

[Federal Register: December 23, 2005 (Volume 70, Number 246)]
[Proposed Rules]
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[DOCID:fr23de05-22]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0322; FRL-7751-3]

Benzaldehyde, Captafol, Hexaconazole, Paraformaldehyde, Sodium dimethyldithiocarbamate, and Tetradifon; Proposed Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revoke specific tolerances and tolerance exemptions for residues of the insecticides paraformaldehyde and tetradifon; fungicides captafol, hexaconazole, and sodium dimethyldithiocarbamate; and bee repellent benzaldehyde. EPA canceled food use registrations or deleted food uses from registrations following requests for voluntary cancellation or use deletion by the registrants, or non-payment of registration maintenance fees. Also, stakeholders have withdrawn their support for import tolerances for captafol and hexaconazole. EPA expects to determine whether any individuals or groups want to support these tolerances. 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 39 tolerances and tolerance exemptions of which 38 would be counted as tolerance reassessments toward the August 2006 review deadline.

DATES: Comments must be received on or before February 21, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2005-0322, by one of the following methods:
Federal eRulemaking Portal: <http://www.regulations.gov/>.

Follow the on-line instructions for submitting comments.
Agency Web Site: EDOCKET, EPA's electronic public docket

and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.

E-mail: Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number EPA-HQ-OPP-2005-0322.

Mail: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number EPA-HQ-OPP-2005-0322.

Hand Delivery: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall 2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number EPA-HQ-OPP-2005-0322. Such deliveries are only accepted during the Docket's normal hours of operation, and

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special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2005-0322. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.epa.gov/edocket/>, including any personal information

provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ``anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the Federal Register of May 31, 2002 (67 FR 38102) (FRL-7181-7).

Docket: All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some

information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be

publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; e-mail address:nevola.joseph@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. How Can I Access Electronic Copies of This Document and Other Related Information?

In addition to using EDOCKET(<http://www.epa.gov/edocket/>), 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 E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

C. What Should I Consider as I Prepare My Comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through EDOCKET, 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 rulemaking 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.

D. 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 60 days for any person to state an interest in retaining a tolerance proposed for revocation. If EPA receives a comment within the 60-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. The order would specify data needed and the time frames for its submission, and would require that within 90 days some person or persons notify EPA that they will submit the data. If the data are not submitted as required in the order, EPA will take appropriate action under FFDCA.

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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

at the time of 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 certain specific tolerances and tolerance exemptions for residues of the insecticides paraformaldehyde and tetradifon; fungicides captafol, hexaconazole, and sodium dimethyldithiocarbamate; and bee repellent benzaldehyde because these specific tolerances and tolerance exemptions correspond to uses which are no longer current or registered under FIFRA in the United States, or no longer supported as import tolerances. It is EPA's general practice to propose revocation of those tolerances for residues of pesticide active ingredients on crop uses 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.

1. Benzaldehyde. The last active registration for use of benzaldehyde as a bee repellent in the harvesting of honey was canceled in 1991 due to non-payment of the maintenance fee, and therefore the tolerance exemption is no longer needed. EPA is proposing to revoke the tolerance exemption in 40 CFR 180.1229 for residues of benzaldehyde when used as a bee repellent in the harvesting of honey.

2. Captafol. The Republic of Indonesia's Indonesian Ministry of Agriculture had commented to a proposed rule to revoke tolerances for captafol and several other pesticides, published in the Federal Register of June 9, 1993 (58 FR 32320)(FRL-4183-6). The commenter had stated that the use of captafol was being reevaluated in that country, might undergo a phase out, and requested that EPA not revoke the onion, potato, and tomato tolerances in 40 CFR 180.267. In the Federal Register of July 21, 1999 (64 FR 39049)(FRL-6092-7), EPA published a final rule in which it revoked specific captafol tolerances and responded to the 1993 comment received from the Republic of Indonesia by stating that the Agency would not take final action on the three tolerances in 40 CFR 180.267 for residues of captafol on onion, potato, and tomato at that time. In April 2005, EPA determined that captafol has not been registered in Indonesia since 1998. Also, the Indonesian Ministry of Agriculture verified that it no longer has a continuing interest in the three captafol tolerances for importation purposes. Therefore, EPA is proposing to revoke the tolerances in 40 CFR 180.267 for residues of the fungicide captafol in or on onion, potato, and tomato.

3. Hexaconazole. There have been no active U.S. registrations for hexaconazole on banana since 1992. Recently, Syngenta has informed EPA that it has voluntarily chosen to no longer support the hexaconazole tolerance on banana for the purpose of importation. Consequently, the tolerance is no longer needed. Therefore, EPA is proposing to revoke the tolerance in 40 CFR 180.488 for residues of the fungicide

hexaconazole in or on banana.

4. Paraformaldehyde. The last active registration for paraformaldehyde use as an insecticide for the soil treatment of sugar beets was canceled in 1989 due to non-payment of the maintenance fee, and therefore the tolerance exemptions are no longer needed. EPA is proposing to revoke the tolerance exemptions in 40 CFR 180.1024 for residues of the insecticide paraformaldehyde in or on beet, sugar, roots and beet, sugar, tops, when applied to the soil not later than planting.

5. Sodium dimethyldithiocarbamate. The last active registration for use of sodium dimethyldithiocarbamate on melons was canceled in 1993 due to non-payment of the maintenance fee, and therefore the tolerance is no longer needed. EPA is proposing to revoke the tolerance in 40 CFR 180.152 for residues of the fungicide sodium dimethyldithiocarbamate, calculated as zinc ethylenebisdithiocarbamate, in or on melon.

6. Tetradifon. The last tetradifon registrations were canceled in 1990 due to non-payment of maintenance fees. Uniroyal Chemical Company (which later became part of Crompton Corporation) had commented to a proposed revocation of tetradifon tolerances published in the Federal Register of August 1, 2001 (66 FR 39705)(FRL-6786-4). Uniroyal noted that it had submitted certain studies to EPA in 1998 and 1996, and requested that EPA not revoke any of the tetradifon tolerances in 40 CFR 180.174. In the Federal Register of January 24, 2003 (68 FR 3425)(FRL-7187-3), EPA published a final rule and responded to Uniroyal's comment by stating that the Agency would not take final action on the tetradifon tolerances in 40 CFR 180.174 at that time. During follow-up communication, EPA received a letter from Crompton Corporation (now Chemtura Corporation) that it no longer supports retention of the tolerances for tetradifon. Therefore, EPA is proposing to revoke all the tolerances in 40 CFR 180.174 for residues of the insecticide tetradifon in or on apple; apricot; cherry; citron, citrus; crabapples; cucumber; fig; fig, dried fruit; grapefruit; grape; hop, dried; hop, vine; lemon; lime; meat; melon; milk; nectarine; orange, sweet; peach; pear; peppermint; plum, prune, fresh; pumpkin; quince; spearmint, tops; strawberry; tangerine; tea, dried; tomato; and winter squash.

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 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 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

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even when corresponding domestic uses are canceled if the tolerances, which EPA refers to as ``import tolerances,' 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 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 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. If the cumulative risk is such that the tolerances in aggregate are not safe, then every one of these tolerances is potentially vulnerable to revocation. Furthermore, if unneeded tolerances 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 to register needed new uses. To avoid potential trade restrictions, the Agency is proposing to revoke tolerances for residues on crops uses for which FIFRA registrations no longer exist, unless someone expresses a need for such tolerances. Through this proposed rule, the Agency is inviting individuals who need these import tolerances to identify themselves and the tolerances that are needed to cover imported commodities.

Parties interested in retention of the tolerances should be aware that additional data may be needed to support retention. These parties should be aware that, under FFDCA section 408(f), if the Agency determines that additional information is reasonably required to support the continuation of a tolerance, EPA may require that parties interested in maintaining the tolerances provide the necessary information. If the requisite information is not submitted, EPA may issue an order revoking the tolerance at issue.

C. When do These Actions Become Effective?

EPA is proposing that revocation of these tolerances and tolerance exemptions become effective on the date of publication of the final rule in the Federal Register because their associated uses have been canceled for several years. The Agency believes 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 tolerance. 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 listed in this proposal treated with the pesticides subject to this proposal, and in the channels of trade following the tolerance revocations, shall be subject to FFDC 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. 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 December 8, 2005, EPA has reassessed over 7,820 tolerances. This document proposes to revoke a total of 39 tolerances and tolerance exemptions of which 38 would be counted as tolerance reassessments toward the August 2006 review deadline of FFDC 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 the FFDC. 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 and tolerance exemptions 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, entitled 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

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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 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 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 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: December 13, 2005.

James Jones,
Director, 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.

Sec. Sec. 180.152, 180.174, 180.267, 180.488, 180.1024 and 180.1229 [Removed]

2. Sections 180.152, 180.174, 180.267, 180.488, 180.1024 and 180.1229 are removed.

[FR Doc. E5-7693 Filed 12-22-05; 8:45 am]

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