

[Federal Register: May 31, 2006 (Volume 71, Number 104)]

[Proposed Rules]

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[DOCID:fr31my06-27]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0123; FRL-8061-7]

Inorganic Bromide; Proposed Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is announcing that 12 specific inorganic bromide tolerances have been reassessed and is proposing to revoke them because they are no longer needed. These twelve tolerances are for residues of inorganic bromide from pre-plant (non-food) use in or on raw agricultural commodities grown in soil fumigated with combinations of chloropicrin, methyl bromide, and propargyl bromide. Although methyl bromide is used as an agricultural pesticide, the Agency considers its application as a soil fumigant to be a non-food use because it is quickly degraded or metabolized in the soil, and subsequently incorporated into natural plant constituents. Methyl bromide is also emitted to the atmosphere. Residues of the parent compound are not likely to be found in foods as a result of prior treatment of fields. While residues of inorganic bromide may be present, these residues are indistinguishable from background because of inorganic bromide's ubiquity in the environment. In addition, the Agency has concluded that inorganic bromide residue from such use is not of risk concern and has determined those twelve tolerances to be safe. Consequently, EPA is proposing to revoke them because no tolerances are needed for those non-food uses and the Agency considers these tolerances to be reassessed. Furthermore, since methyl bromide, when applied as a pre-plant soil fumigant is a non-food use, it should be added as an entry to 40 CFR 180.2020 noting the non-food use determination. The regulatory actions proposed in this document contribute toward the Agency's tolerance reassessment requirements under the Federal Food, Drug, and Cosmetic Act (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. The regulatory actions proposed in this document pertain to the proposed revocation of 12 tolerances that count as tolerance reassessments toward the August 2006 review deadline.

DATES: Comments must be received on or before July 31, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2005-0123, 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-2005-0123. 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 [regulations.gov](http://www.regulations.gov) or e-mail. The Federal [regulations.gov](http://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 [regulations.gov](http://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

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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 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 for 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: Steven Weiss, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 308-8293; e-mail address: weiss.steven@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. 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:

- i. Identify the document by docket ID number and other identifying information (subject heading, Federal Register date and page number).
- ii. 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.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. 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.

II. Background

A. What Action is the Agency Taking?

Previously, EPA had established tolerances for residues of inorganic bromide for soil treatment with methyl bromide. However, EPA has classified methyl bromide as a non-food use pesticide with regard to its soil fumigant uses and proposes to revoke tolerances for inorganic bromide. The Agency stated that although methyl bromide is used as an agricultural pesticide, it is considered a non-food use chemical for soil fumigation uses since it is quickly degraded or metabolized in the soil, and subsequently incorporated into natural plant constituents. Methyl bromide is also emitted to the atmosphere. Residues of the parent compound are not likely to be found in foods as a result of prior treatment of fields. While residues of inorganic bromide may be present, these residues are indistinguishable from background because of inorganic bromide's ubiquity in the environment. Therefore, tolerances are not required for soil fumigant uses of methyl bromide, and tolerances currently established for residues of inorganic bromide resulting from methyl bromide soil fumigation (40 CFR 180.199) should be revoked. Supporting documents are available in the docket of this proposed rule.

Tolerances and tolerance exemptions established under part 180 apply to residues from only preharvest application, unless otherwise specified, in accordance with 40 CFR 180.1(i). On April 17, 2003 (68 FR 18935) (FRL-7180-2), EPA made pesticide tolerance nomenclature changes including a nomenclature change in 40 CFR part 180 regarding the term ``preharvest'' such that in 40 CFR 180.199(c) the regional tolerance for ``ginger, roots, pre-H and post-H'' was revised to ``ginger, roots, postharvest.'' Nevertheless, the tolerance expression in 40 CFR 180.199(c) applies to the raw agricultural commodity grown in soil fumigated with combinations of methyl bromide and chloropicrin, and therefore the regional tolerance on ginger, roots, postharvest should be revoked because that tolerance is no longer needed for soil fumigant use and use on ginger, roots, post-harvest is covered by a tolerance under 40 CFR 180.123.

Considering all the above factors (that the only residue of concern in pre-plant soil fumigation with methyl bromide is methyl bromide per se and there being no reasonable expectation of methyl bromide residues in most crops planted and grown in the fumigated soil, and that inorganic bromide is not of risk concern), as well as the low

likelihood of identifying control samples for tolerance enforcement which would be bromide-free, the conclusion that soil fumigation uses of methyl bromide should be considered non-food uses means that the tolerances for residues of inorganic bromide resulting from such use are therefore unnecessary. Accordingly, EPA believes that the 12 tolerances in 40 CFR 180.199(a) for residues of inorganic bromides in or on

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broccoli, cauliflower, eggplants, muskmelons, peppers, pineapples, strawberries, and tomatoes; in 40 CFR 180.199(b) on asparagus, lettuce, and onions (dry bulb); and in 40 CFR 180.199(c) on ginger, roots are not required under FFDCA and can be revoked. The Agency considers the twelve tolerances to be reassessed and counts them toward meeting the tolerance reassessment requirements listed in FFDCA section 408(q).

Furthermore, since methyl bromide, when applied as a pre-plant soil fumigant is a non-food use, it should be added as an entry to 40 CFR 180.2020 noting the non-food use determination.

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 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 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.

C. When do These Actions Become Effective?

EPA is proposing that revocation of these tolerances become effective on the date of publication of the final rule in the Federal Register. The Agency has determined that there is no reasonable expectation that residues of the pesticides listed in this proposed rule will be found on the commodities discussed in this proposed rule and therefore the lack of the tolerances does not prevent sale of the commodities.

D. What Is the Contribution to Tolerance Reassessment?

By law, EPA is required by August 2006 to reassess the tolerances in existence on August 2, 1996. As of May 18, 2006, EPA has reassessed

over 8,130 tolerances. This document proposes to revoke a total of 12 tolerances and counts them toward the August 2006 review deadline of FFDCa section 408(q), as amended by FQPA in 1996.

III. Are The Proposed Actions Consistent with International Obligations?

The tolerance 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 FFDCa. The same food safety standards apply to domestically produced and imported foods.

EPA is working to ensure that the U.S. tolerance reassessment program under FQPA does not disrupt international trade. EPA considers Codex Maximum Residue Limits (MRLs) in setting U.S. tolerances 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 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 reassessment section of individual Reregistration Eligibility Decision documents. EPA has developed guidance concerning submissions for import tolerance support (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 tolerances established under FFDCa section 408. The Office of Management and Budget (OMB) has exempted this type of action (i.e., 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 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 the fact that there is no reasonable expectation that residues of the pesticides listed in this proposed rule will be found on the commodities discussed in this proposed rule (so that the lack of the tolerance could not prevent sale of the commodity), the Agency hereby certifies that this proposed action will not have a significant negative economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible

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joint probability of all eight conditions holding simultaneously with respect to any particular revocation. (This Agency document is available in the docket of this proposed rule). Furthermore, for the pesticide 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 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: May 19, 2006.

James Jones,
Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 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.

Sec. 180.199 [Removed]

2. Section 180.199 is removed.

3. Section 180.2020 is amended by adding alphabetically the following entry to the table to read as follows.

Sec. 180.2020 Non-food determinations.

* * * * *

Pesticide Chemical	Chemical CAS Reg. No.	Limits
Uses		

Methyl Bromide
All pre-plant soil uses

74-83-9 When applied as a pre-
plant soil fumigant

* * * * *

[FR Doc. E6-8398 Filed 5-30-06; 8:45 am]

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