that this notification would be included in the notice of approval of
345 the current year's application. However, if an exemption is not classified as a candidate for re-certification
346 in the approval notice, and an applicant believes that subsequent information would make it eligible, the
347 applicant may contact the Agency to request an eligibility determination. In some instances, EPA may
348 determine that an emergency condition exists, and that the exemption is eligible for a re-certification
349 application the following year, yet conclude that additional information should be gathered in order to
350 support approval in future years. In such instances, EPA may indicate in the approval notice that the
351 exemption is eligible for re-certification upon submission of the specified information.

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

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

363 Applicants meeting the above requirements would not need to submit new, updated documentation
364 that the emergency condition continues or the additional data elements generally required under 40 CFR
365 166.20, except that the interim report specified in §166.20(a)(11) would still be required where a re-
366 certification is filed before the final report on the previous exemption is available.

367 Eligibility for re-certifying the emergency condition would not determine whether an emergency
368 exemption application could be approved. For applications that are eligible and include a proper re-
369 certification of the emergency condition, EPA would again determine whether the requested use poses a
370 risk to human health or the environment that exceeds statutory and regulatory standards. If the risks posed
371 by the requested use are determined to be unacceptable, the exemption request would be denied unless the
372 risks could be mitigated. Where an application re-certifies that the emergency condition and requested use
373 are the same as in the initial year of the exemption, EPA would only re-evaluate the situation to determine,
374 relative to the first year, whether: 1) any alternative products have been newly registered for the use; 2)
375 any changes have occurred in the status of the chemical's risk assessment; 3) the requested conditions of
376 use have changed; and, 4) the pesticide for the requested use has made sufficient progress towards
377 registration. If an effective product has been registered for the requested use since the previous exemption
378 was approved, then an emergency condition may no longer exist. If the Agency has received new risk
379 information since approving the previous exemption, then the risk would be re-evaluated. Likewise, if the
380 request includes any change in the conditions of use that may increase exposure (application rate, number of

381 applications, type of application, pre-harvest interval, re-entry interval, total number of acres, and all other
382 directions for use) then the risk would also be re-evaluated. Because some applicants may start their three-
383 year re-certification period in later years than others, it is possible that EPA may determine that sufficient
384 progress towards registration has not been made for a pesticide requested by an applicant eligible for re-
385 certification.

386 For eligible requests where the applicant has certified a continuing emergency, if the three remaining
387 review factors (product registrations, risk assessment status, and requested conditions of use) have not
388 changed, the Agency's review time is expected to be significantly reduced. In such cases, applicants are
389 expected to benefit by expedited decisions, in addition to the reduced burden due to the certification of the
390 emergency. Applicants would be permitted to modify the conditions of the emergency use in an application
391 in which they re-certify the emergency. However, EPA would need to determine whether, and how, such
392 changes impact exposure and risk to human health or the environment. Therefore, such changes may
393 undercut the Agency's ability to make an expedited decision. If the conditions of use are the same as the
394 conditions of use in the exemption approved by EPA in the previous year, applicants may include a
395 separate certification that their requested conditions of use have not changed, and incorporate by reference
396 all conditions of use submitted in a previous application or applications. This certification that the conditions
397 of use are unchanged would aid in expediting the Agency's decision.

398 If the Agency determines that there has been insufficient progress towards registration of the
399 requested chemical on the requested crop, a request could be denied, consistent with current regulations
400 and practice, regardless of eligibility for submitting a re-certification application. Registrant progress toward
401 registration is determined for a pesticide-crop combination, whereas the year-count (first, second, third) in
402 the eligibility cycle for re-certification would be determined separately for each State/Federal applicant, and
403 could often differ among section 18 applicants in a given year. Lack of progress towards registration would
404 not cause denials during the first three years of exemptions for a chemical-crop combination. However,
405 since some applicants may apply for the first time in a year subsequent to the first request for a chemical-
406 crop combination by another applicant, lack of progress towards registration could potentially interrupt the
407 eligibility cycle for some applicants.

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

414 3. *Why propose this change?*

415 Allowing applicants for certain eligible exemption requests to re-certify the existence of an ongoing
416 emergency condition and to incorporate by reference all information submitted in a previous application is
417 expected to reduce the burden to both applicants and EPA as well as allow for quicker decisions. When
418 an applicant certifies the continuation of the emergency condition and incorporates previously submitted
419 materials by reference, a complete new application sufficient to characterize the situation in accordance with

420 40 CFR 166.20 will not be required. This will save applicants time and effort in gathering data and
421 preparing their submissions. The Agency will save time and resources by not having to annually repeat each
422 step of its review of the documents supporting the exemption requests. If no pesticides that could avert the
423 emergency have been newly registered, and nothing has changed to affect the assessment of risk, then re-
424 certification of an emergency will lead to significantly shorter Agency review.

425 EPA's experience indicates that emergency situations that continue after the initial year generally are
426 projected to cause comparable yield losses in succeeding years. Therefore, with the certification of a
427 continuing emergency, reliance on the previously submitted data and other supporting information should be
428 adequate to support a decision to approve or deny an emergency exemption application.

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

430 *1. What is our current practice?*

431 In determining whether a pest emergency is likely to result in "significant economic loss," EPA
432 ordinarily compares the affected growers' projected per-acre "profits" (gross revenue less expenses, where
433 expenses have often been poorly defined) for the affected crop, based on anticipated yield losses, to the
434 historical variation in their "profits" for that crop in that region. Applicants are required under 40 CFR
435 166.20(b)(4) to submit economic information necessary to make this determination. In addition to
436 information used to estimate the amount of the anticipated yield and profit losses, EPA generally asks for
437 annual data for five years of average yields, prices, and production costs to establish profit variability.

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

447 *2. How would the proposed approach work?*

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

452 The proposed loss-based approach would use the existing methodology to calculate the economic
453 consequences of an unusual pest outbreak, although the calculation would be done in steps (tiers) and
454 sometimes the later steps would be unnecessary. States would still have to submit data to demonstrate the
455 emergency nature of the outbreak including the expected losses in quantity, and sometimes quality and/or

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

468 Tier 1: Yield Loss - Tier 1 is based on crop yield loss. If the projected yield loss due to the
469 emergency condition is sufficiently large, EPA would conclude that a significant economic loss will occur,
470 due to the magnitude of the expected revenue loss. The yield loss threshold in Tier 1 would be 20 percent
471 for all crops. This threshold is set at a sufficiently high level such that a loss that exceeded the threshold
472 would also meet the thresholds in Tiers 2 and 3, if the additional economic data were submitted and
473 analyzed. Therefore, for such large yield losses it would not be necessary to separately estimate economic
474 loss, which would require detailed economic data.

475 Tier 2: Economic Loss as a Percentage of Gross Revenues - A yield loss that does not satisfy the
476 threshold in Tier 1 may nonetheless cause a significant economic loss because yield loss alone may not
477 reflect all economic losses. In addition to yield losses there may be other impacts that contribute to
478 economic loss. Quality losses may result in reductions in prices received and/or there may be changes in
479 production costs, such as pest control costs and harvesting costs. For situations with yield losses that do
480 not meet the significant economic loss criterion for Tier 1, EPA would evaluate estimates of economic loss
481 as a percent of gross revenue in Tier 2, to determine if the loss meets that threshold for a significant
482 economic loss. The economic loss threshold in Tier 2 would be 20 percent of gross revenue for all crops.
483 Again, this threshold in Tier 2 is set with the intention that losses exceeding the threshold would also meet
484 the threshold in Tier 3, if the additional Tier 3 analysis were performed.

485 Tier 3: Economic Loss as a Percentage of Net Revenues - If neither yield or economic losses were
486 above the required thresholds in Tiers 1 and 2, EPA would compare impacts to net revenues. Net
487 revenues are defined for the purposes of this rule as gross revenues minus operating costs. The loss
488 threshold in Tier 3 would be 50 percent of net revenues for all crops. Some emergency conditions that
489 would fall short of the thresholds in Tiers 1 and 2 may qualify as a significant economic loss in Tier 3,
490 particularly for crops with narrow profit margins (net revenues as a percentage of gross revenues). Even if
491 economic loss seems small in comparison to gross revenues, the situation could still be a significant
492 economic loss if the profit margin is narrow.

493 EPA selected the sizes of the proposed thresholds (20%, 20%, and 50%) based on average farm
494 income and production expenses in the U.S., and an analysis of past requests showing what results the
495 proposed method would provide with various thresholds. Data on farm income in “USDA Agricultural

496 Statistics, 2003” shows that net farm income averages about 20 percent of gross revenue. Therefore, an
497 economic loss of 20 percent of gross revenue would be sufficient to eliminate net farm income. A yield loss
498 of 20 percent results in economic loss of 20 percent or higher. Also, since average net farm income is a
499 little less than 50% of net revenue, an economic loss that is 50% of net revenue would be sufficient to
500 eliminate net farm income. The analysis of past requests indicated that the average and median economic
501 losses that qualified as a significant economic loss were about 18 percent and 15 percent of gross revenue,
502 respectively. Since the first 2 tiers are screening thresholds, these thresholds were rounded up to 20 percent
503 to be a little more stringent, with the intention that if a request did not pass Tiers 1 or 2, it could qualify with
504 Tier 3. The analysis of past requests also showed that the median economic loss that qualified as a
505 significant economic loss was about 51 percent of net revenue. The analysis also showed that these
506 thresholds collectively result in about the same overall likelihood of an application qualifying for a significant
507 economic loss. That is, approximately the same total number of emergency requests that qualified for a
508 significant economic loss using the current approach would qualify using the proposed loss-based
509 approach, although there would be some differences in individual cases.

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

516 For specific emergency exemptions (the only ones in which significant economic loss is a qualifying
517 factor), EPA anticipates that applicants would first determine whether their projected loss meets the Tier 1
518 yield loss threshold of 40 CFR 166.3(h)(1)(i), analytically the least burdensome criterion. The associated
519 data requirements are proposed in §166.20(b)(4)(i). If the projected loss does not meet this threshold,
520 EPA expects that applicants would determine whether their projected loss meets the Tier 2 gross revenue
521 threshold of §166.3(h)(1)(ii), providing additional data as noted in §166.20(b)(4)(ii). Failing to meet that
522 threshold, applicants would submit the data to perform the analysis necessary for the Tier 3 net revenue
523 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),
524 (ii) & (iii) are designed such that when an emergency condition qualifies for significant economic loss under
525 a lower tier, data for higher tiers are not required, and the burden and cost of preparing the emergency
526 exemption application are reduced. Each successive tier builds upon the previous one. That is, the
527 information required for estimating a lower tier is also necessary in estimating each higher tier. This would
528 allow an applicant to collect data, and build a case for significant economic loss, as needed and determined
529 by the conditions, without requiring additional unnecessary data.

530 This loss-based approach is designed to capture the economic impact of pest activity as it affects
531 the current growing season, which will be sufficient for most emergency exemption applications. Although
532 the loss-based approach appears in a proposed revision to the definition of significant economic loss at
533 §166.3(h)(1), EPA is not attempting to revise the approach for other types of losses, at the proposed
534 §166.3(h)(2). Where losses affect more than the current growing season, for example long-term losses in
535 orchard crops, the Agency would continue to make its significant economic loss determinations based on
536 other criteria, such as changes in the net present value of an orchard, if these losses are demonstrated by

537 the applicant. In situations where the simple methods of the loss-based approach would not adequately
538 reflect the likely extent of the economic loss, EPA would still attempt to determine, on a case-by-case
539 basis, whether the pest emergency is likely to result in a substantial loss or impairment of capital assets, or a
540 loss that would affect the long-term financial viability expected from the productive activity.

541 *3. Why propose this change?*

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

552 An analysis of past section 18 requests suggests that this proposed approach would not cause a
553 significant change in the overall likelihood of a significant economic loss finding, although findings may differ
554 in individual cases. Further, it is expected to lead to savings to both applicants and EPA from reduced data
555 and analytical burdens. Under the proposed procedure, applicants could elect to submit the minimum
556 amount of data necessary to demonstrate a significant economic loss in one of three increasingly refined
557 tiers. If the first tier is sufficient, the burden is reduced most significantly. Even in the highest tier, the
558 burden may be reduced relative to the current approach as the analysis focuses on the current year rather
559 than historical data. Like re-certification of emergencies, this would save applicants time and resources in
560 gathering data and preparing submissions. The Agency's burden would be reduced due to streamlined
561 reviews.

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

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

576 in the overall likelihood of a significant economic loss finding, but it may change the findings in individual
577 cases so that determinations of significance are more accurate, appropriate and equitable.

578 Current regulations list certain information that must be included, *as appropriate*, in an application
579 for a specific exemption:

580 166.20(b) *Information required for a specific exemption.* An application for a specific
581 exemption shall provide all of the following information, as appropriate, concerning the nature of
582 the emergency:

583 ***

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

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

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

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

590 The existing regulations state that all of the above information must be included “as appropriate.” EPA
591 recognizes that each pest emergency has individual characteristics, and exercises judgement based on
592 experience, in determining what information is appropriate. For example, under the current approach the
593 Agency typically considers five years of annual data on historical net and gross revenues to be appropriate,
594 and has requested in guidance materials that applicants submit revenue data for the preceding 5 years.
595 However, in some cases, such as a very minor or new crop for which less data is available, the Agency
596 may rely on other credible information. Further, EPA does not compare the emergency situation to the
597 situation with the proposed pesticide, but to the situation without the emergency. Therefore, EPA believes
598 that the proposed approach would allow applicants to focus their applications on the most “appropriate”
599 information for determining whether or not a significant economic loss will occur.

600 Because the analysis of past exemption requests, on which the proposed approach is based,
601 demonstrates that the likelihood of approval of some requests is not significantly changed by the loss-based
602 approach, EPA believes that the current requirement of those additional data in those cases can be
603 improved. However, even when annual historical data are not required, applicants would sometimes
604 continue to utilize historical data under the proposed approach, albeit in a different way. This is because
605 each tier requires a quantitative threshold to be met, that is a certain percentage of a baseline of either crop
606 yield, gross revenues, or net revenues. The best approach to determine the baseline in some cases may be
607 to use the average of historical data, including yield and price data.

608 **VI. Proposed Minor Updates and Revisions**

609 *A. Specifying Invasive Species as Targets under Quarantine Exemptions*

610 Current regulations describe four types of exemptions, one of which is a quarantine exemption. The
611 purpose of a quarantine exemption is stated in the regulations as follows:

612 40 CFR 166.2(b) *Quarantine exemption*. A quarantine exemption may be authorized in an
613 emergency condition to control the introduction or spread of any pest new to or not theretofore
614 known to be widely prevalent or distributed within and throughout the United States and its
615 territories.

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

629 *B. Updating administrative and communication processes*

630 A number of minor revisions to 40 CFR part 166 are being proposed to correct errors or update
631 administrative aspects of the emergency exemption regulations, particularly in light of the fact that FQPA
632 was enacted since the regulations under part 166 were last revised. Each of these revisions is being
633 proposed for one of the following reasons: (1) to correct typographical or administrative errors or
634 inaccuracies, (2) to bring the regulations into agreement with current requirements put in place by the
635 FQPA, or (3) to reflect improvements to the process that have been identified since 40 CFR part 166 was
636 last revised, and that have been voluntarily practiced by applicants. Each of these revisions would be non-
637 substantive or reflect minor changes to the regulatory requirements, but all would correct, improve, or
638 update the regulations. The corrections of typographical or administrative errors or inaccuracies are self-
639 explanatory. The proposed revisions for the other reasons are discussed below.

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

648 First, EPA proposes to amend §166.3(e) to revise the definition of “first food use.” The current
649 definition includes an explanation that no permanent tolerance or food additive regulation has been
650 established for such a use. The proposed definition would remove the word “permanent,” so that any

651 tolerance would be included, and would remove reference to “food additive regulation,” because, owing to
652 the FQPA amendments, EPA no longer issues food additive regulations.

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

657 The third proposed revision made necessary by FQPA is to add, under § 166.40, an additional
658 limitation to the authority of a State to issue a crisis exemption, namely, that a State may issue a crisis
659 exemption for a food use only where a tolerance or exemption is already in effect, or where EPA has
660 provided verbal confirmation that a time-limited tolerance for the proposed use can be established in a
661 timely manner. It is in the best interests of applicants and potential users of the pesticide under the crisis
662 exemption that there is some assurance that an exemption can be established in a timely manner before use
663 of the pesticide begins. EPA also proposes that all crisis exemptions be conditioned upon EPA confirming
664 that it has no other risk-based objection to the use of the pesticide under the crisis provisions.

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

675 Several proposed revisions are to codify minor improvements to the process that have been
676 identified since the current regulations became effective. Applicants have been generally following these
677 practices, in most cases for several years, and EPA believes that the public will generally agree that these
678 are improvements to the regulatory requirements. First, under § 166.20, Application for a specific,
679 quarantine, or public health exemption, EPA is proposing to revise paragraph (a)(2)(i)(A) so that an
680 application must include a copy of the registered label(s) if a specific pesticide product(s) is/are requested,
681 instead of the current requirement to include the registration number and name of the product. This is
682 practical because emergency exemption requests are generally for pesticide products that are already
683 registered for other uses, but not for the requested use.

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

690 and allow tolerances to be established in a timely fashion.

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

695 The existing regulations establish a measure of whether adequate progress toward the registration of
696 a requested use is being made. Existing regulations suggest that the lack of a request for registration, within
697 three years of an emergency exemption first being requested for the use, suggests that adequate progress is
698 not being made. EPA proposes to revise §166.24(a)(6)(i) and §166.25(b)(2)(ii) to relax this presumption
699 for repeat emergency exemption applications for uses being supported by the Interregional Research
700 Project No. 4 (IR-4). The IR-4 program is a cooperative effort of the state land grant universities, USDA
701 and EPA, to address the chronic shortage of pest control options for minor crops. Generally, the crop
702 protection industry lacks economic incentive to pursue registrations on minor crops because of low
703 acreage. IR-4 generates and supplies research data needed by EPA in order to register compounds for
704 use on minor crops. Owing to the limited pest control options available for minor use crops, the
705 significance of the need evidenced by IR-4 action, and the limits on IR-4 resources, EPA believes that a
706 somewhat slower rate of progress towards registration should be accepted for emergency exemptions for
707 uses being supported by the IR-4 program. Accordingly, EPA is proposing that §166.24(a)(6)(i) and
708 §166.25(b)(2)(ii) be revised so that the presumption against adequate progress toward registration of
709 repeat emergency exemptions for uses being supported by the IR-4 program would begin after 5 years, 2
710 years more than allowed for uses supported by the registrant. For such major crop uses, the 3-year
711 presumption in the current regulations would remain in effect.

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

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

717 EPA proposes clarifying the authority of an applicant to issue a crisis exemption by specifying in
718 §166.40(a) that crisis exemptions are to be used only for *unpredictable* emergency conditions. This
719 proposed change is strictly for purposes of clarification, as the term “unpredictable” already appears in the
720 introductory language of 166.40, and does not represent any intention by EPA to change the circumstances
721 that are acceptable for crisis exemptions.

722 EPA is proposing that §166.43(a)(1) be revised to improve the notification process for crisis
723 exemptions, reflect the standard practice of the state agencies, and provide for advance notice so that EPA
724 may make a determination of whether a tolerance may be supported in accordance with FFDCA section
725 408 requirements. EPA is proposing that §166.43(a)(1) be revised to require advance notification for
726 crisis exemptions by applicants. The state’s authority to exercise the crisis exemption would be stayed for
727 up to 36 hours pending verbal confirmation by EPA that a tolerance can be established in a timely manner

728 and that the Agency has no other risk-based objections. This would replace the currently ambiguous
729 requirement that notification must be made at least 36 hours in advance, or no later than 24 hours after the
730 decision of a state to avail itself of a crisis exemption. Notification after the crisis has been declared does
731 not allow EPA to evaluate whether a crisis use can be supported with a section 408 safety finding, or
732 whether other potential risks are unacceptable, before use of the pesticide begins. In any case, EPA
733 would continue to provide the necessary verbal confirmations as quickly as possible, thereby often allowing
734 use of the crisis exemption in less than 36 hours. The Agency recognizes that speed is important for all
735 crisis exemptions, and that certain situations may be particularly urgent, including, but not necessarily limited
736 to, national security threats and some requests under USDA's Animal and Plant Health Inspection Service
737 quarantine program.

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

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

746 **VII. EPA Plans for Resistance Management and Endangered Species Considerations**

747 *A. Revised Plans for Addressing Resistance Management*

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

756 Although the April, 2003, FR Notice indicated that EPA was considering addressing resistance
757 management in this proposed rule, EPA now plans to pursue opportunities to address pest resistance
758 management as it implements the Pesticide Registration Improvement Act (PRIA) enacted January 23,
759 2004. This Act requires the Agency to establish a registration service fee system for applications for
760 pesticide registration and amended registration. Under this new system, fees will be charged for new
761 applications for registration received on or after the effective date of the statute (March 23, 2004) and EPA
762 is required to make a decision on the application within prescribed decision timeframes. Under PRIA, EPA
763 will eliminate its backlog of registration actions and make more timely decisions. This will accelerate the
764 registration of many products that will be beneficial to resistance management, including reduced risk
765 products. EPA's reduced risk process considers resistance management as an important factor. New

766 products that would address significant resistance management needs would reach the market sooner,
767 thereby providing a strong incentive to registrants to incorporate resistance management in their registration
768 submissions.

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

778 *B. Protections for Endangered Species*

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

786 FWS and NMFS, in collaboration with EPA and USDA, have developed a proposed counterpart
787 regulation, that would make the process of consultation about EPA actions involving pesticides more
788 efficient, effective, and timely, thereby strengthening the protections for endangered and threatened species.
789 As part of the work supporting the proposed counterpart rule, the Services and EPA reviewed the
790 Agency’s approach to the assessment of potential risks to listed species resulting from pesticide use. The
791 Services agreed that EPA’s approach to ecological risk assessment “will produce effects determinations
792 that reliably assess the effects of pesticides on . . . listed species and critical habitat pursuant to the ESA
793 and implementing regulations.” The January 26, 2004, letter from the Services to EPA that includes this
794 quote is in the public docket for this proposed rule, and interested parties may access it by following the
795 detailed instructions in Unit I.B. of this Notice.

796 As a result of the Services’ review of the Agency’s ecological risk assessment methodology, EPA
797 anticipates looking more closely at potential risks of pesticide use in connection with decisions on requests
798 for emergency exemptions. EPA currently requires, under 40 CFR 166.20(a)(7), information to be
799 included in applications for emergency exemption that addresses potential risks of the requested use to
800 endangered and threatened species. Although EPA, under existing requirements, routinely considers the
801 impacts of emergency exemptions on endangered and threatened species, the Agency seeks to improve the
802 guidance it gives to applicants concerning data on endangered and threatened species. EPA will need to
803 rely on States and federal agencies to supply information as part of their requests for emergency exemptions

804 that will enable EPA to assess the potential impacts on listed species and critical habitat of pesticide use
805 under the proposed exemption. EPA also plans to work with AAPCO and with individual States, as the
806 primary applicants for emergency exemptions, to improve the quality of their submissions as they try to
807 frame the potential impact of a requested pesticide use on endangered and threatened species. EPA
808 believes these measures fall within existing requirements but should increase the availability of essential
809 information needed to make a timely and substantive determination of the potential impact to endangered
810 and threatened species. EPA also plans through its reevaluation, to refocus and possibly increase
811 consideration of these impacts in its decision process for exemption requests, including any need to consult
812 with USFWS and NMFS.

813 **VIII. FIFRA Review Requirements**

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

818 **IX. Statutory and Executive Order Reviews**

819 *A. Executive Order 12866*

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

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

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

839 The only significant impacts expected would be burden reductions to States and Federal agencies in

840 the application process for emergency exemptions, and to EPA in the review process, as well as quicker
841 responses to emergency conditions. As detailed in the Economic Analysis prepared for this proposed rule,
842 based on predicted future applications affected by the proposed revisions, EPA estimates the annual
843 combined savings for applicants and EPA of around \$1.7 million, a little over \$1.2 million from re-
844 certification and about \$0.5 million from changing to the loss-based method of determining SEL.

845 *B. Paperwork Reduction Act (PRA)*

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

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

862 An agency may not conduct or sponsor, and a person is not required to respond to an information
863 collection request unless it displays a currently valid OMB control number. The OMB control numbers for
864 EPA's regulations in 40 CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9
865 and included on any related collection instrument (*e.g.*, form or survey).

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

871 *C. Regulatory Flexibility Act*

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

877 and State governments.

878 *D. Unfunded Mandates Reform Act*

879 Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4), EPA
880 has determined that this action does not contain a Federal mandate that may result in expenditures of \$100
881 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one
882 year. This proposed rule only applies to Federal and State government agencies, the only entities that can
883 petition the EPA under FIFRA section 18. As described in Unit IX.A., this proposed rule is expected to
884 result in an overall reduction of existing costs for applicants and EPA of around \$1.7 million. As such, this
885 action will not impact local or tribal governments or the private sector, and will not significantly or uniquely
886 affect small governments. Accordingly, this rule is not subject to the requirements of sections 202, 203,
887 204, and 205 of UMRA.

888 *E. Executive Order 13132*

889 Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA
890 has determined that this proposed rule does not have “federalism implications,” because it will not have
891 substantial direct effects on the states, on the relationship between the national government and the states,
892 or on the distribution of power and responsibilities among the various levels of government, as specified in
893 the Order. As indicated above, this proposed rule is expected to reduce burden on Federal and States
894 government agencies that petition EPA under FIFRA section 18, and on EPA in processing the
895 applications. Thus, Executive Order 13132 does not apply to this proposed rule. In the spirit of the Order,
896 and consistent with EPA policy to promote communications between the Agency and State governments,
897 EPA has specifically solicited comment from State officials.

898 *F. Executive Order 13175*

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

906 *G. Executive Order 13211*

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

912 H. Executive Order 13045

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

918 I. National Technology Transfer and Advancement Act

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

925 J. Executive Order 12898

926 This proposed rule does not have an adverse impact on the environmental and health conditions in
927 low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions*
928 *to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR
929 7629, February 16, 1994), the Agency has not considered environmental justice-related issues.

930 **List of Subjects in 40 CFR Part 166**

931 Environmental protection, pesticides, emergency exemptions.

932 Dated: _____

933 _____
934 Administrator

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

936 **PART 166 --[AMENDED]**

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

938 **Authority:** 7 U.S.C. 136-136y.

939 2. By **[amendatory instructions will be added after FAR.]**

940 **§166.2 Types of exemptions.**

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

945 **§166.3 Definitions.**

946 (a) The term *the Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended,
947 7 U.S.C. 136 et. seq.

948 (d)(3)(i) Involves the introduction or dissemination of an invasive species or a pest new to or not
949 theretofore known to be widely prevalent or distributed within or throughout the United States and
950 its territories; or

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

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

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

960 (i) crop yield loss greater than or equal to 20 percent;

961 (ii) economic loss, including revenue losses and cost increases, greater than or
962 equal to 20 percent of gross revenues;

963 (iii) economic loss, including revenue losses and cost increases, greater than or
964 equal to 50 percent of net revenues;

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

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

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

975 **§ 166.20 Application for a specific, quarantine, or public health exemption.**

976 (a)(2)(i)(A) A copy of the label(s) if a specific product(s) is/are requested; or the formulation(s)
977 requested if a specific product is not desired; and

978 Under § 166.20(a)(3), insert new item (iv); accordingly renumber items (iv, v, and vi) to be (v, vi, and vii);
979 revise the new item (vii); and add new items (viii and ix), to read as follows:

980 (iv) The maximum number of applications;

981 (v) The total acreage or other appropriate unit proposed to be treated;

982 (vi) The total amount of pesticide proposed to be used in terms of both active
983 ingredient and product;

984 (vii) All applicable restrictions and requirements concerning the proposed use which
985 may not appear on labeling;

986 (viii) The duration of the proposed use; and

987 (ix) Earliest possible harvest dates.

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

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

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

999 (ii) the information in (i) of this paragraph plus prices reasonably anticipated in the absence
1000 of the emergency and changes in prices and/or production costs due to the emergency;

1001 (iii) the information in (ii) of this paragraph plus operating costs reasonably anticipated in the
1002 absence of the emergency;

1003 (iv) any other information explaining the economic consequences of the emergency.

1004 Under 166.20(b) insert new item (5) to read as follows:

1005 (5) Re-certification of an emergency condition. Applicants for specific exemptions for which the
1006 emergency condition could reasonably be expected to continue for longer than one year, and for

1007 which the exemption was granted for the same pesticide at the same site to the same applicant the
1008 previous year, but no more than twice, may submit less information by basing such application on
1009 previously submitted information. For applications for such exemptions, except for applications
1010 subject to public notice pursuant to §166.24(a)(1)-(5) of this part, the information requirements of
1011 paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this
1012 section, shall not apply where the applicant certifies that all of the following are true:

1013 (i) The emergency condition described in the preceding year's application continues to
1014 exist;

1015 (ii) Except as expressly identified, all information submitted in the preceding year's
1016 application is still accurate;

1017 (iii) Except as expressly identified, the proposed conditions of use are identical to the
1018 conditions of use EPA approved for the preceding year;

1019 (iv) Any conditions or limitations on the eligibility for re-certification identified in the
1020 preceding year's notice of approval of the emergency exemption have been satisfied.

1021 **§ 166.24 Public notice of receipt of application and opportunity for public comment.**

1022 (a) Publication requirement. The Administrator shall issue a notice of receipt in the Federal Register
1023 for a specific, quarantine, or public health exemption and request public comment when any one of
1024 the following criteria is met:

1025 (a)(6)(i) An emergency exemption has been requested or approved for that use in any 3 previous
1026 years, or any 5 previous years if the use is supported by the IR-4 program, and

1027 **§ 166.25 Agency Review.**

1028 (a)(2) The Agency's ability and intention to establish a time-limited tolerance(s) or exemption(s)
1029 from the requirement of a tolerance for any pesticide residues resulting from the authorized use,
1030 identifying the level of permissible residues in or on food or feed resulting from the proposed use;

1031 (a)(4) The potential risks to human health, endangered or threatened species, beneficial organisms,
1032 and the environment from the proposed use.

1033 (b)(2)(ii) The progress which has been made toward registration of the proposed use, if a repeated
1034 specific or public health exemption is sought. It shall be presumed that if a complete application for
1035 registration of a use, which has been under a specific or public health exemption for any 3 previous
1036 years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not
1037 been submitted, reasonable progress towards registration has not been made.

1038 **§ 166.30 Notice of Agency Decision.**

1039 (a)(1) Incomplete applications. The Agency may discontinue the processing of any application that
1040 does not address all of the requirements of §166.20 until such time the additional information is
1041 submitted by the applicant.

1042 Remove §166.30(b) Notification of FDA, USDA, and State health officials, and accordingly re-label item
1043 (c) Federal Register Publication as item (b).

1044 **§166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health**
1045 **exemptions.**

1046 (b) Interim and Final reports. A final report summarizing the results of pesticide use under any
1047 specific, quarantine, or public health exemption must be submitted to the Agency within 6 months
1048 from the expiration of the exemption unless otherwise specified by the Agency. For quarantine
1049 exemptions granted for longer than one year, interim reports must be submitted annually. When an
1050 application for renewal of the exemption is submitted before the expiration of the exemption or
1051 before submission of the final report, an interim report must be submitted with the application. The
1052 information in interim and final reports shall include all of the following:

1053 **§ 166.40 Authorization.**

1054 (a) An unpredictable emergency condition exists; and

1055 add new item (c)

1056 (c) EPA has provided verbal confirmation that, for food uses, a tolerance or exemption from the
1057 requirement of a tolerance can be established in a timely manner, responsive to the projected
1058 timeframe of use of the chemical and harvest of the commodity, and that, for any use, the Agency
1059 has no other risk-based objection.

1060 **§ 166.43 Notice to EPA and registrants or basic manufacturers.**

1061 (a)(1) The State or Federal Agency issuing the crisis exemption must notify the Administrator, and
1062 receive verbal confirmation from EPA required in §166.40(c), in advance of utilization of the crisis
1063 provisions. EPA will attempt to provide such confirmation as quickly as possible, but shall notify
1064 the applicant of its determination within 36 hours.

1065 (b)(1) The name of the product and active ingredient authorized for use, along with the common
1066 name and CAS number if available, including a copy of the EPA registered label and use directions
1067 appropriate to the authorized use;

1068 (b)(4) The date on which the pesticide use is to begin and the date when the use will end;

1069 (b)(5) An estimate of the level of residues of the pesticide expected to result from use under the
1070 crisis exemption;

1071 Revise, and add new items (6), (7), and (8) under §166.43(b)

1072 (b)(6) Earliest anticipated harvest date of the treated commodity;

1073 (b)(7) Description of the emergency situation; and

1074 (b)(8) Any other pertinent information available at the time.

1075 Delete **§166.47 Notification of FDA, USDA, and State health officials.**

1076 §166.49 Public notice of crisis exemptions.

1077 (a) Periodic notices. At least quarterly, the Administrator shall issue a notice in the Federal Register
1078 announcing issuance of crisis exemptions. The notice shall contain all of the following:

1079 (1) The name of the applicant;

1080 (2) The pesticide authorized for use;

1081 (3) The crop or site to be treated; and

1082 (4) The name, address, and telephone number of a person in the Agency who can provide
1083 further information.

1084 [FR Doc. 03-????? Filed ??-??-03; 8:45 am]

1085 **BILLING CODE 6560-50-S**

**** EO 12866 Review Draft - Do Not Cite or Quote ****

Attachment 3

**ECONOMIC ANALYSIS OF THE PROPOSED
PESTICIDES EMERGENCY EXEMPTION PROCESS REVISIONS**

Prepared by:

**BIOLOGICAL AND ECONOMIC ANALYSIS DIVISION
OFFICE OF PESTICIDE PROGRAMS**

Draft: April 30, 2004

**U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20640**

Economic Analysis

I. Background for the Proposed Rule:

EPA is proposing several revisions to the regulations at 40 CFR part 166, which govern such FIFRA section 18 emergency exemptions. The most significant of these proposed improvements are two revisions intended to streamline and improve the application and review process by reducing the burden to both applicants and the EPA, allowing for quicker decisions by the Agency, and providing for more equitable determinations of “significant economic loss” as the basis for an emergency. These two proposals are currently being employed in limited pilot programs. The first would allow applicants for certain exemptions to re-certify that the emergency conditions which initially qualified for an exemption continue to exist in the second and third years. The second proposal would allow greater flexibility in the submission of data to demonstrate significant economic loss (SEL) and corresponds to a change in methodology to make that determination. The new methodology focuses on the loss compared to current economic and agronomic conditions rather than conditions over the past five years. In addition, EPA is proposing to revise the regulations to clarify that quarantine exemptions may be used for control of invasive species, and to update or revise certain administrative aspects of the regulations. All of these proposed revisions can be accomplished without compromising protections for human health and the environment.

A. Overall Approach:

This is primarily a cost saving rule, reducing burden on states and on EPA. In conducting the economic analysis the Agency is analyzing the benefits and impacts of the proposed rule. The benefits of the proposed rule are the cost savings from both the re-certification and reduction in data requirements by using the loss based method. The impacts of the proposed rule are analyzed by comparing the outcomes of SEL findings for both the current method and the proposed method.

1. Benefits—estimating cost savings. The re-certification part of the rule reduces costs for both states and EPA with respect to submitting and reviewing section 18 packages. The new data requirements for demonstrating a SEL do not demand historical information, particularly the more onerous requirement for yearly production costs. Because the proposed SEL method uses a tiered screening system, states may be able to submit less data and will in no case need to submit more. This EA estimates how often a cost savings event occurs and adds up the reduced burden using the section 18 ICR estimates of burden. The analysis demonstrates that the proposed rule would result in considerable cost savings to the applicants and some savings to EPA.
2. Impacts—comparing findings of SEL (significant economic loss) under the current and proposed methods for determining SEL. The analysis demonstrates that there would be no change in the overall likelihood of a SEL finding, although there would be different SEL findings in about 12% of the requests. EPA believes that these differences would be more equitable than the current findings.

B. Reason for the Proposed Changes Are:

1. Re-certification: The Agency believes that most candidates for re-certification can be registered relatively quickly. This will allow applicants for certain repeat exemptions to re-certify that the emergency conditions which initially qualified for an exemption continue to exist in the second and third years. The applicants' own certification that the emergency situation is ongoing, along with their incorporation by reference of their earlier full application, will take the place of the submission of data generally required to support a repeat request for an emergency exemption. In this way, the burden associated with the application process for select repeat requests will be significantly reduced. In addition, re-certification will often allow EPA to make quicker decisions on exemption requests.
2. Determination of Significant Economic Loss (SEL): In developing a more appropriate methodology for determining SEL, the Agency considered three factors:
 - a. To focus the determination of losses due to emergencies caused by urgent and non-routine pest problems on existing conditions. The current methodology may confound the issue with past price volatility and may result in an inappropriate criterion of significant economic loss. Historical data have been used to provide a baseline for estimating both normal profits and variation *in the absence of the emergency condition* for the affected area. However:
 - (1) *Historical data may not be representative of existing physical and economic conditions*. While unusual weather conditions may lead to pest outbreaks, the weather conditions themselves should not influence the calculation or significance of loss. Similarly, many crops have demonstrated high price variability or significant changes in price over the past several years.
 - (2) *Historical data are often affected by the emergency condition*. Pest pressure related to the emergency condition in previous years (even if not significant) may reduce revenues and distort the estimation of baseline revenues and variation. For example, historical data often reflect increasing pesticide resistance that may have begun before an emergency exemption was requested, but where the resistance later becomes the basis for requesting the exemption. In the case of repeat emergency exemptions, the historical data are affected by both the revenue-decreasing emergency condition and revenue-increasing use of the requested pesticide, which will not necessarily equally offset each other.
 - (3) *Historical data may be unavailable in many states for minor and new crops*.
 - (4) *The focus on historical data may make it difficult to demonstrate some pest-related losses*. While pest damage usually results in a loss in quantity harvested, sometimes the losses are due to reduced quality of the product that decrease the price received by growers. Damage to orchards and other perennial crops may result in losses over several years. These types of losses have not fit well under the present method of analysis.

- b. To increase transparency and establish more consistent measures of economic loss. In the current revenue variation method, crops with high yield variability (such as many non-irrigated crops) or with high price variability must have high pest losses to meet the criterion of SEL compared to crops with stable yields and prices. Therefore, this criterion may be unfair to farmers already facing high yield and price risk while inappropriately granting exemptions to farmers of low-risk crops with minor pest losses .
- c. To reduce the burden of data collection and analysis on the part of the states and the Agency. In many cases a decision can be made with less information, thus speeding decisions for these cases and permitting more resources to be devoted to more complex situations.

C. Description of the Current Revenue Variation Method

The revenue variation method defines an economic loss as significant if it would cause expected net revenue to fall below the minimum historical net revenue over a period of typically five years. In some cases, past yields and/or prices may be considered to be outside normal bounds. For example, drought may reduce yields such that one year in the data cannot be considered typical. Analysts may use judgement to eliminate outliers from the determination of the minimum net revenue.

The economic consequences of the emergency are determined separately. In most cases, yield losses are predicted, but the impacts may also include quality losses or increases in pest control costs. For example, an unusual pest outbreak might be controlled by multiple applications of a registered pesticide when typically only one application would be necessary. If these predicted losses would result in net revenue that is lower than the lowest net revenue over the past five years (after eliminating outliers) then these losses are considered significant.

D. Description of the Proposed Loss-based (Tiered) Approach:

The loss-based approach uses the same methodology to calculate the economic consequences of an unusual pest outbreak. States will still have to submit data to demonstrate the emergency nature of the outbreak and the expected losses in quantity, quality and/or additional production costs. The proposed approach would provide applicants with greater flexibility in establishing the baseline scenario. Even though 5 years of historical economic data are not required under the proposed approach, applicants may continue to utilize historical data to establish baseline gross and net revenues from which to estimate economic losses in Tiers 2 and 3 described below. The new approach imposes a standard criterion for determining the significance of that loss, rather than comparing losses to past revenues. The goal of the criterion is to compare losses to expected farm income in a manner that can be easily measured. Further, successive screening levels have been chosen that will permit situations that clearly qualify to be resolved quickly and with a minimum of data.

1. Tier Thresholds

Tier 1, Yield loss \geq 20%: The first screen is based on crop yield loss and is a quantity-based measure. EPA will conclude that a significant economic loss will occur if the projected yield loss due to the emergency condition is verified to be 20% of expected yields or greater. The yield loss threshold in Tier 1 will be the same for all crops and regions. This threshold is set at a level such that a loss which exceeds the threshold would generally also meet the thresholds in Tiers 2 and 3, if the additional economic data were submitted and analyzed. Therefore, for large yield losses it is not necessary to separately estimate economic loss, which requires detailed economic data. Yield losses are measured as the difference between expected yields in the absence of the emergency and yields under the emergency condition when using the best available, registered alternative.

Tier 2, Economic Loss \geq 20% of Gross Revenues: For situations with yield losses that do not meet the yield loss criterion for Tier 1, EPA will evaluate estimates of economic loss as a percent of gross revenue in Tier 2. Economic losses result not only from yield losses, but also from causes such as quality losses and changes in production costs, including pest control, harvesting, sorting and processing. EPA will conclude that a significant loss will occur if the projected losses due to the emergency condition are verified to be 20% of expected gross revenues or higher. This threshold will be the same for all crops and regions. Quality losses occur when damage results such that the commodity fails to meet the market standards for a high-value segment (*e.g.*, export or fresh market) and must be sold in a lower value outlet (*e.g.*, domestic or processed market). Quality losses can occur without loss in quantity or can occur in conjunction with yield losses. This tier will also consider losses due to higher production costs. Higher production costs could include additional pest control costs, for example, mechanical weeding, or additional harvest costs, for example, sorting into different grades. However, these costs must be a result of the emergency before the expenses can be included in the projected loss.

Tier 3, Economic Loss \geq 50% of Net Revenues above Operating Costs: For situations in which losses do not meet the criteria for Tiers 1 and 2, EPA will evaluate estimates of economic loss as a percent of net revenue in Tier 3. Economic losses are defined as in Tier 2. EPA will conclude that a significant loss will occur if the projected losses due to the emergency condition are 50% of expected net revenues or higher. This threshold will be the same for all crops and regions. For this purpose, the Agency defines net revenue as gross revenues less variable operating costs (purchased inputs and hired labor). The Agency considers only variable operating costs because these costs are easier to measure and document than fixed costs, such as overhead and depreciation of machinery, and because they are likely to be more reflective of short-term impacts due to emergency conditions. The Agency recognizes that net revenues above operating costs overstate grower income, but believes the facility of measurement and verification make it a more useful measure.

Losses that do not fit into this general pattern will be evaluated on a case-by-case basis. For example, damage to perennial crops that may result in losses over several years could be evaluated as a loss in capital or in returns on an investment, depending on the situation. In those cases, the states must submit data appropriate to their case.

2. Basis for Tier Thresholds

The choice of thresholds 20%, 20%, and 50% is based on the following three considerations.

a. Farm income

The tier thresholds are based on average farm income and production expenses for the USA. The latest annual report from USDA shows farm production expenditures in the USA to average about 80% of gross revenue (USDA, 2003). The remainder, net farm income, is essentially the wages earned by the growers. See table below.

Table 1. Aggregate Farm Income and Costs for the U.S. in \$ billions

| | 1997 | 1998 | 1999 | 2000 | 2001 | Average | % of gross revenue |
|--|---------|---------|---------|---------|---------|---------|--------------------|
| Gross Revenue | \$238.1 | \$232.1 | \$234.5 | \$241.7 | \$246.5 | \$238.6 | 100.0% |
| Total Production Costs | \$187.6 | \$186.5 | \$188.3 | \$193.7 | \$200.8 | \$191.4 | 80.2% |
| Operating Costs | \$136.1 | \$134.8 | \$136.5 | \$140.4 | \$147.0 | \$139.0 | 58.2% |
| Fixed Costs | \$51.5 | \$51.7 | \$51.8 | \$53.3 | \$53.7 | \$52.4 | 22.0% |
| Net Revenue = gross revenue - operating costs | \$102.0 | \$97.3 | \$98.0 | \$101.3 | \$99.5 | \$99.6 | 41.8% |
| Net Farm Income = gross revenue - total production cost | \$50.5 | \$45.6 | \$46.2 | \$48.0 | \$45.7 | \$47.2 | 19.8% |

Source: USDA Agricultural Statistics, 2003.

An economic loss of 20% of gross revenue would be sufficient to eliminate net farm income, which is on average about 20% of gross revenue. A yield loss of 20% results in economic loss of 20% or more of gross revenue.

Since net farm income is a little less than 50% of net revenue, an economic loss that is 50% of net revenue would be sufficient to eliminate net farm income.

b. Retrospective Analysis

In addition, a retrospective analysis was done on past emergency exemptions and the results are shown in Figure 1. To qualify as a SEL under a direct use (without subjective judgement) of the revenue variation approach, the losses caused by the emergency must result in the expected net revenue being equal to or less than the minimum net revenue over the last 5 years. According to the retrospective analysis:

- (1) Tiers 1 and 2. The average and median economic losses that would have qualified as a SEL under the current method (i.e. calculated thresholds of losses) were about 18% and 15% of gross revenue, respectively.
- (2) Tier 3. The median economic loss that would have qualified as a SEL under the current method was about 51% of net revenue.

Since the first 2 tiers are screening thresholds, these thresholds were rounded up to 20% to be a little more stringent, with the idea being that if they did not pass Tiers 1 or 2, they could qualify with Tier 3. Tier 3 compares losses to net revenue (gross revenue minus operating costs).

c. Neutral to Likelihood of a SEL

The proposed approach is not expected to significantly change the likelihood of an application qualifying for a SEL. That is, approximately the same number of emergency requests that qualified for a SEL using the current revenue variation approach, would have qualified using the proposed loss-based (tiered) approach, although there would be differences in individual cases. That is, some cases would have qualified for a SEL under the proposed method that did not qualify under the current method and visa-versa with the total number qualifying being the about the same with both methods. See Section III E, Comparison of Findings. EPA believes that the differences in which cases qualify would be more equitable and consistent under the proposed method.

E. Statutory and Regulatory Requirements:

1. Statutory Provisions: FIFRA, Section 18

FIFRA generally prohibits the sale and distribution of any pesticide product, unless it has been registered by EPA in accordance with section 3. One exception to this general prohibition is section 18 of FIFRA, which gives the Administrator of EPA broad authority to exempt any Federal or State agency from any provision of FIFRA if the Administrator determines that emergency conditions exist which require such exemption.

2. Regulatory Provisions: 40 CFR, Part 166

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

II. Methodology of Economic Analysis

A. Purpose of EA (economic analysis)

The purpose of this EA is to evaluate the costs and benefits of the proposed rule change. The EA:

1. Compares findings (both the overall likelihood of a finding and the findings for individual cases) to determine if there would be an impact with substantially different conclusions under more flexible data requirements, given changes in guidance for evaluating SEL. The analysis indicates that there would be virtually no impact in the overall likelihood of a finding of SEL, and that small differences in findings for individual cases would be more equitable.
2. To estimate the cost savings of the rule as a result of :
 - a. More flexible data requirements for determining SEL (significant economic loss).
 - b. Reduced data requirements for re-certification of emergency conditions.

B. Significant Economic Loss (SEL)

1. SEL Database. The first step in this analysis was to populate a database of SEL findings under different approaches. EPA developed a SEL spreadsheet template that determines SEL findings under both the current and proposed methods, as well as what the analyst concluded. This SEL spreadsheet was used to analyze many of the exemption requests since 2000 and to populate the SEL database used for this analysis.
2. Cost Savings Analysis.
 - a. Number of cases qualifying. With the SEL database EPA determined the number of cases which would have qualified as a SEL under each Tier. Then EPA assumed the same proportion would qualify in the future. A significant economic loss (SEL) is defined as a loss that would pass any one of the following tiers:
 - Tier 1** - Yield loss $\geq 20\%$. Significant cost savings for both states and EPA.
 - Tier 2** - Economic loss as a percent of gross revenue $\geq 20\%$. This tier also covers quality losses and cost increases. Economic loss is defined as loss in revenue from yield and quality losses plus increased costs as a result of the emergency, such as increased pest control or harvesting costs. This tier would also save resources because production costs other than cost increases are not required.
 - Tier 3** - Economic loss as a percent of net revenue $\geq 50\%$. This tier also considers the impact on net revenue. This tier has the same numerator, economic loss as Tier 2, but compares that economic loss to a different denominator, net revenue. Net revenue is defined as gross revenue minus operating costs. This tier should still save some resources since historical data are not required. However, operating cost information needs to be more documented than has often been the case in the past, when states have not clearly defined the costs included in the submitted data. Therefore, BEAD assumes that the resource requirements would be comparable to the revenue variation method.

- b. Cost saving per case. Using ICRs (information collection requests) and expert opinion from scientists in EPA, the agency estimated the savings.
- c. Estimate cost impacts. The agency can estimate the total cost savings by multiplying the number of cases qualifying for a SEL per year under Tiers 1 and 2 by the cost savings per case for each respective tier, *i.e.*:

$$\Sigma (\text{cost savings for Tiers 1 \& 2 requests}) \times (\text{number of cases qualifying for Tiers 1 \& 2})$$

This calculation may overestimate the cost savings, since states may choose to submit more data than would be necessary in case EPA does not concur with their loss estimates. That is, states claiming yield losses in excess of 20% may still decide to submit price and production cost data in case EPA's evaluation suggests that yield losses will be less severe. This calculation also assumes that there will be no savings under Tier 3, although more flexible data requirements may mean that applicants will be able to provide adequate baseline data more easily than under the revenue variation method.

3. Comparison of SEL Findings. The database can also be used to compare findings with respect to the likelihood of a SEL finding and the findings in individual cases. The database provides what the findings:
 - a. Would be with a direct use (without judgement) of revenue variation method,
 - b. Would have been with the proposed loss-based approach *given data submitted under the current methodology*, and
 - c. What they actually were determined to be by the analyst.

C. Re-certification

To estimate the potential cost savings EPA estimated the:

1. Number of section 18s that would have been eligible for re-certification. EPA assumes that the same proportion will be eligible in the future.
2. Resources required by the state and EPA for a full application & review compared to a review with re-certification.

III. Results of the Analysis of Proposed Method for Determining SEL

A. Summary of exemption requests. See Table 2 below.

Table 2. Summary of emergency exemption requests received by EPA annually, and the numbers of requests used in the Economic Assessment for the section 18 proposed rule.

| Set of exemption requests | Average Annual Number | Comments |
|--|-----------------------|---|
| Total exemption requests received/year | 541 | Includes all specific, quarantine, public health, and crisis exemption requests |
| Number of <u>specific exemption</u> requests received/year | 500 | The proposed process revisions only apply to specific exemptions |
| Number of <u>specific exemption</u> requests received/year for which bio/econ analysis is done | 95 | The Biological and Economic Analysis Division (BEAD) does not do analysis when the emergency is not SEL-type, when BEAD's conclusion for one state applies to others for same emergency in same year, or for many repeat requests |
| Number of <u>specific exemption</u> requests received/year for which bio/econ analysis is done, AND for which we have complete data to do comparative analysis of revenue variation and loss-based methods | 45 | BEAD keeps a database in which analysts record certain data from the application, the results of the revenue variation method, and the analyst's SEL conclusion. However, in some cases the data is incomplete |
| Number of <u>specific exemption</u> requests received/year for which bio/econ analysis is done, AND for which we have complete data to do comparative analysis of revenue variation and loss-based methods, AND for which we have the analyst's SEL conclusion available in the database | 26 | In some cases, the BEAD database is complete, except for the conclusion on SEL. |

NOTE: average annual numbers are based on four-year averages for FY2000-FY2003. Each set of exemption requests is a subset of the set(s) described in the row(s) above it.

B. Dataset

1. Number of Applications Received for specific exemptions from 2000 through 2003 averaged about 500 annually. This average is assumed to be the likely number of applications to be received in the future. (EPA, 2003b) The proposed rule only applies to specific exemption requests.
2. Number of Applications Reviewed for SEL by BEAD¹ from 2000 through 2003 averaged about 95 annually for specific exemptions only. This average is assumed to be the likely number of

¹ BEAD is the Biological and Economic Analysis Division of the Office of Pesticide Programs of EPA. BEAD does the biological and economic reviews and analyses of emergency exemption requests to determine if there is an emergency condition and if the emergency condition would lead to a SEL.

applications to be reviewed by BEAD for SEL in the future. A BEAD review for SEL was conducted on less than one-fifth of the applications received. Many requests are not reviewed by BEAD for SEL for various reasons such as repeat requests, low risk, and similar conditions to granted requests from another state. (EPA, 2003a)

3. SEL Database

- a. As explained above, this database derived from SEL spreadsheet templates was used to estimate the likelihood of an application qualifying for a SEL
 - (1) as recommended by the analyst using the current method, including the analyst's judgement,
 - (2) under a direct use of the revenue variation method without the analyst's judgement or conclusion, and
 - (3) under the loss-based method, *given data submitted under the current methodology*.
- b. The SEL database contains information from 181 (45 per year) SEL spreadsheets compiled in the course of the BEAD review covering almost one-half of the 378 (95 per year) requests reviewed for SEL by BEAD from 2000 through 2003. SEL spreadsheets were not necessarily utilized nor complete for each review for a number of reasons including:
 - (1) Incomplete data submitted by the applicant.
 - (2) Determination by the biologist that there was not an emergency condition.
 - (3) Withdrawal of request by the applicant.
 - (4) The revenue variation methodology was not appropriate for the situation.
- c. Of the 181 (45 per year) observations, the analyst's recommendation is known for 103 (26 per year) observations because of incomplete data in the SEL database. Some requests in the database were determined to be routine or non-urgent situations. However, these data may be used to calculate what losses would be required to be significant even if a SEL was not determined.

4. Specific exemption requests eligible for self-certification are estimated to be about 130 per year. (EPA, 2003b)

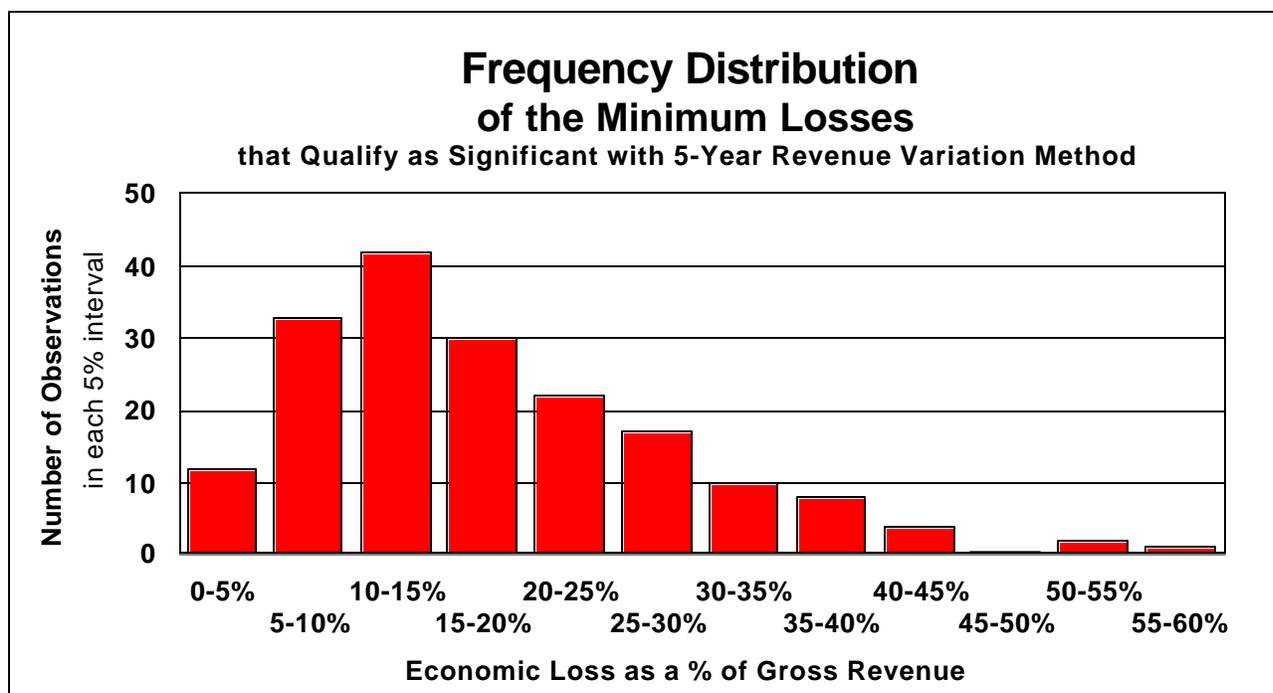
5. ICR (Information Collection Request). The ICR for emergency exemptions was used to estimate the resources required to apply for an emergency exemption and for EPA to review these requests. (EPA, 2000)

C. Losses Qualifying as a SEL under the Revenue Variation Method.

To qualify as a SEL under the revenue variation method, the loss should cause expected net revenue as a result of the emergency to fall below the minimum net revenue over a period of 5 years. This loss threshold is calculated as a percent of gross revenue as follows:

$$\frac{\text{baseline net revenue} - \text{minimum revenue over past 5 years}}{\text{baseline gross revenue}}$$

The chart below presents the frequency distribution of the losses as a percent of gross revenue that



would have resulted in the expected net revenue being equal to the minimum net revenue for the 181 analyses available for observation from the period 2000-2003.

Figure 1. Frequency Distribution of Minimum Losses Qualifying as SEL.

This frequency distribution demonstrates the perverse nature of the current method of determining SEL. Out of the 181 observations, the following number (and percent) of requests could have qualified as having a SEL under a direct interpretation (without judgement) of the revenue variation method with the following losses as a percent of gross revenue:

1. 12 (7% of 181) requests with a loss of 5%.
2. 45 (25%) requests with a loss of 10%.
3. 91 (50%—the median) requests would have qualified with a loss of 15.3%. The other 90 would have required losses ranging between 15.3 % and 60% to qualify with a SEL.
4. 117 (65%) requests with a loss of 20%. The other 64 (181-117 or 35%) requests would have required losses ranging between 20% and 60% to qualify with a SEL.
5. 3 (2%) requests would have required a loss of 50% or more to qualify as having a SEL under a direct interpretation of the revenue variation (current) method.
6. Conclusion. A consistent standard of loss (as the proposed loss-based method) that would qualify as a SEL would be more equitable.

7. Average. The average calculated loss threshold under the current variation method was about 18% of gross revenue. The average was higher than the median of 15% because of the skewed distribution. The calculated loss threshold is the loss minimum loss required to qualify as a SEL.

D. Cost Savings as a Result of Changing Data Requirements for Determining SEL

1. Requests Passing Each Tier with a Finding of a SEL. Table 3 below shows the percent and number of requests that would have qualified for a SEL under the proposed loss-based method, *given data submitted under the current methodology*².
 - a. About 55% would qualify for Tier 1 and would not require economic data nor an economic review.
 - b. Another 10% that would not qualify for Tier 1 would qualify for Tier 2 and not require production cost data.
 - c. Another 15% would qualify only for Tier 3, for which we assume no savings compared to the current method.
 - d. No savings are assumed for requests not qualifying for any tier.
 - e. EPA receives about 500 specific exemption requests per year. Of these about 95 are reviewed for SEL. Therefore, the annual applicant savings are based on 500 requests submitted, while the annual EPA savings are based 95 applications reviewed for SEL.

² Results may be slightly different under more flexible data requirements since the historical data used for this analysis may not be representative of situation growers face. For example, under the current method average historical price was generally used as a baseline, while proposed method may use other information to determine the price most likely to be received by growers.

Table 3. Requests Likely to Pass Each Tier Using the Loss-based Method

| Tier | Threshold | Required Data & Analysis | Requests likely to pass tier* | | |
|---|----------------------------------|---|-------------------------------|--------|-----------|
| | | | % | Total* | Bio/Econ* |
| Tier 1 | ≥ 20% yield loss | Yield loss | 55% | 276 | 52 |
| Tier 2, but not Tier 1 | Loss ≥ 20% <u>gross</u> revenue | Yield loss + prices, cost changes & gross revenue | 10.5% | 53 | 10 |
| Tier 3, but not Tiers 1 & 2 | Loss ≥ 50% of <u>net</u> revenue | All of the above + operating cost & net revenue | 15.5% | 77 | 15 |
| Requests passing any tier | | | 81% | 406 | 77 |
| Requests not passing any tier | | | 19% | 94 | 18 |
| Total requests per year (Average 2000-03) | | | 100% | 500 | 95 |

Numbers may not exactly add, due to rounding

* While the average number of requests per year is 500, about 95 are reviewed for SEL. The percentages passing each tier are based on 181 observations (2000-03) where EPA had data on past analyses of SEL. These percentages are applied to all 500 applications (total) for estimating annual applicant savings, but only to the 95 applications in which a biological and economic review (Bio/Econ) was done to determine SEL when estimating annual EPA savings.

2. Cost Savings for the Applicants (States). The table below estimates the application cost savings that are likely to occur as a result of changing to the loss-based method.
 - a. The ICR (EPA, 2000) estimates that it takes about 99 hours to apply for an emergency exemption at a cost of \$54 per hour or over \$5000 per application. Of this 99 hours, an estimated 74 hours is spent processing, compiling, reviewing, and providing all the requested data, including efficacy and risk data. EPA assumes that about 25% of the time providing all of the data is required to provide the economic data under the current method. If the application qualifies for a SEL in Tier 1, the economic data would not be required, thus saving almost 19 hours or almost \$1000 per application. For 276 applications that are likely to qualify under Tier 1, the savings would be almost \$276,000.
 - b. If an applicant qualifies for a SEL under Tier 2, but not under Tier 1, limited economic data is required. EPA assumes that this limited data would require about half of the time required for economic data under the current method. Therefore, the savings would be about 12.5% of the time required to provide all data under the current method – about 9 hours or \$500 per application. With about 53 applications that are likely to qualify for a SEL in Tier 2, but not Tier 1, and that would provide limited economic data, the savings would be almost \$26,500.
 - c. While the data required under Tier 3 may be less than required under the current method, EPA makes the conservative assumption that there would be no savings. Often an applicant may provide historical data to establish a baseline from which to calculate the loss. Also, no savings are assumed for requests with no finding of SEL.

- d. EPA estimates the total annual savings to the applicants to be almost 5,600 hours or over \$300,000.

Table 4. Cost Savings for Applicants from Proposed Loss-based Method

| Applicant | Current Cost | | Savings as a Result of Qualifying for a SEL Under: | | |
|--------------------|---------------|-------------|--|----------|---------------|
| | Application | Data * | Tier 1 | Tier 2 | Total Savings |
| Avg wage rate | \$54 per hour | | | | |
| % savings | | | 25% | 12.5% | |
| Hour/application | 99 | 74 | 18.5 | 9.25 | |
| Applications/year | 500 | 500 | 276 | 53 | 329 |
| Hours per year | 49,500 | 37,000 | 5,106 | 490 | 5,596 |
| \$ per application | \$5,346 | \$3,996 | \$999 | \$500 | |
| Total \$ per year | \$2,673,000 | \$1,998,000 | \$275,724 | \$26,474 | \$302,198 |

Numbers may not exactly add, due to rounding

* The estimate of the time and cost required to process, compile, review, and provide data.

3. Cost Savings for EPA. The table below estimates the review cost savings that are likely to occur as a result of changing to the loss-based method.
- The ICR (EPA, 2000) estimates that it takes about 108 hours for EPA to review an emergency exemption. Of this 108 hours, it takes about 28 hours to review the biological and economic data in order to determine if there is an emergency condition and a SEL³. Most of the time is spent by the biologist in reviewing the emergency condition. EPA assumes that 25% of the time (about 7 hours) is spent by the economist in the determination of SEL under the current method. At a cost of \$67.25 per hour the biologic and economic review costs almost \$1900 per application, with the economic analysis costing about \$470.
 - If the application qualifies for a SEL in Tier 1, the economist review would not be required, thus saving about 7 hours or about \$470 per application or about \$24,500 annually for 52 applications likely to qualify for a SEL in Tier 1.
 - If an applicant qualifies for a SEL under Tier 2, a limited economic review would be required. EPA estimates that this limited review would require about 40% of the normal time to do a full economic analysis or 10% (40% x 25%) of the time required for the biologic and economic review under the current method with a savings of about \$190 per application or almost \$1,900 for 10 applications that are likely to qualify for a SEL in Tier 2.

³ Based on TAIS (Time Accounting Information System) of OPP (Office of Pesticide Programs), the time spent for the biologic and economic review is slightly over 25% of the time reported by all of OPP in processing emergency exemptions. (EPA, 2003c)

- d. EPA makes the conservative assumption that there would be no savings in the review of Tier 3, including those requests with no finding of SEL.
- e. EPA estimates the total annual savings of the biologic and economic review to be almost 400 hours or about \$26,000.

Table 5. Cost Savings for EPA from Proposed Loss-based Method

| EPA | Current Cost | | Savings as a Result of Qualifying for a SEL Under: | | |
|--------------------|------------------|---------------------|--|---------|---------------|
| | EPA | Biologic & Economic | Tier 1 | Tier 2 | Total Savings |
| Avg wage rate | \$67.25 per hour | | | | |
| Savings | | | 25% | 10% | |
| Hours/application | 108 | 28 | 7 | 2.8 | |
| # of applications | 95 | 95 | 52 | 10 | 62 |
| Total hours | 10,206 | 2,646 | 364 | 28 | 392 |
| \$ per application | \$7,263 | \$1,883 | \$471 | \$188 | |
| Total \$ per year | \$686,354 | \$177,944 | \$24,479 | \$1,883 | \$26,362 |

- 4. Total Saving. EPA estimates the total potential savings for the states and EPA combined to be about a third of a million dollars as a result of changing data requirements and using the loss-based method of determining SEL.

E. Comparison of Findings

1. Likelihood of a SEL Finding

The table below compares the number and percent of findings under a direct use (without judgement) of the current and proposed methods, and what the analyst actually concluded using judgement.

- a. The analyst found a SEL a higher percentage of time (83%) than a direct use of the revenue variation method would indicate (72%). The higher findings of a SEL by the analyst were mainly the result of the analyst eliminating outliers where past revenues were very low due to unusual conditions. Such outliers distort typical conditions and the loss as a result of the emergency condition would have to be overly large to qualify for a SEL. By eliminating the outliers, the historical data is more indicative of normal conditions and the calculated threshold needed to qualify as a SEL is less biased.

- b. The percent of time the loss qualified as a SEL under the loss-based method (given that the data were submitted under the present methodology) was closer to what the analysts found than what a direct use of the revenue variation method found. Since the loss-based method is less affected by outliers in the historical data⁴, it is less dependent on subjective decisions of the analyst.

Table 6. Comparison of Findings

| Finding | Number and Likelihood of a Finding | | |
|--------------------------------|------------------------------------|--------------------|-----------------|
| | Current Method | | Proposed Method |
| | Actual by Analyst* | Revenue Variation* | Loss-based |
| SEL | 86 (83%) | 131 (72%) | 147 (81%) |
| No SEL | 17 (17%) | 50 (28%) | 34 (19%) |
| Total Observations* 2000-03 | 103 | 181 | 181 |

* Out of 181 observations, the actual finding by the analyst is known in 103 cases. The actual findings of SEL by the analyst exceeds what the current revenue variation method would have found without judgement. The analyst uses judgement to eliminate outliers in annual revenue data that distort the findings of SEL.

2. Cross Agreement of Findings

The table below shows the percent of time that the findings of a SEL agreed with each other under the following:

- a. What a direct use of the revenue variation method would have determined.
- b. What the analyst actually determined.
- c. What the loss-based method would have determined.

This table below is based on 103 observations where the recommendation of the analyst was known. The results show a high degree of agreement between the various methods.

Table 7. Cross Agreement of Findings

⁴ Using data submitted under the present approach may result in some bias if average values for yield and prices are used to represent typical conditions. Under revised data requirements, states could submit data that better represents typical conditions if historical averages are inappropriate.

| Cross Agreement of Findings based on 103 observations 2000-03* | % Agreement | | |
|---|-------------|--------|-------|
| | SEL | no SEL | total |
| Analyst with Revenue Variation Method | 76% | 14% | 90% |
| Analyst with Loss-based Method | 82% | 6% | 88% |
| Revenue Variation Method with Loss-based Method | 76% | 6% | 82% |
| Analyst with Revenue Variation & Loss-based Methods | 74% | 6% | 80% |

* Out of 181 observations, the finding of the analyst is known in 103 cases.

3. Conclusions of comparisons. The two tables above demonstrate that changing from the current method to the proposed loss-based method would:
 - a. Not cause a significant change in the overall likelihood of a SEL finding as compared to the current revenue variation method as modified by analyst judgement such as eliminating outliers. The analyst made a finding of SEL in 83% of the cases studied, while the loss-based method would have found a SEL in 81% of cases.
 - b. Result in some different findings in individual cases. The analyst and the loss-based method arrived at different conclusions 12% of the time. In a few cases the analyst found a SEL with a yield loss and economic loss as a percent of gross revenue of less than 20% because these losses were sufficient to cause the net revenue to fall below the lowest net revenue of the past 5 years. In other cases, the analyst did not find a SEL with a yield loss greater than 20% because these losses were not sufficient to cause the net revenue to fall below the lowest net revenue of the past 5 years. In some cases there was not good data on the expected yield loss, so a judgement was made whether or not the expected loss would exceed the minimum loss needed to qualify as significant with the revenue variation method.

IV. Results of Analysis of Re-certification

A. Applicant (States) Savings

The table below estimates the likely savings to the applicants from re-certification. The calculations are similar to the cost savings analysis of the loss-based method for determining SEL. If an applicant re-certifies, data will not be required, thus saving the 74 hours that the ICR estimates is needed to provide the data, thus saving about \$4000 per application. EPA estimates that about 130 applications per year may qualify for re-certification resulting in a total savings to the applicants of over \$0.5 million per year.

Table 8. Cost Savings to Applicants from Re-certification

| Applicant | Current Cost | Savings from Re-certification | |
|------------------------|---------------------|--------------------------------------|-----|
| Average wage rate | \$54 per hour | | |
| Hours per application | 99 | 74 | 75% |
| Number of applications | 500 | 130 | |
| Total hours | 49,500 | 9,620 | |
| \$ per application | \$5,346 | \$3,996 | |
| Total \$ per year | \$2,673,000 | \$519,480 | |

B. EPA Savings

The table below estimates the likely savings to EPA from re-certification. Since many repeat requests that would have qualified for re-certification are currently not as thoroughly reviewed as new requests, the EPA savings would not be as great as the applicants'. EPA estimates (conservatively low) that it would save about 10% of the average time it currently takes to review an application. According to the ICR it takes about 108 hours to review an application, thus savings for EPA would be almost 11 hours or over \$700 per application, with a total annual savings of over 1,400 hours or \$94,000.

Table 9. Cost Savings to EPA from Re-certification

| EPA | Current Average Cost | Savings from Re-certification | |
|------------------------|-----------------------------|--------------------------------------|-----|
| Average wage rate | \$67.25 per hour | | |
| Hours per application | 108 | 11 | 10% |
| Number of applications | 500 | 130 | |
| Total hours | 54,000 | 1,404 | |
| \$ per application | \$7,263 | \$726 | |
| Total \$ per year | \$3,631,500 | \$94,419 | |

C. Total Savings from Re-certification. EPA estimates the annual combined savings for the applicants and EPA from re-certification to be over \$600,000.

V. Combined Savings

The savings from re-certification and the loss-based method for determining SEL are summarized and rounded in \$ millions in the table below:

Table 10. Summary of Cost Savings

| Savings | Loss-based Method | Re-certification | Total |
|-------------------|--------------------------|-------------------------|----------------|
| Applicants | \$0.30 million | \$0.52 million | \$0.82 million |
| EPA | \$0.03 million | \$0.09 million | \$0.12 million |
| Total | \$0.33 million | \$0.61 million | \$0.94 million |

By provision. The total savings from the loss-based method are about a third of a million dollars, and from re-certification are over \$600,000 for a grand total of almost \$1 million.

By entities. The total savings to the applicant and EPA are over \$800,000 and \$100,000, respectively, for a grand total of almost \$1 million.

VI. Information Collection Request (ICR)

This economic analysis is based on the ICR for emergency exemptions (EPA, 2000). The provisions of the proposed rule only reduce the paperwork burdens as estimated in this economic analysis. Therefore, the current ICR is still valid and provides an estimate of the paperwork burden for those applications that would not benefit from the proposed rule. For the applicants that benefit from the proposed rule, the burden will be reduced. The applicants that benefit include:

1. Those qualifying for self-certification
2. Those applicants who can show a SEL in Tiers 1 or 2 of the loss-based method.

In those applications where the applicant burden is reduced, EPA's burden is also reduced.

VII. Limitations of Analysis

- A. Total Savings. The savings for the loss-based method and re-certification were each estimated as if the other were not going to be implemented, *i.e.*, the number of applications would benefit from the savings of the loss-based method would be slightly less as a result of economic data and analysis not being required because of re-certification. Also, the savings from re-certification were based on the current method. Since the loss-based method would usually require less time to prepare, the savings from re-certification would be slightly less for the applicant. However, this double counting of savings is likely to be small because repeat applications benefitting from re-certification are not likely to be the same applications that would benefit from the loss-based method.
- B. Average Savings. This analysis was based on average hours and costs required to prepare and review applications. However, such costs vary widely. The costs to prepare and review a first-time application for an emergency exemption are likely to be higher. Since these first-time applications are more likely to benefit from the savings of the loss-based method for determining SEL, the savings from the loss-based method are likely to be underestimated. On the other hand, the costs for preparing repeat applications are likely to be less. Since repeat applications are more likely to benefit from the savings of re-certification, the savings from re-certification are likely to be over estimated for the applicants. Since EPA has no basis to differentiate the costs of first time vs. repeat applications, it did not fully attempt to do so, except that EPA assumed a conservatively low savings for EPA for re-certification. These under and over estimates are likely to offset each other somewhat.
- C. Unrealized Savings. Some applicants that qualify for Tier 1 or 2 of the loss-based method may not realize their potential savings because they might provide additional data in case they do not pass those tiers. Similarly, some applicants that would qualify for re-certification may not take advantage of it. However, with almost no experience from the pilot program, EPA has no basis to estimate these unrealized savings. Instead, EPA has estimated the potential saving applicants could realize if they chose to do so.

- D. Time Savings. The hours that would be saved under the various scenarios (Tier 1, Tier 2, re-certification) were mostly assumed. In making these assumptions, EPA has tried to be conservative toward underestimating the savings. Several factors were used to help make some of these assumptions. For example, the 74 hours required to provide data is the basis of the savings for re-certification. Other savings are possible from other parts of the application that are likely to be simpler, but were not estimated. Therefore, the savings from re-certification may be underestimated. However, repeat applications are likely to be less costly, thus offsetting this underestimation.
- E. Conclusions. In spite of these limitations, the conclusions are valid. There should be substantial savings from re-certification and from changing data requirements for determining SEL. Increasing flexibility in the data requirements in conjunction with changing the methodology for determining SEL will also increase fairness, openness and objectivity.

VIII. Conclusions

A. Benefits

1. Cost Savings. EPA estimates substantial cost savings to applicants and some savings to EPA from the proposed loss-based method for determining SEL and re-certification. EPA estimates savings of over \$800,000 to the applicants and over \$100,000 to EPA. Different assumptions in the analysis would change the magnitude of the savings estimates, but would not change the conclusion that there will be cost savings.
 2. Transparency, Consistency, and Equity. EPA believes that the determination of SEL under the loss-based method will be more consistent and transparent. Currently, differences in variations in revenue result in differences in the magnitude of the losses that would qualify as SEL. To avoid extremes in inequities, analysts use judgement; however, such judgement is not consistent nor transparent. By reducing judgement the loss-based method is more transparent. With established thresholds for SEL, the loss-based method is also more consistent and equitable. EPA believes decision making will be improved under the proposed method.
 3. Timeliness. Reduced analysis by EPA means more timely decisions on emergency exemptions.
- B. Impacts. There are no costs associated with the proposed rule, only cost savings. With respect to the proposed loss-based method, our analysis shows that the overall likelihood of a finding of SEL would not be changed. However, in individual cases, the proposed method would result in different findings of SEL in about 12% of the requests. As discussed above, EPA believes that these different findings would be better since they would be more transparent, consistent, equitable, and timely.

IX. References

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