

levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

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

Dated: May 25, 2006.

Laura Yoshii,

Acting Regional Administrator, Region IX.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0495; FRL-8072-8]

Food-Contact Surface Sanitizing Solutions; Proposed Revocation of Tolerance Exemptions for Sanitizers with No Food-Contact Uses in Registered Pesticide Products and with Insufficient Data for Reassessment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes under section 408(e)(1) of the Federal Food, Drug and Cosmetic Act (FFDCA) to revoke the existing exemption from the requirement of a tolerance for the food-contact surface sanitizing solution use of certain antimicrobial pesticides because the Agency has determined that the tolerance exemption corresponds to the food-contact sanitizing use for which there are no longer registered pesticide products, and because there are insufficient data to make the determination of safety required by FFDCA section 408(b)(2). The regulatory actions proposed in this document will contribute toward the Agency's tolerance reassessment requirements under the FFDCA section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required by August 2006 to reassess the tolerances that were in existence on August 2, 1996.

DATES: Comments must be received on or before July 10, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-0495, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2006-0495. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, 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 www.regulations.gov or e-mail. The Federal www.regulations.gov website is an "anonymous access" system, 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 www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the 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.

Docket: All documents in the docket are listed in the docket index. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are 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: Laura Bailey, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6212; e-mail address: bailey.laura@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.A. 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. What Should I Consider as I Prepare My Comments for EPA?

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

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

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

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

C. What Can I do if I Wish the Agency to Maintain a Tolerance that the Agency Proposes to Revoke?

This proposed rule provides a comment period of 30 days for any person to state an interest in retaining a tolerance proposed for revocation. If EPA receives a comment within the 30-day period to that effect, EPA will not proceed to revoke the tolerance immediately. However, EPA will take steps to ensure the submission of any needed supporting data and will issue an order in the **Federal Register** under FFDCA section 408(f) if needed.

EPA issues a final rule after considering comments that are submitted in response to this proposed rule. In addition to submitting comments in response to this proposal, you may also submit an objection to the final rule. If you fail to file an objection to the final rule within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

II. Background

A. What Action is the Agency Taking?

EPA is proposing to revoke several food-contact surface sanitizing solutions tolerance exemptions in 40 CFR 180.940, because these specific tolerance exemptions correspond to uses no longer current or registered in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and because there are insufficient data to make the determination of safety required by FFDCA. It is EPA's general practice to propose revocation of those tolerances for residues of pesticide active or inert ingredients on crops for which there are no active registrations under FIFRA, unless any person in comments on the proposal indicates a need for the tolerance to cover residues in or on imported commodities or domestic commodities legally treated. In addition, the safety finding required by FFDCA section 408(b)(2) cannot be made for certain antimicrobial ingredient tolerance exemptions because there are insufficient data.

The specific tolerance exemptions proposed for revocation in 40 CFR 180.940 are as follows:

1. The entry for Potassium Permanganate; CAS Reg. No. 7722-64-7; is proposed to be removed from the tables in paragraphs (a) and (c).

2. The entry for Sodium mono- and didodecylphenoxy-benzenedisulfonate; CAS Reg. No. None; is proposed to be removed from the tables in paragraphs (b) and (c).

3. The entry for Alkyl (C₁₂-C₁₅) monoether of mixed (ethylene-propylene) polyalkylene glycol, cloud point of 70-77 °C in 1% aqueous solution, average molecular weight (in amu), 807; CAS Reg. No. None; is proposed to be removed from the table in paragraph (c).

4. The entry for Benzensulfonamide, N-chloro-4-methyl, sodium salt; CAS Reg. No. 127-65-1; is proposed to be removed from the table in paragraph (c).

5. The entry for Benzenesulfonic acid, oxybis[dodecyl-]; CAS Reg. No. 30260-73-2; is proposed to be removed from the table in paragraph (c).

6. The entry for Calcium bromide; CAS Reg. No. 7789-41-5; is proposed to be removed from the table in paragraph (c).

7. The entry for Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediylidinitrilo)tetrakis [propanol] (4:1); CAS No. 11111-34-5; is proposed to be removed from the tables in paragraphs (b) and (c).

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

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996, Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore "adulterated" under section 402(a) of the FFDCA, 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under FIFRA (7 U.S.C. 136 *et seq.*). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States.

EPA's general practice is to propose revocation of tolerances for residues of pesticide active or inert ingredients on crops for which FIFRA registrations no longer exist and on which the pesticide may therefore no longer be used in the United States. EPA has historically been concerned that retention of tolerances or exemptions that are not necessary to cover residues in or on legally treated foods may encourage misuse of pesticides within the United States. Nonetheless, EPA will establish and maintain tolerances or exemptions even when corresponding domestic uses are canceled if the tolerances or exemptions are necessary to allow importation into the United States of food containing such pesticide residues. However, where there are no imported commodities that require these import tolerances, the Agency believes it is appropriate to revoke tolerances for unregistered pesticides in order to prevent potential misuse.

Furthermore, as a general matter, the Agency believes that retention of import tolerances or exemptions not needed to cover any imported food may result in unnecessary restriction on trade of pesticides and foods. Under section 408 of the FFDCA, a tolerance or exemption may only be established or maintained if EPA determines that the tolerance is safe based on a number of factors, including an assessment of the aggregate exposure to the pesticide and an assessment of the cumulative effects of such pesticide and other substances that have a common mechanism of toxicity. In doing so, EPA must consider potential contributions to such exposure from all tolerances and exemptions. If the cumulative risk is such that the tolerances or exemptions in aggregate are not safe, then every one of these tolerances and/or exemptions is potentially vulnerable to revocation. Furthermore, if unneeded tolerances or exemptions are included in the aggregate and cumulative risk assessments, the estimated exposure to the pesticide would be inflated. Consequently, it may be more difficult for others to obtain needed tolerances or exemptions or to register needed new uses. To avoid potential trade restrictions, the Agency is proposing to revoke tolerances or exemptions for residues on crops for which FIFRA registrations no longer exist, unless someone expresses a need for such tolerances or exemptions. Through this proposed rule, the Agency is inviting individuals who need these import tolerances or exemptions to identify themselves and the tolerances or

exemptions that are needed to cover imported commodities.

Parties interested in retention of the exemptions in this proposal should be aware that additional data are needed to support retention. The data needed include: A set of basic toxicity studies, chemistry studies and exposure studies. Especially important to reassessment is an acceptable repeat-dose study. In the absence of this data, EPA cannot make the required reasonable certainty of no harm finding. If the needed data is not submitted during the comment period on this proposal, these tolerances will be revoked on this ground as well.

C. When do These Actions Become Effective?

EPA is proposing that revocation of these exemptions become effective 90 days following publication of a final rule in the **Federal Register** to ensure that all affected parties receive notice of EPA's actions. For this rule, the proposed revocations will affect exemptions for active or inert ingredients which have not been used in registered products, in some cases, for many years. The Agency believes that existing stocks of pesticide products containing active or inert ingredients covered by the exemptions proposed for revocation have been completely exhausted and that treated commodities have had sufficient time for passage through the channels of trade. However, if EPA is presented with information that existing stocks would still be available and that information is verified, the Agency will consider extending the expiration date of the exemption. If you have comments regarding existing stocks and whether the effective date allows sufficient time for treated commodities to clear the channels of trade, please submit comments as described under **SUPPLEMENTARY INFORMATION**.

Any commodities treated with the pesticides subject to this proposal, and in the channels of trade following the exemption revocations, shall be subject to FFDCA section 408(1)(5), as established by FQPA. Under this section, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and
2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that

food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

D. Length of Comment Period

Pursuant to section 408(e)(2) EPA concludes that there is good cause for providing a comment period of 30, as opposed to 60, days. The lack of use of the pesticides covered by this proposal in pesticide products indicates a lack of interest in these particular pesticides. Should any person need additional time to comment on this proposal, a request for a comment extension should be filed with EPA well before the expiration of the 30-day comment period.

III. Are the Proposed Actions Consistent with International Obligations?

The exemption revocations in this proposal are not discriminatory and are designed to ensure that both domestically-produced and imported foods meet the food safety standard established by the FFDCA. The same food safety standards apply to domestically produced and imported foods.

EPA is working to ensure that the U.S. tolerance and exemption reassessment program under FQPA does not disrupt international trade. EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances and exemptions and in reassessing them. MRLs are established by the Codex Committee on Pesticide Residues, a committee within the Codex Alimentarius Commission, an international organization formed to promote the coordination of international food standards. It is EPA's policy to harmonize U.S. tolerances and exemptions with Codex MRLs to the extent possible, provided that the MRLs achieve the level of protection required under FFDCA. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance and exemption reassessment section of individual Reregistration Eligibility Decision documents. EPA has developed guidance concerning submissions for tolerances or exemptions pertaining to imported foods (65 FR 35069, June 1, 2000) (FRL-6559-3). This guidance will be made available to interested persons. Electronic copies are available on the internet at <http://www.epa.gov/>. On the Home Page select "Laws, Regulations, and Dockets," then select Regulations and Proposed Rules and then look up the entry for this document under "**Federal Register**—Environmental Documents." You can also go directly to

the “Federal Register” listings at <http://www.epa.gov/fedrgstr/>.

IV. Statutory and Executive Order Reviews

In this proposed rule, EPA is proposing to revoke specific tolerance exemptions established under FFDCA section 408. The Office of Management and Budget (OMB) has exempted this type of action (e.g., tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed 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 as required by 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 other 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).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances or exemptions might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby

certifies that this proposed action will not have a significant negative economic impact on a substantial number of small entities. Specifically, as per the 1997 notice, EPA has reviewed its available data on imports and foreign pesticide usage and concludes that there is a reasonable international supply of food not treated with canceled pesticides. Furthermore, for the pesticides named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposal that would change the EPA’s previous analysis. Any comments about the Agency’s determination should be submitted to the EPA along with comments on the proposal, and will be addressed prior to issuing a final rule. 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 proposed 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: June 2, 2006.

Betty Shackelford,

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

Therefore, it is proposed that 40 CFR chapter I be 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), 346a and 371.

§ 180.940 [Amended]

2. Section 180.940 is amended as follows:

i. In the tables to paragraphs (a) and (c) by removing the entry for “Potassium Permanganate” (CAS Reg. No. 7722–64–7).

ii. In the tables to paragraphs (b) and (c) by removing the entries for “Sodium mono- and didodecylphenoxy-benzenedisulfonate” (CAS Reg. No. None); and “Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetraakis [propanol] (4:1)” (CAS Reg. No. 11111–34–5).

iii. In the table to paragraph (c) by removing the entries for “Alkyl (C₁₂-C₁₅) monoether of mixed (ethylene-propylene) polyalkylene glycol, cloud point of 70-77 °C in 1% aqueous solution, average molecular weight (in amu), 807;” (CAS Reg. No. None); “Benzensulfonamide, N-chloro-4-methyl, sodium salt;” (CAS Reg. No. 127–65–1); “Benzenesulfonic acid, oxybis[dodecyl-” (CAS Reg. No. 30260–73–2); and “Calcium bromide” (CAS Reg. No. 7789–41–5)

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