

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 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.

XII. 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: March 22, 2004.

James Jones,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.1245 is added to subpart D to read as follows:

§ 180.1245 Rhamnolipid biosurfactant; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of rhamnolipid biosurfactant when used in accordance with good agricultural practices as a fungicide in or on all food commodities.

[FR Doc. 04-6933 Filed 3-30-04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0052; FRL-7349-3]

Zoxamide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of zoxamide in or on ginseng. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on ginseng. This regulation establishes a maximum permissible level for residues of zoxamide in this food commodity. The tolerance will expire and is revoked on December 31, 2006.

DATES: This regulation is effective March 31, 2004. Objections and requests for hearings, identified by docket ID number OPP-2004-0052, must be received on or before June 1, 2004.

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

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: Madden.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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2004-0052. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document

electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at <http://ecfr.gpoaccess.gov/ecfr/>.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select “search,” then key in the appropriate docket ID number.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide), in or on ginseng at 0.06 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2006. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18-related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of the FFDCA

defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Zoxamide on Ginseng and FFDCA Tolerances

Leaf and stem blight are diseases caused by pathogens for *Alternaria* and *Phytophthora*. If left unchecked, their damage to growing ginseng is seen in root rot, premature defoliation, and loss in root yields (ginseng is a root crop). Total yield loss is likely. The ginseng industry maintains that the alternative pesticide and cultural control means are insufficient. Although there are, in fact, pesticides that are labeled for these problems on ginseng, the alternatives are not effective or have a resistance issue in regards to the pathogens. Azoxystrobin was also labeled under section 3 for ginseng in 2000, however, its use is limited to six treatments per season, in order to preserve its efficacy. EPA has authorized under FIFRA section 18 the use of zoxamide on ginseng for control of *Alternaria* and *Phytophthora* in Michigan and Wisconsin. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of zoxamide in or on ginseng. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section

18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2006, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on ginseng after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether zoxamide meets EPA’s registration requirements for use on ginseng or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of zoxamide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Michigan and Wisconsin to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA’s regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for zoxamide, contact the Agency’s Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of zoxamide and to make a determination on aggregate exposure,

consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of zoxamide in or on ginseng at 0.06 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

Tolerances have been established for residues of zoxamide in or on grapes, potatoes, tomatoes and the cucurbit vegetable group 9 (40 CFR 180.567). EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. A summary of the toxicological dose and endpoints for zoxamide for use in human risk assessment is discussed in Unit III.A. of the **Federal Register** of April 11, 2001 (66 FR 18725) (FRL-6774-8).

Briefly, an endpoint for acute dietary exposures was not identified since no effects were observed in oral toxicity studies that could be attributable to a single dose. For chronic dietary exposures, the chronic reference dose (cRfD) is 0.48 milligrams/kilogram/day (mg/kg/day). The FQPA safety factor was removed (i.e., reduced to 1x) for zoxamide, because there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study conducted with zoxamide is not required. Therefore, the chronic population adjusted dose (cPAD) is 0.48 mg/kg/day. Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Zoxamide is not registered for use on any sites that would result in residential exposure. Therefore, short-term and intermediate-term aggregate risks were not assessed. Zoxamide has been classified as not likely to be carcinogenic to humans. Therefore, the only exposure scenario the Agency assessed is for chronic (non-cancer) exposures to zoxamide.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.567) for the combined residues of zoxamide and its metabolites 3,5-dichloro-1,4-benzenedicarboxylic acid (RH-1455 and RH-141455) and 3,5-dichloro-4-hydroxymethylbenzoic acid (RH-1452

and RH-141452) in or on potatoes, tomatoes and the cucurbit vegetable group 9 and for only residues of zoxamide on grapes. Risk assessments were conducted by EPA to assess dietary exposures from zoxamide in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No acute dietary endpoint was identified since no effects were observed in oral toxicity studies that could be attributable to a single dose. Therefore, acute dietary risk assessments were not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCIDT, Version 1.3) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994-1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Published and proposed tolerances level residues were used. Default processing factors and 100% crop treated were assumed for all commodities.

iii. *Cancer.* Zoxamide has been classified as not likely to be carcinogenic to humans. Therefore, risk assessments to estimate risk from cancer were not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for zoxamide in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of zoxamide.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and screening concentration in ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier I model) before using PRZM/EXAMS (a Tier II model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides.

GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are the theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to zoxamide, they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of zoxamide for chronic exposures are estimated to be 21.8 parts per billion (ppb) for surface water and 2.1 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Zoxamide is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether zoxamide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, zoxamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that zoxamide has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Conclusion.* There is a complete toxicity data base for zoxamide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10x safety factor to protect infants and children should be removed. The FQPA factor is removed because:

- i. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure;
- ii. A developmental neurotoxicity study conducted with zoxamide is not required;
- iii. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children. Additionally, there are currently no residential uses.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments.

Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to zoxamide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of zoxamide on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* No acute dietary endpoint was identified since no effects were observed in oral toxicity studies that could be attributable to a single dose. Therefore, acute dietary risk assessments were not performed.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to zoxamide from food will utilize 1% of the cPAD for the U.S. population, 1% of the cPAD for all infants (<1 year old), and 4% of the cPAD for children 1–2 years old, the subpopulation at greatest exposure. There are no residential uses for zoxamide. In addition, despite the potential for chronic dietary exposure to zoxamide in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of zoxamide in surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 1 of this unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO ZOXAMIDE

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.48	1%	21.8	2.1	16,600
All Infants (<1 year old)	0.48	1%	21.8	2.1	4,600
Children (1–6 years old)	0.48	4%	21.8	2.1	4,600

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered

to be a background exposure level). Zoxamide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk

is the sum of the risk from food and water, which were previously addressed.

4. *Intermediate-term risk.*

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Zoxamide is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S.*

population. Zoxamide has been classified as not likely to be carcinogenic to humans. Therefore, risk assessments to estimate risk from cancer were not performed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to zoxamide residues.

V. Other Considerations

A. *Analytical Enforcement Methodology*

Adequate enforcement methodology (e.g., gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. *International Residue Limits*

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of zoxamide in/on ginseng. Therefore, no compatibility issues exist with regard to the proposed U.S. ginseng time-limited tolerance.

VI. Conclusion

Therefore, the tolerance is established for residues of zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide), in or on ginseng at 0.06 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the

necessary modifications can be made. The new section 408(g) of the 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 the FFDCA, as was provided in the old sections 408 and 409 of the 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-2004-0052 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 1, 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 Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, 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 VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP-2004-0052, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. 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).

VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the

Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the 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.

IX. 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: March 19, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.567 is amended by adding text to paragraph (b) to read as follows:

§ 180.567 Zoxamide.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide) in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Revocation date
Ginseng	0.06	12/31/06

* * * * *

[FR Doc. 04-6932 Filed 3-30-04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-2004-0035; FRL-7350-8]

Time-Limited Exemption from Requirement of a Tolerance; Exemption from the Requirement of a Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* VIP3A insect control protein as expressed in event COT102 and the genetic material necessary for its production on cotton when applied/used as a plant-incorporated protectant. Syngenta Seeds submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis* VIP3A insect control protein as expressed in event COT102 and the genetic material necessary for its production.

DATES: This regulation is effective March 31, 2004. Objections and requests for hearings, identified by docket ID number OPP-2004-0035, must be received on or before June 1, 2004.

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

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail address: cole.leonard@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 categories and 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2004-0035. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through 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 on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents

of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of November 26, 2003 (68 FR 66422) (FRL-7332-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (3F6756) by Syngenta Seeds, Incorporated, P.O. Box 12257, 3054 Cornwallis Road, Research Triangle Park, NC 27709-2257. This notice included a summary of the petition prepared by the petitioner Syngenta Seeds, Incorporated. Comments were received from grower groups, and the National Cotton Council supporting this petition.

The petition requested that 40 CFR 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* VIP3A Insect Control Protein as Expressed in Event COT102 and the genetic material necessary for its production.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of the FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408 of the FFDCA (b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”