

EPA-APPROVED NEBRASKA REGULATIONS—Continued

Nebraska citation	Title	State effective date	EPA approval date	Comments
129-30	Open Fires, Prohibited; Ex-ceptions.	11/20/02	9/5/03 and FR page citation.	

\* \* \* \* \*  
**PART 70—[AMENDED]**

■ 1. The authority citation for part 70 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

**Appendix A—[Amended]**

■ 2. Appendix A to part 70 is amended by adding paragraph (g) under Nebraska; City of Omaha; Lincoln-Lancaster County Health Department to read as follows:

**Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs**

\* \* \* \* \*  
 Nebraska; City of Omaha; Lincoln-Lancaster County Health Department.  
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(g) The Nebraska Department of Environmental Quality approved revisions to NDEQ Title 129, chapters 1, 5, 6, and appendix III (which codifies its prior Federally approved Insignificant Activities List) on September 5, 2002, which became effective on November 20, 2002. These revisions were submitted on May 1, 2003. We are approving these program revisions effective November 4, 2003.

\* \* \* \* \*

[FR Doc. 03-22539 Filed 9-4-03; 8:45 am]  
**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2003-0284; FRL-7323-7]

**Propylene Carbonate; Exemption from the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of propylene carbonate when used as an inert ingredient in pesticide formulations applied pre- and post-harvest to

agricultural commodities. Huntsman Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of propylene carbonate.

**DATES:** This regulation is effective September 5, 2003. Objections and requests for hearings, identified by docket ID number OPP-2003-0284, must be received on or before November 4, 2003.

**ADDRESSES:** Written objections and hearing requests submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; e-mail address: [boyle.kathryn@epa.gov](mailto:boyle.kathryn@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 an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0284. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still

access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

## II. Background and Statutory Findings

In the **Federal Register** of December 30, 1998 (63 FR 71920) (FRL-6050-1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 8E4992) by Huntsman Corporation, Houston, Texas. This notice included a summary of the petition prepared by the petitioner Huntsman. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of propylene carbonate, also known as 1,3-Dioxolan-2-one, 4-methyl- (CAS Reg. No. 108-32-7).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

## III. Human Health Assessment

### A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by propylene carbonate are discussed in this unit. The Agency has reviewed 12 toxicity studies using propylene carbonate as the test substance. The results of those reviews are listed in the following Table 1:

TABLE 1.—TOXICITY STUDIES USING PROPYLENE CARBONATE

Study Type	Results
Acute oral (rat)	LD <sub>50</sub> > 5,000 mg/kg (Toxicity Category IV)
Acute dermal (rabbit)	LD <sub>50</sub> > 2,000 mg/kg (Toxicity Category III)
Primary eye irritation (rabbit)	Not a significant ocular irritant (Toxicity Category III)
Primary dermal irritation	(Toxicity Category IV)
Developmental (rat)	Maternal NOAEL = 1,000 mg/kg/day Maternal LOAEL = 3,000 mg/kg/day based on mortality, clinical signs and decreased food consumption Developmental NOAEL = 3,000 mg/kg/day Developmental LOAEL = 5,000 mg/kg/day based on increase in skeletal variations
113-week feeding (rat)	NOAEL = equal to or greater than 5,000 mg/kg/day (HTD - highest dose tested) LOAEL = would be greater than 5,000 mg/kg/day

TABLE 1.—TOXICITY STUDIES USING PROPYLENE CARBONATE—Continued

Study Type	Results
113-week inhalation (rat) with neurotox	NOAEL = 0.5 mg/L/day LOAEL = 1.0 mg/L/day based on clinical signs in both sexes No evidence of neurotoxic potential
Cancer dermal (skin-painting) (mouse)	Negative, but dosing was considered inadequate
9-day inhalation (rat)	NOAEL = not determined - effects seen at lowest dose tested LOAEL = 1 mg/L/day based on clinical signs of toxicity, ocular irritation
Mouse micronucleus	Not mutagenic
UDS	Negative
Gene mutation (S. typhimurium)	Negative

### B. Structure Activity Relationship Assessment

For propylene carbonate, toxicity was assessed, in part, by a process called structure-activity-relationship (SAR). In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high.

For propylene carbonate the SAR assessment determined that the chemical was not structurally related to any known carcinogens. The following human exposures were examined as part of the analysis: Inhalation, dermal, exposures to the eyes, and drinking water. Absorption of propylene carbonate is expected to be good (well-absorbed) via all routes (oral, dermal and inhalation) based on physical/chemical properties. There are concerns for effects on the liver and kidneys, solvent-type neurotoxicity and developmental toxicity at high dose levels, and irritation to mucous

membranes. The overall SAR rating for human health is low/moderate concern.

The SAR did note a concern for solvent neurotoxicity, i.e., neurotoxic effects that can occur due to "high" and/or "prolonged" dermal and inhalation exposures to organic solvents. It should be noted that the inclusion of the phrase "solvent-type neurotoxicity" in the SAR assessment does not necessarily indicate chemical-specific concerns. By including this statement those performing the SAR assessment are acknowledging that the chemical is a member of a class of chemicals that can exhibit solvent neurotoxicity.

### C. Conclusions

The Agency used two sources of information to determine the toxicity of propylene carbonate: The 12 toxicity studies submitted by the petitioner and reviewed by the Agency, and a SAR assessment. The two sources of data support each other. However, results of the SAR Assessment are a type of predicted data based in part on surrogate data. There is actual data generated using propylene carbonate as the test substance, and actual data has precedence over predicted data.

The Agency reviewed a propylene carbonate developmental toxicity study in the rat with a maternal no observed adverse effect level (NOAEL) of 1,000 milligrams/kilogram/day (mg/kg/day) and a maternal lowest observed adverse effect level (LOAEL) of 3,000 mg/kg/day based on mortality, clinical signs and decreased food consumption. In the same study, the developmental NOAEL is 3,000 mg/kg/day and the developmental LOAEL is 5,000 mg/kg/day based on an increase in skeletal variations. In a propylene carbonate 13-week rat feeding study the NOAEL is equal to or greater than 5,000 mg/kg/day, the highest dose tested. A LOAEL was not identified in that study, but it would be even greater than 5,000 mg/kg/day. It is noted that each of these NOAELs is equal to or greater than 1,000 mg/kg/day. As a matter of practice, for both the developmental and the 13-week toxicity study, the Agency does not encourage testing above 1,000 mg/kg/day. The lack of effects at 1,000 mg/kg/day is considered adequate to define the toxicity, without pushing the dose levels higher until effects are apparent.

The SAR assessment judged propylene carbonate to be of low/moderate concern. It did not identify any carcinogenic concerns. One identified concern was for possible irritation to mucous membranes. This concern would involve the dermal and

inhalation exposure routes and would be addressed through the use of protective equipment such as gloves and respirators, not through establishment of tolerance exemptions.

A concern predicted by the SAR, based on its structural chemistry and chemical class, is for possible solvent neurotoxicity from exposure to propylene carbonate. As previously explained, this statement acknowledges that propylene carbonate is a member of a class of chemicals that can exhibit solvent neurotoxicity. However, the propylene carbonate data base includes a 13-week inhalation toxicity study in the rat with a neurotoxicity evaluation. Based on its review and evaluation of this inhalation toxicity study, the Agency determined that there was no evidence of neurotoxicity potential.

The SAR also indicated a concern for developmental toxicity at high dose levels. However, the Agency reviewed a propylene carbonate developmental toxicity study in the rat with a maternal NOAEL of 1,000 mg/kg/day and a maternal LOAEL of 3,000 mg/kg/day based on mortality, clinical signs and decreased food consumption. In the same study, the developmental NOAEL is 3,000 mg/kg/day and the developmental LOAEL is 5,000 mg/kg/day based on increase in skeletal variations.

Considering the NOAELs of greater than 1,000 mg/kg/day for the propylene carbonate toxicity studies and the overall judgement of low/moderate concern from the SAR assessment, propylene carbonate is of low toxicological concern.

### IV. Aggregate Exposures

In examining aggregate exposure, FFDC section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Over 1 million pounds of propylene carbonate are either produced or imported per year. Some of this propylene carbonate production is used as a chemical intermediate, in the production of other chemicals. Propylene carbonate has been approved by the Food and Drug Administration for use as an indirect food additive as a component of adhesives. According to 21 CFR 175.105, propylene carbonate can be a component of an adhesive used as part of "articles intended for use in packaging, transporting, or holding

food." Propylene carbonate is also used in cosmetics. Information on the internet (Huntsman website) indicates that propylene carbonate is used in tub and tile cleaners, hard surface and floor cleaners that could be used in and around the home.

The Agency has used various screening-level models to estimate some of the existing levels of exposure, and those that could occur as a result of establishing this tolerance exemption. To assure protectiveness, these estimates are deliberately intended to over-estimate exposure as shown in the following Table 2:

TABLE 2.—SCREENING-LEVELS OF EXPOSURE USING PROPYLENE CARBONATE

Type of Exposure	Exposure Level
Dietary - Food (as a result of application to crops)	Acute exposure: Less than 1 mg/kg/day at 95th percentile Chronic exposure: Less than 1 mg/kg/day
Dietary - Drinking Water	Acute exposure: Much less than 1 mg/kg/day Chronic exposure: Much less than 1 mg/kg/day
Residential (as a result of using a cleaning product)	Approximately 6 mg/kg/day
Residential (as a result of using a laundry detergent)	Approximately 1 mg/kg/day
Residential (as a result of application to a lawn)	Less than 1 mg/kg/day

With one exception all of the screening-level exposure estimates are in the range of or less than 1 mg/kg/day. The existing studies for propylene carbonate yielded NOAELs that were equal to or greater than 1,000 mg/kg/day. The screening-level exposure estimates are orders of magnitude lower than these NOAELs. Even considering the reported uses, the use of propylene carbonate as an inert ingredient should result in human exposure far below any dose level that could possibly produce an adverse effect.

### V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of the FFDC requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency

consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether propylene carbonate has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to propylene carbonate and any other substances and propylene carbonate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propylene carbonate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### VI. Determination of Safety for U.S. Population, Infants and Children

Based on the available data, the SAR assessment indicating low/moderate concern and the data submitted by the petitioner, Huntsman Corporation, which indicate that the chemical is of low toxicological concern, EPA concludes that propylene carbonate does not pose a dietary risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to propylene carbonate. Due to the expected low oral toxicity, a safety factor analysis has not been used to assess the risk. For the same reasons and especially considering the developmental toxicity NOAEL, the additional tenfold safety factor for the protection of infants and children is unnecessary.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of 1,3-Dioxolan-2-one, 4-methyl- (propylene carbonate). Accordingly, EPA finds that exempting 1,3-Dioxolan-2-one, 4-methyl- (propylene carbonate) (CAS Reg.

No. 108-32-7) from the requirement of a tolerance will be safe.

#### VII. Other Considerations

##### A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . ." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing propylene carbonate for endocrine effects may be required.

##### B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

##### C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for propylene carbonate.

##### D. International Tolerances

The Agency is not aware of any country requiring a tolerance for propylene carbonate nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

##### E. List 4A (Minimal Risk) Classification

The Agency established 40 CFR 180.950 (see the rationale in the proposed rule published January 15, 2002 (67 FR 1925) (FRL-6807-8)) to collect the tolerance exemptions for those substances classified as List 4A, i.e., minimal risk substances. As part of evaluating an inert ingredient and establishing the tolerance exemption, the Agency determines the chemical's list classification.

The available data and the SAR assessment indicated propylene carbonate is of lower toxicity. Given the NOAELs of greater than 1,000 mg/kg/day and the acute toxicity studies that were category III and IV, it has been determined that propylene carbonate, also known as 1,3-Dioxolan-2-one, 4-methyl- (CAS Reg. No. 108-32-7) is to be classified as a List 4A inert ingredient. Thus, the tolerance exemption will be established in 40 CFR 180.950 instead of 40 CFR 180.1001(c) as requested by the petitioner, Huntsman.

#### VIII. Conclusions

Based on the information in the record, summarized in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of propylene carbonate (CAS Reg. No. 108-32-7). Accordingly, EPA finds that exempting propylene carbonate from the requirement of a tolerance will be safe.

#### IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

##### A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0284 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 4, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in

40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at [tompkins.jim@epa.gov](mailto:tompkins.jim@epa.gov), or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0284, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### *B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

#### **X. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency

action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 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 directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on

one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**XI. Congressional Review Act**

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

(e) \* \* \*

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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: August 22, 2003.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

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

**PART 180—[AMENDED]**

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.950 is amended by adding alphabetically the following ingredient to the table in paragraph (e) to read as follows.

**§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.**

\* \* \* \* \*

Chemical	CAS No.
* * * * *	
1,3-Dioxolan-2-one, 4-methyl-(propylene carbonate) .....	108-32-7
* * * * *	

[FR Doc. 03-22546 Filed 9-4-03; 8:45am]  
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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**44 CFR Part 62**

**RIN 1660-AA29**

**National Flood Insurance Program (NFIP); Assistance to Private Sector Property Insurers; Extension of Term of Arrangement**

**AGENCY:** Federal Emergency Management Agency (FEMA).  
 Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Interim final rule.

**SUMMARY:** FEMA is changing the current Financial Assistance/Subsidy Arrangement (the Arrangement) to extend its term of October 1, 2002, through September 30, 2003, to a term of October 1, 2002, through December 31, 2003. The Arrangement defines the duties and responsibilities of insurers that sell and service insurance under the Write Your Own (WYO) program. It also

identifies the responsibilities of the Government to provide financial and technical assistance to these insurers.

**DATES:** Effective October 1, 2003. Comments on this interim final rule, should be received on or before October 6, 2003.

**ADDRESSES:** Please send your comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, 500 C Street, SW., Room 840, Washington, DC 20472, (facsimile) 202-646-4536, or (e-mail) [rules@fema.gov](mailto:rules@fema.gov).

**FOR FURTHER INFORMATION CONTACT:** Edward L. Connor, FEMA, 500 C Street, SW., Washington, DC 20472, 202-646-3429 (Phone), 202-646-3445 (facsimile), or [Edward.Connor@dhs.gov](mailto:Edward.Connor@dhs.gov) (e-mail).

**SUPPLEMENTARY INFORMATION:** On August 9, 2002, FEMA published in the **Federal Register**, 67 FR 51768, a final rule to revise the effective date of the Arrangement to agree with the new Arrangement year beginning October 1, 2002, and ending September 30, 2003.

FEMA had planned to make significant changes in the Arrangement regarding litigation issues effective October 1, 2003. However, as the proposed rule for these changes has not yet been published in the **Federal Register**, it is not feasible to complete the rulemaking for an effective date of

October 1, 2003. WYO insurers need to receive an offer to enter into the Arrangement each year well in advance of the beginning of the Arrangement year. By extending the current Arrangement for an additional 3 months, the revised Arrangement with the litigation changes can be effective January 1, 2004, instead of postponing these changes to October 1, 2004. WYO insurers can always elect to cease participation in the WYO program at any time, so any insurer not desiring to participate for the additional 3 months of this extension may cease participation as of October 1, 2003.

Under this extension of the current Arrangement, the expense allowance provided for in Article III, Section B of APPENDIX A TO PART 62—FEDERAL EMERGENCY MANAGEMENT AGENCY, FEDERAL INSURANCE ADMINISTRATION, FINANCIAL ASSISTANCE/SUBSIDY ARRANGEMENT will remain the same for the additional 3 months as it is now, except there will be no additional expense allowance of up to two percentage points for meeting marketing goals for the three-month extension. This additional expense allowance will be based on the period October 1, 2002, through September 30, 2003.