

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2003-0416;FRL-7353-5]

### Revocation of Tolerance Exemptions for Certain Biopesticides

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

**ACTION:** Final rule.

**SUMMARY:** This document revokes exemptions from the requirement of a tolerance, as expressed in 40 CFR part 180, for residues of the following pesticide active ingredients because of non-payment of maintenance fees and because there are no active FIFRA product registrations applicable to these exemptions: Dihydroazadirachtin; Kontrol HV; *Metarhizium anisopliae* strain ESF1 in attractant stations; polyhedral occlusion bodies of *Autographa californica* NPV; *Pseudomonas fluorescens* EG-1053; *Pseudomonas fluorescens* NCIB 12089; and *Puccinia canaliculata* (ATCC 40199). In addition, this document revokes the tolerance exemption for *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn because that tolerance exemption has been replaced by a tolerance exemption that applies to all plants. The regulatory actions in this document contribute toward the Agency's tolerance reassessment requirements of 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 tolerances in existence on August 2, 1996. For counting purposes, the revocations in this document count as nine (9) FQPA tolerance/exemption reassessments.

**DATES:** This regulation is effective July 22, 2004. Objections and requests for hearings must be received on or before June 22, 2004.

**ADDRESSES:** To submit a written objection or hearing request following the detailed instructions as provided in Unit IV. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP-2003-0416. 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, 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.

**FOR FURTHER INFORMATION CONTACT:** Barbara Mandula, Biopesticides and Pollution Prevention Division (MC 7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-7378; e-mail address: [mandula.barbara@epa.gov](mailto:mandula.barbara@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 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/>.

## II. Background

### A. What Action is the Agency Taking?

In the **Federal Register** of November 26, 2003 (68 FR 66390) (FRL-7332-4), EPA issued a proposed rule to revoke exemptions from the requirement of a tolerance, as expressed in 40 CFR part 180, for residues of the following pesticide active ingredients because of non-payment of maintenance fees and because there are no active FIFRA product registrations applicable to these exemptions: Dihydroazadirachtin; Kontrol HV; *Metarhizium anisopliae* strain ESF1 in attractant stations; polyhedral occlusion bodies of *Autographa californica* NPV; *Pseudomonas fluorescens* EG-1053; *Pseudomonas fluorescens* NCIB 12089; and *Puccinia canaliculata* (ATCC 40199). In addition, the November 26, 2003 FR notice proposed to revoke the tolerance exemption for *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn because that tolerance exemption has been replaced by a tolerance exemption that applies to all plants. Also, the November 26, 2003 proposal provided a 60-day comment period which invited public comment for consideration and for support of tolerance retention under FFDCA standards.

This final rule revokes all FFDCA tolerance exemptions for residues of: Polyhedral occlusion bodies of *Autographa californica* NPV in 40 CFR 180.1125; Dihydroazadirachtin in 40 CFR 180.1169; Kontrol H.V. in 40 CFR 180.1063; *Metarhizium anisopliae* strain ESF1 in attractant stations in 40 CFR 180.1116; *Pseudomonas fluorescens* EG-1053 in 40 CFR 180.1088; *Pseudomonas fluorescens* NCIB 12089 in 40 CFR 180.1129; and *Puccinia canaliculata* (ATCC 40199) in 40 CFR 180.1123. The tolerance exemptions revoked by this final rule are no longer necessary to cover residues of the relevant pesticides in or on domestically treated commodities or commodities treated outside but imported into the United States.

This final rule also revokes the tolerance exemption in 40 CFR 180.1152 for *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production in corn because that tolerance exemption has been replaced by a tolerance exemption in 40 CFR 180.1173 that applies to all plants.

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

Under section 408(e) of the FFDCA, it is EPA's general practice to propose

revocation of tolerances/tolerance exemptions for residues of pesticide active ingredients on crop uses for which FIFRA registrations no longer exist. EPA has historically been concerned that retention of tolerances/tolerance 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/tolerance exemptions even when corresponding domestic uses are canceled if the tolerances/tolerance 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/tolerance exemptions, the Agency believes it is appropriate to revoke tolerances/tolerance exemptions for unregistered pesticides in order to prevent potential misuse. Thus, it is EPA's policy to issue a final rule revoking tolerances/tolerance exemptions for residues of pesticide chemicals for which there are no active registrations under FIFRA, unless any person commenting on the proposal demonstrates a need for the tolerance/tolerance exemption to cover residues in or on imported commodities or domestic commodities legally treated.

In response to the proposed revocations of tolerance exemptions published in the **Federal Register** of November 26, 2003 (68 FR 66390), EPA did not receive any comments regarding a need to retain any of the tolerance exemptions proposed for revocation. Therefore, the Agency is revoking the tolerance exemptions as proposed in the November 26, 2003 FR notice.

#### *C. When Do These Actions Become Effective?*

These actions become effective 90 days following publication of this final rule in the **Federal Register**. EPA has delayed the effectiveness of these revocations for 90 days following publication of this final rule to ensure that all affected parties receive notice of EPA's actions. Consequently, the effective date is July 22, 2004. For this final rule, tolerance exemptions are being revoked for products and uses that have been canceled for more than two years. No other registered pesticide products exist for these uses. The Agency believes that sufficient time has passed for stocks to have been exhausted and for treated commodities to have cleared channels of trade.

Any commodities listed in the regulatory text of this document that are treated with the pesticides subject to

this final rule, and that are in the channels of trade following the tolerance revocations, shall be subject to section 408(1)(5) of FFDCA, as established by the FQPA. Under this section, any residue of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of FDA 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 a tolerance. Evidence to show that food was lawfully treated may include records that verify the dates that 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 March 15, 2003, EPA has reassessed over 6,630 tolerances. The tolerance exemptions being revoked in this final rule contribute nine (9) tolerance reassessments towards the total due in August 2006.

#### **III. Are There Any International Trade Issues Raised by this Final Action?**

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. When possible, EPA seeks to harmonize U.S. tolerances with Codex MRLs. EPA may establish a tolerance that is different from a Codex MRL; however, section 408(b)(4) of FFDCA requires that EPA explain in a **Federal Register** document the reasons for departing from the Codex level. EPA's effort to harmonize with Codex MRLs is summarized in the tolerance reassessment section of individual REDs. The U.S. 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 and Regulations," 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. Objections and Hearing Requests**

Under section 408(g) of FFDCA, as amended by 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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-0416 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 June 22, 2004.

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 Objection 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 IV.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-0416, 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 **ADDRESSES**. 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).

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

This final rule revokes tolerance exemptions established under section 408 of FFDCA. The Office of Management and Budget (OMB) has exempted this type of action (i.e., a tolerance exemption 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 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 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 rule, I certify that this action will not have a significant 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, the Agency knows of no extraordinary circumstances that exist as to the present revocations that would change EPA's previous analysis. 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 section 408(n)(4) of FFDCA. 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.

#### VI. 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 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: April 8, 2004.

**James Jones,**

*Director, Office of Pesticide Programs.*

■ Therefore, 40 CFR part 180 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), 346a and 371.

§ 180.1063 [Removed]

■ 2. Section 180.1063 is removed.

§ 180.1088 [Removed]

■ 3. Section 180.1088 is removed.

§ 180.1116 [Removed]

■ 4. Section 180.1116 is removed.

§ 180.1123 [Removed]

■ 5. Section 180.1123 is removed.

§ 180.1125 [Removed]

■ 6. Section 180.1125 is removed.

§ 180.1129 [Removed]

■ 7. Section 180.1129 is removed.

§ 180.1152 [Removed]

■ 8. Section 180.1152 is removed.

§ 180.1169 [Removed]

■ 9. Section 180.1169 is removed.

[FR Doc. 04-9136 Filed 4-22-04; 8:45 am]

BILLING CODE 6560-50-S

#### ENVIRONMENTAL PROTECTION AGENCY

##### 40 CFR Part 271

[FRL-7653-2]

##### South Dakota: Final Authorization of State Hazardous Waste Management Program Revision

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

**ACTION:** Final rule and response to comments.

**SUMMARY:** The EPA is granting final authorization to the hazardous waste program revisions submitted by South Dakota. The Agency published a Proposed Rule on November 3, 2003, and provided for public comment. The public comment period ended on December 3, 2003. No comments were received regarding Resource Conservation and Recovery Act (RCRA) program issues. There was one comment from the South Dakota State Attorney General regarding Indian country language. No further opportunity for comment will be provided.

**DATES:** This authorization will be effective on May 24, 2004.

**ADDRESSES:** You can view and copy South Dakota's applications at the following addresses: SDDENR, from 9

a.m. to 5 p.m., Joe Foss Building, 523 E. Capitol, Pierre, South Dakota 57501-3181, contact: Carrie Jacobson, phone number: (605) 773-3153 and EPA Region VIII, from 8 a.m. to 3 p.m., 999 18th Street, Suite 300, Denver, Colorado 80202-2466, contact: Kris Shurr, phone number: (303) 312-6139, e-mail: [shurr.kris@epa.gov](mailto:shurr.kris@epa.gov).

**FOR FURTHER INFORMATION CONTACT:** Kris Shurr, EPA Region VIII, 999 18th Street, Suite 300, Denver, Colorado 80202-2466, phone number: (303) 312-6139, e-mail: [shurr.kris@epa.gov](mailto:shurr.kris@epa.gov).

**SUPPLEMENTARY INFORMATION:** On August 16, 2002, and February 14, 2003, South Dakota submitted final complete program revision applications seeking authorization of their changes in accordance with 40 CFR 271.21. We now make a Final decision that South Dakota's hazardous waste program revisions satisfy all of the requirements necessary to qualify for Final authorization. For a list of rules that become effective with this Final Rule, please see the Proposed Rule published in the November 3, 2003 **Federal Register** at 68 FR 62264.

**Response to Comments:** EPA proposed to authorize South Dakota's State Hazardous Waste Management Program Revisions on November 3, 2003 (68 FR 62264). EPA received only one comment, from the State of South Dakota, objecting to EPA's definition of Indian country, where the State is not authorized to administer its program. Specifically, the State disagreed that all "trust land" in South Dakota is Indian country. However, through a letter dated March 12, 2004, the State of South Dakota conveyed to EPA that "while we [the State] continue to object and disagree on this issue, the state will accept EPA's authorization of the hazardous waste program revisions as described in EPA's November 3, 2003, notice in the **Federal Register**."

EPA maintains the interpretation of Indian country in South Dakota as described in the November 3, 2003 **Federal Register** notice of proposed rulemaking. Further explanation of this interpretation of Indian country can be found at 67 FR 45684-45686 (July 10, 2002).

**Administrative Requirements:** The Office of Management and Budget has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, I certify that this