• A firm optional endorsement line, followed by the 5-digit destination ZIP Code of the parcel.

• A blue, pressure-sensitive, barcoded Label F on the address side of the parcel.

We provide the new standards, and how they are applied for Bound Printed Matter, below.

We adopt the following amendments to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

■ Accordingly, 39 CFR Part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

400 Discount Mail Parcels

* * * * *

402 Elements on the Face of a Mailpiece

* * * * *

2.0 PLACEMENT AND CONTENT OF MARKINGS

* * * * *

2.2 Parcel Post, Bound Printed Matter, Media Mail, and Library Mail Markings

* * * * *

[Renumber 2.2.5 and 2.2.6 as 2.2.6 and 2.2.7. Add new 2.2.5, as follows:]

2.2.5 Address and Firm Designation on Bound Printed Matter Machinable Parcels

When a Bound Printed Matter machinable parcel consists of multiple pieces for a single address secured with transparent shrinkwrap, the delivery address information and barcoded pressure-sensitive Label F or firm optional endorsement line must be visible and readable by the naked eye. Mailers must label the parcel using one of the following options:

a. A firm optional endorsement line under 708.7.0, followed by the 5-digit destination ZIP Code of the parcel.

b. A blue, pressure-sensitive, barcoded Label F on the address side of the parcel.

* * * * *

700 Special Standards

* * * * *

708 Technical Specifications

* * * * *

7.0 OPTIONAL ENDORSEMENT LINES (OELs)

* * * * *

7.1 OEL Use

* * * * *

Exhibit 7.1.1 OEL Formats

[Revise Exhibit 7.1.1 by adding an OEL example for BPM parcels, as follows:]

Sortation level	OEL Example
Firm—BPM machinable parcels	******** Firm 12345.

* * * * *

Neva R. Watson,

Attorney, Legislative.

[FR Doc. 06–2454 Filed 3–14–06; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2006–0174; FRL–7766–6]

Modified Cry3A Protein and the Genetic Material for Its Production in Corn; Extension of a Temporary Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends an existing temporary exemption from the requirement of a tolerance for residues of the *Bacillus thuringiensis* modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn on field corn, sweet corn, and popcorn when applied/used as a plant-incorporated protectant. Syngenta Seeds, Inc. 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 this extension of the existing temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn. The temporary tolerance exemption as extended will expire on October 15, 2007.

DATES: This regulation is effective March 15, 2006. Objections and requests for hearings must be received on or before May 15, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2006–0174. All documents in the docket are listed on the *http://www.regulations.gov* Web site. (EDOCKET, EPA's electronic public docket system was replaced on November 25, 2005, by an enhanced federal-wide eletronic management and comment system located at *http//www.regulations.gov/*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. 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 174 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of January 25, 2006 (71 FR 4140) (FRL–7757–6), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4G6808) by Syngenta Seeds, Inc., P.O. Box 12257, 3054 East Cornwallis Road, Research Triangle Park, NC 27709–2257. The petition requested that 40 CFR part 174 be amended by extending by 1 year a temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn on field corn, sweet corn, and popcorn when applied/used as a plant-incorporated protectant (40 CFR 174.456). This notice included a summary of the petition prepared by the petitioner Syngenta Seeds, Inc.. One comment was received in response to the notice of filing. The commentor objected to an exemption from the requirement of a tolerance, stated that she does not favor genetically engineered corn, and objected to the lack of long term tests. The Agency understands the commenter's concerns and recognizes that some individuals believe that genetically modified crops and food should be banned completely. Regarding the commenter's concern regarding a lack of long term tests; 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 the plant-incorporated protectants, even at relatively high dose levels, the mCry3A protein is not considered toxic. Pursuant to its authority under the FFDCA, EPA conducted a comprehensive assessment of the modified Cry3A protein and the genetic material necessary for its production in corn, including a review of acute oral toxicity data on the mCry3A protein, amino acid sequence comparisons to known toxins and allergens, as well as data demonstrating that the mCry3A protein is rapidly degraded by gastric fluid *in vitro*, is not glycosylated, is inactivated when heated to 95 °C for 30 minutes, and is present in low levels in corn tissue, and has concluded that there is a reasonable certainty that no harm will result from dietary exposure to this protein as expressed in genetically modified corn.

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 exemption 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. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require 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.''

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.

III. Toxicological Profile

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 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 mCry3A protein. 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-incorporated protectant 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).

An acute oral toxicity study was submitted for the mCry3A protein. The acute oral toxicity data submitted support the prediction that the mCry3A protein would be non-toxic to humans. Male and female mice (5 of each) were dosed with 2,377 milligrams/kilograms bodyweight (mg/kg bwt) of mCry3A protein. With the exception of one female in the test group that was euthanized on day 2 (due to adverse clinical signs consistent with a dosing injury), all other mice survived the study, gained weight, had no test material-related clinical signs, and had no test material-related findings at necropsy.

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-incorporated protectants, even at relatively high dose levels, the mCry3A protein is not considered toxic. Further, amino acid sequence comparisons showed no similarity between the mCry3A protein to known toxic proteins available in public protein data bases.

Since mCry3A is a protein, 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 oncentrations in the food.

Data have been submitted that demonstrate that the mCry3A protein is rapidly degraded by gastric fluid *in vitro*. In a solution of simulated gastric fluid 1 milligrams/milliliter (mg/mL) mCry3A test protein mixed with simulated gastric fluid (pH 1.2, containing 2 mg/mL NaCl, 14 muL 6 N HCl, and 2.7 mg/mL pepsin) resulting in 10 pepsin activity units/ mug protein (complies with year 2000 U.S. Pharmacopoeia recommendations), complete degradation of detectable mCry3A protein occurred within 2 minutes. A comparison of amino acid sequences of known allergens uncovered no evidence of any homology with mCry3A, even at the level of eight contiguous amino acids residues. Further, data demonstrate that mCry3A is not glycosylated, is inactivated when heated to 95 °C for 30 minutes, and is present in low levels in corn tissue. Therefore, the potential for the mCry3A protein to be a food allergens is minimal. As noted above, toxic proteins typically act as acute toxins with low dose levels. Therefore, since no effects were shown to be caused by the plant-incorporated protectant, even at relatively high dose levels, the mCry3A protein is not considered toxic.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning 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-incorporated protectant chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-incorporated protectant is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the mCry3A protein are all agricultural for control of insects. Oral exposure, at very low levels, may occur from ingestion of processed corn products and, potentially, drinking water. However, oral toxicity testing done at a dose in excess of 2 grams/kilogram (gm/kg) showed no adverse effects. Furthermore, the expression of the modified Cry3A protein in corn kernals has been shown to be in the parts per million range, which makes the expected dietary exposure several orders of magnitude lower than the amounts of mCry3A protein shown to have no toxicity. Therefore, even if negligible aggregate exposure should occur, the Agency concludes that such exposure would prevent no harm due to the lack of mammalian toxicity and the rapid digestibility demonstrated for the mCry3A protein.

V. 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, resulting from the plant-incorporated protectant, we conclude that there are no cumulative effects for the mCry3A protein.

VI. 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 mCry3A protein include the characterization of the expressed mCry3A protein in corn, 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 mCry3A protein test material derived from microbial cultures was biochemically and functionally similar to the protein produced by the plant-incorporated protectant ingredients in corn. 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 mCry3A protein would be non-toxic to humans. As mentioned above, 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 mCry3A protein, even at relatively high dose levels (2,377 mg/kg bwt), the mCry3A protein is 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-incorporated protectant 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 thesource of these effects (Tiers II and III).

MCry3A protein residue chemistry data were not required for a human health effects assessment of the subject plant-incorporated protectant ingredients because of the lack of mammalian toxicity. However, data submitted demonstrated low levels of mCry3A in corn tissues with less than 2 micrograms mCry3A protein/gram dry weight in kernals and less than 30 micrograms mCry3A protein/gram dry weight of whole corn plant.

Since modified Cry3A is a protein, its potential allergenicity is also considered as part of the toxicity assessment. Data considered as part of the allergenicity assessment include that the modified Cry3A protein came from *Bacillus thuringiensis* which is not a known allergenic source, showed no sequence similarity to known allergens, was readily degraded by pepsin, was inactivated by heat and was not glycosylated when expressed in the plant. Therefore, there is a reasonable certainty that modified Cry3A protein will not be an allergen.

Neither available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers

including infants and children); nor safety factors that are generally recognized as appropriate for the use of animal experimentation data were evaluated. The lack of mammalian toxicity at high levels of exposure to the mCry3A protein, as well as the minimal potential to be a food allergen 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-incorporated protectant active ingredients are the nucleic acids (DNA, RNA) which comprise genetic material encoding these proteins and their regulatory regions. The genetic material (DNA, RNA), necessary for theproduction of mCry3A protein has been exempted under the blanket exemption for all nucleic acids (40 CFR 174.475).

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, also referred to as margins of exposure (MOEs), 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 MOE 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 mCry3A protein and the genetic material necessary for their production. Thus, there are no threshold effects of concern to infants and children when the mCry3A protein is used as a plant-incorporated protectant. Accordingly, the Agency concludes that the additional MOE is not necessary to protect infants and children, and that not adding any additional MOE will be safe for infants and children.

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 mCry3A protein and the genetic material necessary for its 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, nor any indication of allergenicity potential for the plant-incorporated protectant.

VII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredient is a protein, 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 the plant-incorporated protectant at this time.

B. Analytical Method(s)

A method for extraction and ELISA analysis of mCry3A protein in corn has been submitted and found acceptable by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the plant-incorporated protectant *Bacillus thuringiensis* mCry3A protein and the genetic material necessary for its production in corn.

VIII. 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), 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 EPA–HQ–OPP–2006–0174 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 May 15, 2006.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.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 EPA–HQ–OPP–2006–0174, to: Public Information and Records Integrity Branch, Information Technology and Resources Management 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*. 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).

IX. Statutory and Executive Order Reviews

This final rule establishes a temporary exemption from the tolerance requirement under section 408(d) of the FFDCA 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). 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 petition under section 408(d) of the FFDCA, such as the exemption 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.

X. 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 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 2, 2006.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136-136y; 21 U.S.C. 346a and 371.

■ 2. Section 174.456 is revised to read as follows:

§ 174.456 Bacillus thuringiensis modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn.

Bacillus thuringiensis modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn is temporarily exempt from the requirement of a tolerance when used as plant-incorporated protectant 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 mCry3A 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 mCry3A protein. This temporary exemption from the requirement of a tolerance will permit

the use of the food commodities in this paragraph when treated in accordance with the provisions of the experimental use permit 67979–EUP–4 which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked October 15, 2007; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[FR Doc. 06–2431 Filed 3–14–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0103; FRL–7765–3]

Triflumizole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino-2-propoxyethyl)-1*H*-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on filberts. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of1996 (FQPA).

DATES: This regulation is effective March 15, 2006. Objections and requests for hearings must be received on or before May 15, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0103. All documents in the docket are listed on the *http://www.regulations.gov* Web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhancedFederal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: 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 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 on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of January 18, 2006 (71 FR 2930) (FRL–7757–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6535) by IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902. The petition requested that 40 CFR 180.476 be amended by establishing a tolerance for combined residues of the fungicide triflumizole, 1-(1-((4-chloro-2-(trifluoromethyl)phenyl)imino-2-propoxyethyl]-1*H*-imidazole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound in or on filberts at 0.05 parts per million (ppm). That notice included a summary of the petition prepared by Chemtura, the registrant. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of 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 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 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. . . .''