

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 176

[OPP-181051A; FRL-6749-7]

RIN 2070-AD15

Time-Limited Tolerances for Pesticide Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule governs the establishment of time-limited tolerances and exemptions for residues of a pesticide chemical resulting from its emergency use as authorized under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The purpose of this rule is to set into place a process that will ensure timely decisions on any tolerance

related issue in response to a request for an emergency use of a pesticide chemical to be used in or on food or feed. Under this rule, EPA will implement the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) related to FIFRA section 18 time-limited tolerances by evaluating each petition on a case-by-case basis to determine if adequate reliable data are available to make the required safety finding mandated under FFDCA section 408. This rule pertains only to regulatory changes resulting from the 1996 enactment of the Food Quality Protection Act (FQPA) which amended FFDCA.

DATES: This rule is effective November 24, 2000.

FOR FURTHER INFORMATION CONTACT: For general information contact: Joseph E. Hogue, Office of Pesticide Programs (7506C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460; telephone number: (703) 308-9072; e-mail address: hogue.joe@epa.gov.

For applicability questions contact: Robert Forrest, Chief, Minor Use, Inerts and Emergency Response Branch (7505C), Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9376; e-mail address: forrest.robert@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this final rule if you are the Federal government or a State or Territorial government agency charged with pesticide authority. Regulated categories and entities may include, but are not limited to:

Category	NAICS codes	Examples of potentially affected entities
Federal government State or Territorial governments	9241	Federal agencies that petition EPA for FIFRA section 18 use authorization States or territories charged with pesticide authority that petition EPA for FIFRA section 18 use authorization

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this table could also be affected. The North American Industrial Classification System (NAICS) codes are provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult § 176.1 or the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-181051A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Room 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background

A. What Action is the Agency Taking?

The amendments to FFDCA, as prescribed by FQPA, went into effect

immediately upon enactment on August 3, 1996. Under these amendments, EPA is required to conduct all pesticide tolerance-setting activities, including those approved for section 18 emergency exemptions, under an amended FFDCA section 408 with a new safety standard and new regulatory procedures. In the **Federal Register** of June 3, 1999 (64 FR 29823) (FRL-5750-1), EPA published, and opened for public comment, proposed regulations for setting time-limited tolerances for section 18 emergency exemptions. In its proposal, EPA described its current emergency exemption program and the interim practices taken to evaluate requests for section 18 tolerances or tolerance exemptions, and to establish section 18 tolerances, prior to the issuance of this final rule.

In the time period spanning from August 1996 to the present, EPA has been evaluating section 18 exemption requests and issuing associated tolerances or tolerance exemptions on a case-by-case basis. These evaluations have been determined based on materials submitted by Federal and State agencies in accordance with EPA guidance and interim procedures sent to them in September 1996 and further elaborated in Pesticide Registration Notice 97-1, dated January 1997, which

is available in the OPP Docket (see Unit I.B.2). This non-binding interim approach to current section 18 tolerance decisions has remained in place while the Agency has developed this FFDCA section 408(l)(6) procedural regulation.

The June 3, 1999 proposal was strictly a procedural scheme and did not modify any regulatory policies associated with the approval of the emergency exemption itself under FIFRA. EPA proposed to establish a new part 176 in the CFR to house exclusively regulations governing the setting of time-limited tolerances for emergency exemptions. In summary, EPA proposed to:

1. Review data for establishing a time-limited tolerance only after a section 18 request has been submitted;

2. Evaluate each submission individually on a case-by-case basis to determine if adequate reliable information is available to make the required safety finding;

3. Not routinely require additional data to be generated and instead rely on submitted data already reviewed and evaluated; and

4. Strive to make a regulatory decision in a timely manner.

If a tolerance could not be established then the emergency exemption would not be granted. Time-limited tolerances would typically be set for a period of 24 months to allow the treated crop from the previous year's emergency application to clear the channels of trade.

In addition to the above proposed procedure, EPA solicited comments on several other options for addressing time-limited tolerances. One approach was to require a full data set to support section 18 tolerances in the same manner as is required for the establishment of permanent tolerances. EPA also considered requiring a minimum data set in which the applicant would need to provide a specific subset of the data normally required to establish a permanent tolerance. Under this approach, the Agency would evaluate only those defined studies in making its safety finding. EPA did not include either approach as its primary option because they did not allow for timely decisions. Another approach for setting time-limited tolerances was suggested by the National Food Processors' Association. If this approach were adopted, EPA would not conduct a full-risk assessment for a section 18 tolerance, but would instead assess the incremental risk of the proposed emergency pesticide use, that is, the amount that the proposed use would

increase dietary risk above the risk from existing uses.

B. What is the Agency's Authority for Taking this Action?

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." Regulations regarding EPA's implementation of FIFRA section 18 are codified in 40 CFR part 166.

FQPA amended the FFDCA by directing EPA to establish time-limited tolerances or tolerance exemptions for pesticide use authorized by EPA under section 18 of FIFRA that may result in residues in or on food or feed. Specifically the FFDCA section 408(l)(6) requires EPA to establish a tolerance or exemption from the requirement of a tolerance for pesticide chemical residues in or on food that will result from the use of a pesticide under an emergency exemption. Section 408(l)(6) also requires EPA to promulgate regulations governing the establishment of tolerances and tolerance exemptions for pesticide uses approved for emergency situations under FIFRA section 18. Section 408(e)(1) authorizes the Administrator to establish, modify, suspend, or revoke any tolerance or exemption from the requirement of a tolerance on her own initiative, and to establish general procedures and requirements to implement section 408. This final rule is issued under the authority of sections 408(e)(1)(c) and 408(l)(6) of FFDCA, as amended by FQPA.

III. Public Comment and EPA Response

EPA received a total of 10 comments in response to its proposed rule. Five States, two growers groups, two pesticide manufacturing companies, and one public interest group submitted comments. In addition, the National Food Processors' Association attached its previously submitted petition requesting that EPA use an incremented risk approach to its comments. This petition, entitled "Petition To Issue A Regulation Governing Establishment Of Section 18 Tolerances," was co-sponsored by 19 associated grower groups. Everyone expressed support of EPA's premise that timeliness and rapid review of section 18 requests is the essence of the program. In this regard, all parties agreed that the Agency should only utilize "available data in its section 18 tolerance reviews."

EPA, in addition to considering changes based on public comments, also made minor changes to §§ 176.5 and 176.11(a) in the final rule to clarify the

provisions and to conform to other regulations (particularly 40 CFR part 166). EPA has also changed the text of § 176.3 slightly by changing "a State, U.S. Territory, or Federal agency" to "any entity, authorized under section 18 of FIFRA to request an emergency exemption," and by changing "declares" a crisis exemption to "issues." A similar change has been made to § 176.15. These changes will eliminate any future need to amend these rules in the event that EPA's regulations or FIFRA are ever changed so that an entity other than a State, U.S. Territory, or Federal agency would be allowed to request an emergency exemption. Other changes to the final rule were made as discussed in this unit. Following is a summary of the significant comments received by EPA and its response to these comments.

A. EPA Should Adopt an Incremental Risk Approach to Setting Tolerances for Emergency Exemptions

Eight submitters commented on the approach EPA should take to establish time-limited tolerances for emergencies. Two commenters agreed with EPA's proposed scheme to set tolerances on a case-by-case basis using available, reliable information to make the required safety finding. Six commenters, while not critical of EPA's proposed approach, urged the Agency to instead implement an accelerated review process based on the incremental risk of the emergency use. One commenter thought that the minimum data set approach was "intriguing" and could deserve further consideration. This approach, it was stated, had the potential to lend clarity and objectivity to the section 18 process and eliminate the need for the Agency to use "best judgement."

The proponents of the incremental-risk approach argued that since emergency exemptions are by their very nature extreme situations, the process for addressing them should take this into account and they should be given special treatment. Pesticide use in an emergency is for a short term and generally is limited to a single-geographic area, therefore there is less exposure to the pesticide and minimal associated risk. One commenter noted that the Agency's policy of conducting a full-risk assessment for section 18 tolerances does not consider the limited scope and duration of the use. The commenter stated that performing full risk assessments each time a section 18 tolerance is requested not only slows down the entire section 18 review process, but also diverts Agency resources. According to the commenter

an incremental-risk approach would eliminate the time pressures and would avoid the disruption to EPA's base pesticide regulatory programs.

In spite of the thoughtful comments on the fourth option, EPA believes that the case-by-case approach outlined in its proposal is the most practical approach that does not significantly sacrifice timeliness or efficiency and is in compliance with the law. It allows the Agency to make appropriate decisions quickly while fully protecting human health, especially infants and children, and safeguarding the environment. Moreover, this approach, coupled with the Agency's newly established Threshold of Regulation Policy for pesticide tolerances (see Unit IV.) may resolve many concerns expressed by those who favor the incremental-risk approach.

EPA is not prepared at this time to adopt the approach suggested by the commenters. In addition to presenting difficult legal issues, the incremental-risk approach may not be needed to address the commenters' concerns regarding purported EPA denial of section 18 emergency exemption petitions or a lack of timely review by the Agency of such petitions. EPA's initial implementation of the new tolerance requirement necessitated adjusting Agency procedures and involved some deviation from past EPA review times in handling section 18 emergency exemption requests. Now that EPA has had 4 years experience in setting section 18 emergency exemption tolerances, it believes that it has adequately adapted the emergency exemption process to deal with the longer lead-time inherent in the requirement for establishment of these tolerances. Further, as noted in this unit, the Agency's newly established Threshold of Regulation Policy for pesticide tolerances (see Unit IV.) may address many of the commenters' concerns.

B. The Timely Establishment of a Tolerance After Granting an Emergency Exemption is Crucial

Several commenters said that EPA should establish a tolerance at the time of the section 18 approval. The underlying concern was that the Agency would not be able to establish a tolerance before the crop is harvested or the commodity enters into interstate commerce. One person remarked that in addition to the presence of an emergency condition, growers are subject to increased uncertainty and anxiety the longer it takes the Agency to establish a tolerance. The commenters were concerned that crops treated in the

course of an emergency would be considered adulterated and seized for the lack of an established tolerance.

As a general matter, the Agency agrees with the submitter. For new pesticides, the Agency grants a registration and establishes the required tolerances simultaneously. However, due to the urgent nature of pest emergencies, growers need to be able to lawfully apply a pesticide as soon as possible or face significant economic loss for that year. If the Agency concludes that it is unable to establish a time-limited tolerance for that use, it will notify the applicant immediately so that some other method of control for the emergency pest situation can be sought. EPA often has to balance its workload between establishing tolerances and processing section 18 requests. During peak periods for emergency exemption requests, resources used to set a tolerance could result in the delay of another State's section 18 application. Nonetheless, EPA is committed to working toward the goal of being able to set a tolerance at the same time as granting the emergency exemption. For example, in Fiscal Year (FY) 1999, EPA's average time to establish a tolerance once the exemption was granted was 66 days. This is significantly faster than the average of 87 days it took the Agency in FY 1998.

FFDCA section 408(l)(5) explains the conditions upon which foods and feeds may be subject to enforcement action due to pesticide residues. Under this subsection, if a tolerance is no longer in effect, i.e., it has been revoked or has expired, the crop may continue to be marketed if:

1. The crop was treated with an approved use of the pesticide at the time of treatment, and

2. The level of the residues do not exceed the tolerance in effect at the time the pesticide was applied.

In the second instance, it is important to note that the tolerance must be in place at the time the pesticide is used. This is why many States often submit section 18 emergency exemption requests several months prior to the onset of the emergency in anticipation of the 2–3 month time between issuing the exemption and establishing the tolerance. They acknowledge that for residues resulting from the use to be considered lawful once the tolerance has expired, the tolerance must be in place at the time of application, not the time of harvest. Nonetheless, EPA's policy of setting tolerances for longer duration than the exemption ensures that crops treated during an emergency situation should lawfully clear trade

channels while the tolerance is still in effect.

C. All Emergency Exemptions Issued Under Section 18 Should Be Covered Under the "Pipeline" Provision

Many of those who submitted comments thought that the "pipeline" provision of 408(l)(5) should apply to exemptions declared under crisis situations. The "pipeline" can be described as those crops that have been treated legally with a pesticide that are still in the channels of trade when the tolerance is either revoked or, as in the case of an emergency exemption, has expired. Those who commented on this felt that although a tolerance is not in place at the time the unregistered pesticide is used, since the pesticide use was legal under FIFRA section 18, any resulting pesticide residues should also be considered legal and not subject to enforcement actions.

Crisis exemptions are by definition unpredictable. In instances where an emergency condition occurs suddenly and there is no time to formally request a specific emergency exemption, a State or Federal agency may issue a crisis exemption and permit the use of an unregistered pesticide (40 CFR 166.40). Under a crisis exemption a pesticide is almost always used in the field prior to the establishment of a tolerance. However, this situation can occur for specific exemptions as well. In many instances, a specific exemption request (especially with first-time tolerance requests) is granted and the pesticide may be used in the field prior to the establishment of the time-limited tolerance, where appropriate. EPA later conducts a full review and establishes the time-limited tolerance. If the time-limited tolerance is not set at a length of time to allow for crops to clear trade channels, or is not extended and therefore expires, commodities treated under these circumstances could be adulterated and subject to seizure.

In both of these instances the "pipeline" provision does not apply because a tolerance was not set at the time the pesticide is applied. The statutory requirement of FFDCA section 408(l)(5)(B) is not met. EPA cannot alter the requirements in the FFDCA through regulations. Nonetheless, as noted in this unit, EPA's policy of setting tolerances for longer duration than the section 18 exemption generally ensures that crops treated during an emergency situation should clear trade channels while the tolerance is still in effect.

Some commenters expressed concern that even though they legally applied a pesticide under a crisis emergency exemption, if after EPA review the

necessary tolerance level would exceed the safety standard and by law could not be set, their entire crop could be subject to Federal enforcement measures. To avoid this potentially dire situation, States and Federal agencies are urged to consult with the Agency to determine whether the pesticide in question has particular safety issues or concerns before declaring a crisis.

D. Time-Limited Tolerances Should Be Set for Longer Than 24 Months

A few commenters thought EPA should consider establishing time-limited tolerances for longer than 2 years. One commenter remarked that certain exemptions will likely be needed for 3 or more years because issues such as new pest pressures or the development of resistance are not likely to go away once they have appeared. The commenter suggested EPA set tolerances for 3 years upon initially granting the section 18 request based on circumstances which are likely to persist over several years. The commenter added that an exemption such as one based on unusual weather patterns probably will not reoccur in succeeding years and a 2-year tolerance is adequate in this situation.

Under EPA's regulations, specific exemptions and public health exemptions can be authorized for periods of up to 1 year (40 CFR 166.28(a)). Since actions taken under this section are intended to address an emergency need for temporary pest relief, most section 18 exemptions are granted for one growing season. In the preamble to the proposed rule, EPA stated that it will typically set a time-limited tolerance for a 2-year period. This is expected to allow treated crops from the previous year to clear the channels of trade. The Agency is flexible on this point and may set time-limited tolerances for longer time periods if warranted. In addition, EPA may modify or extend a time-limited tolerance at any time on its own initiative or at the applicant's request. EPA has changed § 176.13 in the final rule to clarify that it may extend the duration of a tolerance for various reasons. EPA strongly recommends that if an applicant believes that 24 months is insufficient for a time-limited tolerance, the applicant should request a more appropriate length of time in the initial section 18 request. This will permit the Agency to judge whether a longer period would be appropriate.

One commenter noted that in the proposed regulatory text, the words "unless extended" should be added to § 176.11(b) to be consistent with the language in § 176.13. Section 176.11(b)

states that "(b) Tolerances will automatically expire and be revoked, without further action by EPA, at the time set out in the **Federal Register** notice establishing the tolerance." EPA agrees with this suggestion and has added the phrase to this section.

E. This Rulemaking Should Be Considered a "Significant Action" that Requires OMB Review

Two commenters disagreed with the determination that the proposed rule was not a "significant regulatory action" as defined under section 3(f) of Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), and stated it should have therefore undergone review by the Office of Management and Budget (OMB), and that the final rule should be reviewed by OMB. One commenter stated that emergency exemptions are by definition "of economic importance." In addition, crop losses associated with emergency exemptions are routinely multi-million dollar situations and that individual States and individual growers are "significantly" impacted by a cumbersome tolerance setting process. It was suggested that OMB review the potential impacts associated with delays in establishing tolerances.

E.O. 12866 defines as "significant" a regulatory action that is likely to:

1. Have an annual effect on the economy of \$100 million or more, or adversely and materially affect a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;
2. Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;
3. Materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs; or
4. Raise novel legal or policy issues.

The determination of whether or not a regulatory action should be reviewed by OMB under E.O. 12866 is made in consultation with OMB. Since this rule is a procedural rule that codifies the internal process by which EPA will set emergency tolerances, OMB determined that it was not a significant regulatory action that required OMB review under E.O. 12866. As stated in the proposal's preamble, EPA estimates that the direct cost of this rule will be minimal because only EPA and applicants are directly affected, and this action does not require applicants to submit new or additional information.

The Agency determined that this rule, once promulgated, is not expected to significantly change applicant activities,

such that it would increase the current burden to applicants and therefore is unlikely to have a major economic impact on the States or Federal agencies that apply for section 18 exemptions. In addition, EPA affirms that promulgation of this rule will have no direct impact on any other sector of the economy, or on any other government entities, programs, or policies. A copy of the economic analysis is available in the public version of the official record for this rule (see Unit I.B.2.).

IV. Is a Tolerance Needed?

On October 27, 1999, EPA published in the **Federal Register** a notice of availability of a policy entitled, "Threshold of Regulation Policy—Deciding Whether a Pesticide With a Food Use Pattern Requires a Tolerance" (64 FR 57881) (FRL-6388-2). This policy pertains to the use of a pesticide (including an emergency use) on, in, or near food which does not result in residues that are detectable in food. EPA is adopting this policy which sets forth criteria to consider in evaluating whether there is no "need" to establish a tolerance, i.e., there is no reasonable expectation of finite residues of the pesticide in the food. If the criteria are met, there is no requirement for a tolerance or tolerance exemption. The Threshold of Regulation policy will be applicable for pesticide uses that result in no detected residues in food and for which the degree of potential risk posed by any theoretically possible residues is so minimal that tolerance setting serves no purpose.

The Threshold of Regulation Policy can apply to time-limited tolerances for section 18 emergency exemptions. In these instances, the Agency will consider surrogate data in the case of emergency exemption requests where all the data needed on the performance of the analytical method or the magnitude of the residue as determined by field trial studies on the subject commodity are unavailable. Given the emergency circumstances, EPA may consider accepting data from a different crop to establish eligibility for the threshold of regulation. Persons wishing a Threshold of Regulation policy decision should make the request in writing and submit materials and information that are ordinarily required to support time-limited tolerances or tolerance exemptions.

V. Regulatory Assessment Requirements

A. Executive Order 12866

Pursuant to Executive Order 12866, entitled *Regulatory Planning and*

Review (58 FR 51735, October 4, 1993), it has been determined that this action is not a "significant regulatory action" and is therefore not subject to review by OMB. OMB has made this determination because this final rule is a procedural rule that codifies the internal process by which EPA will set emergency tolerances. Applicants for section 18 emergency exemptions (i.e., Federal and State agencies) are the only parties, other than EPA, directly affected by this action. According to the economic assessment conducted by the Agency, the applicants of section 18 emergency exemptions are not expected to experience any adverse impacts as a result of this rule because the rule does not require any new or additional data from applicants.

A copy of the economic assessment is available in the public version of the official record for this rule (see Unit I.B.2.).

B. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this regulatory action does not have a significant economic impact on a substantial number of small entities. Applicants for section 18 emergency exemptions are U.S. States, territories, or Federal agencies which, by definition, are not small entities under the RFA. Applicants for section 18 emergency exemptions are the only parties, other than EPA, directly affected by this action.

Information regarding this determination will be provided to the Chief Counsel for Advocacy of the Small Business Administration (SBA) upon request.

C. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after appearing in the preamble of the final rule, are listed in 40 CFR part 9 and 48 CFR chapter 15, and included on the related collection instrument. This regulatory action does not contain any new information collection requirements that would require additional OMB review and approval.

The information collection activities related to the procedures for emergency exemptions under section 18 of FIFRA, which are contained in 40 CFR part 166, are already approved by OMB under OMB control number 2070-0032 (EPA

ICR No. 596), and the process and informational needs for requesting that the Agency establish or provide an exemption from the establishment of a tolerance or maximum-residue level for the use of a pesticide on food or feed crops, which are contained in 40 CFR part 180, are already approved by OMB under OMB control number 2070-0024 (EPA ICR No.597). As described in the information collection instruments, the annual respondent burden for the information collection activities in 40 CFR part 166 is estimated to average 103 hours per application, including time for reading the regulations, processing, compiling and reviewing the requested data, generating application correspondence or summary reports, and storing, filing, and maintaining the data. The annual respondent burden for the information collection activities in 40 CFR part 180 is estimated to average 1,726 hours per petition, including time for reading the regulations, processing, compiling and reviewing the requested data, generating the request, storing, filing, and maintaining the data.

As defined by the PRA and 5 CFR 1320.3(b), "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

D. Environmental Justice Considerations

This final rule does not involve special considerations of environmental-justice issues pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The Agency has determined that this final rule does not affect the environmental and health conditions in low-income and minority communities because this rule codifies the internal process by which EPA will set emergency tolerances, and only applies to applicants for section 18 emergency exemptions (i.e., Federal and State agencies). In general, low-income and minority communities are more

likely to benefit from the risk assessment process needed for the establishment of tolerances for section 18 actions that might impact their community.

E. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. As applicants for section 18 emergency exemptions, Federal and State agencies are the only parties, other than EPA, directly affected by this action. The potential impact on State agencies, however, is expected to be minimal because this action does not require applicants to submit new or additional information. In addition, EPA has determined that this rule does not significantly or uniquely affect small governments. Accordingly, this action is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

F. Federalism

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Since this rule codifies an internal process for the Agency, and does not impose requirements on others, the Agency determined that this rule will not adversely impact the entities that apply for section 18 exemptions. The process established by this final rule will more likely benefit applicants and others by establishing an effective and efficient process for the Agency to take the necessary tolerance actions in a timely manner. Thus, the requirements of

section 6 of the Executive Order do not apply to this rule. Nevertheless, the Agency provided an opportunity for Federal and State agencies to review and provide comments on the proposed process. A discussion of the comments EPA received, which includes comments from several State and local officials, and how those comments are addressed in the final rule, is provided in Unit III.

G. Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. This final rule implements requirements specifically set forth by the Congress in FFDCA section 408(l)(6) without the exercise of any discretion by EPA. The final rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this final rule.

H. Children's Health Protection

This final rule is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866 (see Unit V.A.). In addition, this final rule is procedural in nature and does not involve decisions on environmental health or safety risks that may disproportionately affect children.

I. National Technology Transfer and Advancement Act

This regulatory action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Section 12(d) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary

consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

J. Civil Justice Reform

In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

K. Constitutionally Protected Property Rights

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the Executive Order.

VI. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 176

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

Dated: October 16, 2000.

Carol M. Browner,
Administrator.

Therefore, 40 CFR chapter I is amended by adding new part 176 to read as follows:

PART 176—Time-Limited Tolerances for Emergency Exemptions

Sec.

176.1 Scope and applicability.

176.3 Definitions.

176.5 Establishment of a time-limited tolerance or exemption.

176.7 Information needed to establish a tolerance.

176.9 Publication of a tolerance.

176.11 Duration of a tolerance.

176.13 Modification of a time-limited tolerance.

176.15 Effect of a tolerance.

Authority: 21 U.S.C. 346a and 371.

§ 176.1 Scope and applicability.

This part describes the procedures and criteria under which EPA will establish time-limited tolerances and exemptions from the requirement of a tolerance for pesticide chemical residues associated with use of pesticides under emergency or crisis exemptions under FIFRA section 18. This part applies only to tolerances issued on the initiative of EPA as the result of the issuance of an emergency exemption or the declaration of a crisis exemption. This part does not cover time-limited tolerances in any other circumstances.

§ 176.3 Definitions.

The terms have the same meaning as in the Federal Insecticide, Fungicide, and Rodenticide Act section 2, and in the Federal Food, Drug, and Cosmetic Act section 201 and § 166.3 of this chapter. In addition, the following terms are defined for the purposes of this part.

Agency means the U.S. Environmental Protection Agency.

Applicant means any entity authorized under section 18 of FIFRA to request an emergency exemption that requests such an exemption under § 166.20 of this chapter, or issues a crisis exemption under § 166.40 of this chapter.

Crisis exemption means an exemption authorized under FIFRA section 18, in accordance with §§ 166.40 through 166.53 of this chapter.

Emergency exemption means a specific, quarantine, or public health exemption authorized under FIFRA section 18 and the regulations at §§ 166.20 through 166.35 of this chapter.

EPA means the U.S. Environmental Protection Agency.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Tolerance means the maximum amount of a pesticide chemical residue that may lawfully be present in or on a raw agricultural commodity, or processed food, or animal feed, expressed as parts per million by weight of the pesticide chemical residue in the food or feed.

Tolerance exemption means a formal determination by the Agency pursuant to FFDCA section 408(c), 21 U.S.C. 346a(c), that no tolerance is needed for a given pesticide chemical residue in or on a particular food commodity. For purposes of this part, the term "tolerance" shall include an exemption from the requirement of a tolerance.

§ 176.5 Establishment of a time-limited tolerance or exemption.

EPA will establish a time-limited tolerance for pesticide chemical residues in or on raw or processed food or feed resulting from the use of a pesticide chemical, if EPA authorizes an emergency exemption or a crisis exemption. EPA will consider establishing such a tolerance only if an applicant acting under authority of FIFRA section 18 either has requested an emergency exemption, has stated its intention to issue a crisis exemption, or has issued a crisis exemption for a use that may result, directly or indirectly, in pesticide chemical residues in food or feed.

§ 176.7 Information needed to establish a tolerance.

(a) EPA will establish a time-limited tolerance only if EPA can determine that the tolerance is safe, that is, there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. EPA will base its determination upon data submitted by the applicant and other readily available data. If, taking into account the limited duration and emergency nature of a section 18 application, and based on the available data the Agency cannot conclude that there is a reasonable certainty that no harm will result from the use proposed by the applicant or granted pursuant to a crisis exemption, EPA will not establish a tolerance.

(b) Data and other relevant information to support the establishment of a time-limited tolerance may be submitted by the applicant, or by any other person, in support of the time-limited tolerance. The applicant may also cite relevant data previously submitted to the Agency.

§ 176.9 Publication of a tolerance.

(a) If EPA issues an emergency exemption or crisis exemption under FIFRA section 18, and EPA concludes that the tolerance for residues resulting from use of the pesticide under the exemption will be safe, then EPA will establish the tolerance by publishing an amendment to 40 CFR part 180 in the **Federal Register**.

(b) A tolerance under this part may be established without prior publication of a proposed tolerance or comment period.

§ 176.11 Duration of a tolerance.

(a) Tolerances issued under this part will become effective upon publication in the **Federal Register**, unless otherwise specified by the Administrator.

(b) Unless extended, tolerances will automatically expire and be revoked, without further action by EPA, at the time set out in the final rule published in **Federal Register**.

(c) The Administrator may revoke a tolerance at any time if the Administrator determines that the tolerance is no longer safe.

§ 176.13 Modification of a time-limited tolerance.

If additional emergency or crisis exemptions are authorized that would extend use beyond the date originally authorized, or if EPA determines that the duration of a time-limited tolerance is insufficient to allow treated commodities to clear the channels of trade, EPA may modify the time-limited tolerance by publication of a final rule in the **Federal Register**. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

§ 176.15 Effect of a tolerance.

The establishment of a tolerance under this part does not alter the requirement that any applicant comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

[FR Doc. 00-27405 Filed 10-24-00; 8:45 am]

BILLING CODE 6560-50-S