List of Subjects in 17 CFR Part 160

Brokers, Consumer protection, Privacy, Reporting and recordkeeping requirements.

Accordingly, 17 CFR Part 160 is corrected by making the following correcting amendment:

PART 160—PRIVACY OF CONSUMER FINANCIAL INFORMATION

1. The authority citation for part 160 continues to read as follows:

Authority: U.S.C. 7g and 8a(5); 15 U.S.C. 6801 *et seq.*

2. Revise paragraph (b)(1) of § 160.18 to read as follows:

§ 160.18 Effective Date; compliance date; transition rule.

* * * * *

(b)(1) *Notice requirement for consumers who are your customers on the effective date.* By March 31, 2002, you must have provided an initial notice, as required by § 160.4, to consumers who are your customers on March 31, 2002.

Dated: May 7, 2001.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 01–11861 Filed 5–10–01; 8:45 am]

BILLING CODE 6351–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[TN–T5–2001–02; FRL–6977–6]

Clean Air Act Full Approval of Operating Permit Program; Tennessee and Memphis-Shelby County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to adverse comments, EPA is withdrawing the direct final rule published in the **Federal Register** on March 20, 2001, promulgating full approval of the operating permit programs submitted by the Tennessee Department of Environment and Conservation and the Memphis-Shelby County Health Department.

DATES: The direct final rule published on March 20, 2001, in the **Federal Register** (66 FR 15635) is withdrawn as of May 11, 2001.

ADDRESSES: The docket containing supporting information used in the development of this notice is available for inspection during normal business hours at EPA Region 4, Air & Radiation Technology Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8909. Anyone wanting to examine these documents should make an appointment by calling the person listed below at least two working days in advance.

FOR FURTHER INFORMATION CONTACT: Kim Pierce, EPA Region 4, at (404) 562–9124 or *pierce.kim@epa.gov/.*

SUPPLEMENTARY INFORMATION: On March 20, 2001, EPA published a direct final rule (66 FR 15635) and a parallel proposal (66 FR 15680) to fully approve the operating permit programs of the Tennessee Department of Environment and Conservation and the Memphis-Shelby County Health Department. The Tennessee and Memphis-Shelby County operating permit programs were submitted in response to the directive in the 1990 Clean Air Act (CAA) Amendments that permitting authorities develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources within the permitting authorities' jurisdiction. EPA granted interim approval to the Tennessee and Memphis-Shelby County operating permit programs on July 29, 1996. Tennessee and Memphis-Shelby County revised their programs to satisfy the conditions of the interim approval and the direct final rule published on March 20, 2001, would have approved those revisions along with other program changes made by Tennessee since the interim approval was granted.

The EPA stated in the March 20, 2001, action that if adverse comments were received by April 19, 2001, EPA would publish a timely withdrawal of the direct final rule. The EPA did receive adverse comments and is, therefore, withdrawing the March 20, 2001, action and informing the public that the direct final rule will not take effect on May 21, 2001. The commenter expressed concern that Tennessee is issuing operating permits that do not provide for compliance with all applicable requirements. The EPA will address the specific comments in a subsequent final action based on the parallel proposal published on March 20, 2001.

As stated in the parallel proposal, EPA will not institute a second comment period on this action. However, in response to a request from George Hays as counsel for the National Parks Conservation Association, EPA is publishing a notice in the proposed rules section of this **Federal Register** to reopen the public comment period in the March 20, 2001, proposal.

Dated: May 2, 2001.

A. Stanley Meiburg,

Acting, Regional Administrator, Region 4.

[FR Doc. 01–11910 Filed 5–10–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301123; FRL–6781–6]

RIN 2070–AB78

Bacillus Thuringiensis Cry3Bb1 and Cry2Ab2 Protein and the Genetic Material Necessary for its Production in Corn and Cotton; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited exemption from the requirement of a tolerance for residues of the plant-pesticides Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production in corn on field corn, sweet corn, and popcorn and the plant-pesticides Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production in corn on field corn, sweet corn, popcorn, or in cotton on cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts when applied/used as a plant-pesticide. Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This exemption from the requirement of a tolerance will expire on May 1, 2004.

DATES: This regulation is effective May 11, 2001. Objections and requests for hearings, identified by docket control number [OPP–301123], must be received by EPA, on or before July 10, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301123 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, c/o Product Manager (PM) 90, Biopesticides and

Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–8715; and e-mail address: mendelsohn.mike@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301123. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of October 10, 1997 (62 FR 52998) (FRL–5748–5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition, petition number 7F4888, by Monsanto Company, 700 Chesterfield Parkway, North, St. Louis, MO 63198. This notice included a summary of the petition prepared by the petitioner Monsanto Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the plant pesticides consisting of *Bacillus thuringiensis* Cry1, Cry2, and Cry3 classes of proteins and the genetic material necessary for the production of these proteins in or on all raw agricultural commodities. In August and November of 1999, Monsanto amended their petition to narrow its scope to the following Cry proteins: Cry1Ab, Cry1Ac, Cry2Aa, Cry2Ab, Cry3Aa, and Cry3Bb in or on all plant raw agricultural commodities. While this final rule is limited to particular Cry3Bb in or on corn and Cry2Ab proteins in or on corn and cotton (Cry3Bb1 and Cry2Ab2), the Agency may at future dates issue final rules for the other specified Cry protein plant-pesticides on particular plant agricultural commodities.

III. Risk Assessment

Pursuant to section 408(c)(2)(A)(i) of the FFDCA, EPA may establish or leave in effect 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 exemption is ''safe.'' With respect to an exemption for a pesticide chemical residue, section 408(c)(2)(A)(ii) 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) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption 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) requires that the Agency consider ''available information'' concerning, *inter alia*, the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Pursuant to section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

Data have been submitted demonstrating the lack of mammalian toxicity at high levels of exposure to the pure Cry3Bb1 and Cry2Ab2 proteins. These data demonstrate the safety of the products at levels well above maximum possible exposure levels that are reasonably anticipated in the crops. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-pesticide was derived

(See 40 CFR 158.740(b)(2)(i)). For microbial products, further toxicity testing and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study, to verify the observed effects and clarify the source of these effects (Tiers II and III).

Two acute oral studies were submitted for Cry3Bb1 proteins. These studies were done with two variants of the Cry3Bb1 protein engineered with either four or five internal amino acid sequence changes to enhance activity against the corn rootworm. The acute oral toxicity data submitted support the prediction that the Cry3Bb1 protein would be non-toxic to humans. Male and female mice (10 of each) were dosed with 36, 396, or 3,780 milligrams/kilograms bodyweight (mg/kg bwt) of Cry3Bb1 protein for one variant. The mice were dosed with 38.7, 419, or 2,980 mg/kg bwt of Cry3Bb1 protein for the other variant. In one study, two animals in the high dose group died within a day of dosing. These animals both had signs of trauma probably due to dose administration (i.e., lung perforation or severe discoloration of lung, stomach, brain and small intestine). No clinical signs were observed in the surviving animals and body weight gains were recorded throughout the 14–day study for the remaining animals. Gross necropsies performed at the end of the study indicated no findings of toxicity attributed to exposure to the test substance in either study. No other mortality or clinical signs attributed to the test substance were noted during either study.

The acute oral toxicity data submitted support the prediction that the Cry2Ab2 protein would be non-toxic to humans. Male and female mice (10 of each) were dosed with 67, 359, and 1,450 mg/kg bwt of Cry2Ab2 protein. Outward clinical signs were observed and body weights recorded throughout the 14–day study. Gross necropsies performed at the end of the study indicated no findings of toxicity attributed to exposure to the test substance. No mortality or clinical signs attributed to the test substance were noted during the study. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology* 15, 3-9 (1992)). Therefore, since no effects were shown to be caused by the plant-pesticides, even at relatively high dose levels, the Cry3Bb1 and Cry2Ab2 proteins are not considered toxic.

Further, amino acid sequence comparisons showed no similarity between Cry3Bb1 and Cry2Ab2 proteins to known toxic proteins available in public protein data bases.

Since Cry3Bb1 and Cry2Ab2 are proteins, allergenic sensitivities were considered. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by heat, acid, and proteases, may be glycosylated and present at high concentrations in the food.

Data have been submitted that demonstrate that the Cry3Bb1 protein is rapidly degraded by gastric fluid *in vitro*. In a solution of simulated gastric fluid (pH 1.2 - U.S. Pharmacopeia), complete degradation of detectable Cry3Bb1 protein occurred within 30 seconds. Insect bioassay data indicated that the protein loss insecticidal activity within 2 minutes of incubation in SGF. Incubation in simulated intestinal fluid resulted in a~59 kDa protein digestion product. A comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Cry3Bb1, even at the level of 8 contiguous amino acids residues.

Data have been submitted that demonstrate that the Cry2Ab2 delta-endotoxin is rapidly degraded by gastric fluid *in vitro*. In a solution of simulated gastric fluid (pH 1.2 - U.S. Pharmacopeia), complete degradation of detectable Cry2Ab2 protein occurred within 15 seconds. Incubation in simulated intestinal fluid resulted in a ~50 kDa protein digestion product. A comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Cry2Ab2, even at the level of 8 contiguous amino acids residues.

The potential for the Cry3Bb1 and Cry2Ab2 proteins to be food allergens is minimal. Regarding toxicity to the immune system, the acute oral toxicity data submitted support the prediction that the Cry3Bb1 and Cry2Ab2 proteins would be non-toxic to humans. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology* 15, 3-9 (1992)). Therefore, since no effects were shown to be caused by the plant-pesticides, even at relatively high dose levels, the Cry3Bb1 and Cry2Ab2 proteins are not considered toxic.

V. Aggregate Exposures

Pursuant to FFDCA section 408(b)(2)(D)(vi), EPA considers available information concerning aggregate exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-pesticide chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-pesticide is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, potentially, drinking water. However a lack of mammalian toxicity and the digestibility of the plant-pesticides have been demonstrated. The use sites for the Cry3Bb1 and Cry2Ab2 proteins are all agricultural for control of insects. Therefore, exposure via residential or lawn use to infants and children is not expected. Even if negligible exposure should occur, the Agency concludes that such exposure would present no risk due to the lack of toxicity demonstrated for the Cry3Bb1 and Cry2Ab2 proteins.

VI. Cumulative Effects

Pursuant to FFDCA section 408(b)(2)(D)(v), EPA has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity to these plant-pesticides, we conclude that there are no cumulative effects for the Cry3Bb1 and Cry2Ab2 proteins.

VII. Determination of Safety for U.S. Population, Infants and Children

A. Toxicity and Allergenicity Conclusions

The data submitted and cited regarding potential health effects for the Cry3Bb1 and Cry2Ab2 proteins include the characterization of the expressed Cry3Bb1 protein in corn and the

expressed Cry2Ab2 protein in corn and cotton, as well as the acute oral toxicity, and *in vitro* digestibility of the proteins. The results of these studies were determined applicable to evaluate human risk and the validity, completeness, and reliability of the available data from the studies were considered.

Adequate information was submitted to show that the Cry3Bb1 test material derived from microbial cultures was biochemically and, functionally similar to the protein produced by the plant-pesticide ingredients in corn. Adequate information was submitted to show that the Cry2Ab2 test material derived from microbial cultures was biochemically and, functionally similar to the protein produced by the plant-pesticide ingredients in corn and cotton. Production of microbially produced protein was chosen in order to obtain sufficient material for testing.

The acute oral toxicity data submitted supports the prediction that the Cry3Bb1 and Cry2Ab2 proteins would be non-toxic to humans. When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Sjoblad, Roy D., et al. ''Toxicological Considerations for Protein Components of Biological Pesticide Products,'' *Regulatory Toxicology and Pharmacology* 15, 3-9 (1992)). Since no effects were shown to be caused by Cry3Bb1 and Cry2Ab2 proteins, even at relatively high dose levels (3,780 mg Cry3Bb1/kg bwt and 1,450 mg/kg bwt of Cry2Ab2 protein), the Cry3Bb1 and Cry2Ab2 proteins are not considered toxic. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-pesticide was derived. See 40 CFR 158.740(b)(2)(i). For microbial products, further toxicity testing and residue data are triggered by significant acute effects in studies such as the mouse oral toxicity study to verify the observed effects and clarify the source of these effects (Tiers II and III).

Cry3Bb1 and Cry2Ab2 residue chemistry data were not required for a human health effects assessment of the subject plant-pesticide ingredients because of the lack of mammalian toxicity.

Both available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children); and safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data were not evaluated. The lack of mammalian toxicity at high levels of exposure to the Cry3Bb1 and Cry2Ab2 proteins demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated in the crop.

The genetic material necessary for the production of the plant-pesticides active ingredients are the nucleic acids (DNA, RNA) which comprise genetic material encoding these proteins and their regulatory regions. ''Regulatory regions'' are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the proteins. DNA and RNA are common to all forms of plant and animal life and the Agency knows of no instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food. These ubiquitous nucleic acids, as they appear in the subject active ingredient, have been adequately characterized by the applicant. Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the subject active plant pesticidal ingredients.

B. Infants and Children Risk Conclusions

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(B)(2)(C) also 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 unless EPA determines that a different margin of safety will be safe for infants and children.

In this instance, based on all the available information, the Agency concludes that there is a finding of no toxicity for the Cry3Bb1 and Cry2Ab2 proteins and the genetic material necessary for their production. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply.

C. Overall Safety Conclusion

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to the Cry3Bb1 and Cry2Ab2 proteins and the genetic material necessary for their production. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for the plant-pesticides.

VIII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredients are proteins, derived from sources that are not known to exert an influence on the endocrine system. Therefore, the Agency is not requiring information on the endocrine effects of these plant-pesticides at this time.

B. Analytical Method(s)

Validated methods for extraction and direct ELISA analysis of Cry3Bb1 in corn grain, Cry2Ab2 in corn grain, and Cry2Ab2 in cotton seed have been submitted and found acceptable by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exists for the plant-pesticides*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in corn and *Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production in corn or cotton.

IX. 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 that 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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409.

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 control number OPP–301123 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 July 10, 2001.

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 (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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.

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.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.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.2. Mail your copies, identified by docket number OPP–301123, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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).

X. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. 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). 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 petition under FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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.

XI. Submission to Congress and the Comptroller General

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 27, 2001.

Anne E. Lindsay,

Acting 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(q), 346(a) and 371.

2. Section 180.1214 is added to subpart D to read as follows:

§ 180.1214 Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production in corn; exemption from the requirement of a tolerance.

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production in corn are exempt from the requirement of a tolerance when used as plant-pesticides in the food and feed commodities of field corn, sweet corn and popcorn. *Genetic material necessary for its production* means the genetic material which comprise genetic material encoding the Cry3Bb1 protein and its regulatory regions. *Regulatory regions* are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the Cry3Bb1 protein.This exemption from the requirement of a tolerance will expire on May 1, 2004.

3. Section 180.1215 is added to subpart D to read as follows:

§ 180.1215 Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production in corn or cotton; exemption from the requirement of a tolerance.

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production in corn or cotton are exempt from the requirement of a tolerance when used as plant-pesticides in the food and feed commodities of field corn, sweet corn, popcorn, cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts. *Genetic material necessary for its production* means the genetic material which comprise genetic material encoding the Cry2Ab2 protein and its regulatory regions. *Regulatory regions* are the genetic material, such as promoters, terminators, and enhancers, that control the expression of the genetic material encoding the Cry2Ab2 protein. This exemption from the requirement of a tolerance will expire on May 1, 2004.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 372

[OPPTS–400134A; FRL–6722–9]

RIN 2025–AA00

Chromite Ore from the Transvaal Region of South Africa; Toxic Chemical Release Reporting; Community Right-to-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is granting a petition to delete both chromite ore mined in the Transvaal Region of South Africa and the unreacted ore component of the chromite ore processing residue (COPR) from the reporting requirements under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and section 6607 of the Pollution Prevention Act of 1990 (PPA). These chemicals are currently reported as part of the category ''chromium compounds'' on the list of toxic chemicals in section 313(c) of EPCRA. The action is based on EPA's conclusion that this particular chromite ore from the Transvaal Region and the unreacted ore component of the COPR (in the case of this delisting decision, COPR includes the solid waste remaining after the aqueous extraction of oxidized chromite ore that has been combined with soda ash and kiln roasted at approximately 2,000 °F) meet the deletion criterion under EPCRA section 313(d)(3). By promulgating this rule, EPA is relieving facilities of their obligation to report releases of and other waste management information on chromite ore mined in the Transvaal Region of South Africa and the unreacted ore component of the COPR that occurred during the 2000 reporting year, and for activities in the future.

EFFECTIVE DATE: This rule is effective May 11, 2001.

FOR FURTHER INFORMATION CONTACT: Daniel R. Bushman, Petitions Coordinator, (202) 260–3882, e-mail: bushman.daniel@epa.gov, for specific information on this document, or for more information on EPCRA section 313, the Emergency Planning and Community Right-to-Know Hotline, Environmental Protection Agency, Mail Code 5101, 1200 Pennsylvania Ave.,