ethylene oxide blends containing HCFC–22, this section lists: (1) Sterilants that EPA previously found acceptable as substitutes for ethylene oxide blends containing HCFC–22; and (2) sterilants that EPA is newly finding acceptable as substitutes for ethylene oxide blends containing HCFC–22.

At the end of the decision for the end use, there is narrative comparing environmental, flammability, and toxicity information of the newly acceptable alternative with other currently or potentially available alternatives. Flammable and highly reactive sterilants are hazardous waste when disposed. Sterilants must be registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prior to use. Also, requirements of the Food and Drug Administration for medical devices apply to equipment using sterilants.

More environmental and health information is also available in the original SNAP rule of March 18, 1994, the notice of acceptability in which each substitute was first listed, or the sector table for each of the acceptable alternatives to ethylene oxide blends containing HCFC–22, in the sterilant end use. The sector table is available at *http://www.epa.gov/ozone/snap/sterilants/index.html*. The sector table also includes further identification information (including composition and trade names) for each substitute.

1. EPA previously found the following acceptable as substitutes for ethylene oxide blends containing HCFC–22 as sterilants:

- IoGas™ Sterilant Blends 1, 3, and 6 (blends of $CF_3I/CO_2/EtO$)
- Mini-Max® Cleaner

2. EPA is newly finding the following acceptable as substitutes for ethylene oxide blends containing HCFC–22 as sterilants:

- CO_2/EtO
- Hydrogen peroxide gas plasma systems
- Peroxyacetic acid/hydrogen peroxide gas plasma systems
- Pure EtO
- Steam

The newly listed substitutes for HCFC–22, HCFC–142b, and blends thereof listed above in section VII.A.2. are non-ozone-depleting, in contrast to HCFC–22 blends. They are comparable to other acceptable substitutes for HCFC–22 blends in their lack of risk for ozone depletion. The newly listed substitutes have GWPs of one or less, comparable to or lower than that of other substitutes for HCFC–22 blends. For example, the GWP of the IoGas blends is less than one.

Peroxyacetic acid and ethylene oxide are considered VOCs under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the national ambient air quality standards. Ethylene oxide is a hazardous air pollutant under EPA regulations. EPA's National Emission Standards for Hospital Ethylene Oxide Sterilizers apply to this substance and blends that contain it (*see* subpart WWWWW of 40 CFR part 63). EPA has previously found other blends containing ethylene oxide to be acceptable as sterilants. Further, blends that do not contain ethylene oxide are often still reactive.

Among the newly listed substitutes for HCFC–22 blends, pure ethylene oxide and peroxyacetic acid, a component in a peroxyacetic acid/hydrogen peroxide gas plasma system, are flammable. Hydrogen peroxide is not flammable per se, but is highly reactive and must be handled cautiously at the concentrations required for use in sterilization equipment. These sterilants should be used in equipment designed to reduce the risks of flammable or highly reactive chemicals. EPA believes that the flammability and reactivity risks can be addressed by existing standards from OSHA, NIOSH, and EPA, and/or by guidelines from the manufacturer, and other safety precautions common during sterilization.

The toxicity risks of the newly listed substitutes for HCFC–22 blends are comparable to the risks of the IoGas blends that EPA previously found acceptable as substitutes for blends of ethylene oxide and HCFCs. Ethylene oxide has an OSHA PEL of 1 ppm on an 8-hour time-weighted average and a NIOSH IDLH of 800 ppm (30-minute). This compound may be carcinogenic. Hydrogen peroxide, used in gas plasma systems, has an OSHA PEL of 1 ppm (8-hr TWA) and a NIOSH IDLH value of 75 ppm (30 min). Peroxyacetic acid, used together with hydrogen peroxide in gas plasma systems, has an AEGL–1 of 0.17 ppm from 10 min to 8 hours to avoid irritation and an AEGL–2 of 0.5 ppm from 10 min to 8 hours to avoid "irreversible or other serious, long-lasting adverse health effects * * *." (*Acute Exposure Guideline Levels for Selected Airborne Chemicals,* Committee on Acute Exposure Guideline Levels, National Research Council of the National Academies, 2009). EPA anticipates that users will be able to meet the workplace exposure limits (PELs, IDLHs, and AEGLs) and will address potential health risks by following requirements and recommendations in the MSDSs and other safety precautions common when working with sterilants. For the above reasons, we find the newly listed substitutes (in VII.A.2, above) acceptable because they do not pose a greater overall risk to human health and the environment than the other substitutes available in the end use.

You can find a complete chronology of SNAP decisions and the appropriate **Federal Register** citations from the SNAP section of EPA's Ozone Depletion Web site at *http://www.epa.gov/ozone/snap/chron.html.* This information is also available from the Air Docket (*see* **ADDRESSES** section above for contact information).

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: June 10, 2010.

Brian J. McLean,

Director, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 2010–14510 Filed 6–15–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2009–0609; FRL–8829–9]

Bacillus thuringiensis eCry3.1Ab Protein in Corn; Temporary Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop, when used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit 67979-EUP-8. Syngenta Seeds, Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting a temporary exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn under the FFDCA. The temporary tolerance exemption expires on June 1, 2012.

DATES: This regulation is effective June 16, 2010. Objections and requests for

hearings must be received on or before August 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0609. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), 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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 174 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0609 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 16, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0609, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of September 30, 2009 (74 FR 50196) (FRL–8433–3), 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 tolerance petition (PP 9F7561) by Syngenta Seeds, Incorporated, P.O. Box 12257, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn. This notice referenced a summary of the petition prepared by the petitioner Syngenta Seeds, Incorporated, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit VII.C.

Section 408(c)(2)(A)(i) of 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 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) of FFDCA, 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) of FFDCA, 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 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 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.

A. Product Characterization Overview

Based on amino acid sequence homology and crystal structures, known Cry proteins have a similar three-dimensional structure comprised of three domains, Domain I, II, and III (Refs. 3, 5, 6 and 7). The toxin portions of Cry proteins are characterized by having five conserved blocks (CB) across their amino acid sequence. These are numbered CB1 to CB5 from the N-terminus to the C-terminus (Ref. 4). The sequences preceding and following these conserved blocks are highly variable and are designated as variable regions V1 to V6.

Syngenta Seeds, Incorporated developed Event 5307 maize (*Zea mays*) through *Agrobacterium*-mediated transformation (via plasmid vector PV-ZMIR245) to express eCry3.1Ab protein for use as a plant-incorporated protectant (PIP). This proposed PIP is a chimeric *Bacillus thuringiensis* protein, composed of portions of Cry1Ab and modified Cry3A proteins. The eCry3.1Ab protein was genetically engineered via exchanging the variable regions (V1 to V6) between the mCry3A and the Cry1Ab proteins for enhanced toxicity against western corn rootworm (WCR, *Diabrotica virgifera*). The eCry3.1Ab protein consists of a fusion between the N-terminus (Domain I, Domain II, and a portion of Domain III) of mCry3 A and the C-terminus (a portion of Domain III and variable region 6) of Cry1Ab. The eCry3.1Ab protein is 654 amino acid residues in size and is approximately 73.7 kilodaltons.

B. Mammalian Toxicity and Allergenicity Assessment

Syngenta has submitted acute oral toxicity data demonstrating the lack of mammalian toxicity at high levels of exposure to the pure eCry3.1Ab protein. These data demonstrate the safety of the product at a level well above maximum possible exposure levels that are reasonably anticipated in the crop. Basing this conclusion on acute oral toxicity data without requiring further toxicity testing and residue data is similar to the Agency position regarding toxicity testing and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this PIP was derived (see 40 CFR 158.2130(d)(1)(i) and 158.2140(d)(7)). For microbial products, further toxicity testing and residue data are triggered by significant adverse acute effects in studies, such as the mouse oral toxicity study, to verify and quantify the observed adverse effects and clarify the source of these effects (Tiers II & III).

An acute oral toxicity study in mice (Master Record Identification Number MRID No. 477539-01) indicated that eCry3.1Ab is nontoxic. Two groups of 10 male and 10 female mice were orally dosed (via gavage) with 2,000 milligrams/kilograms bodyweight (mg/kg bwt) (eCry3.1Ab protein mg/kg bwt) of the eCry3.1Ab-0208 test substance, the microbial-produced eCry3.1Ab protein. All treated animals gained weight and had no test material-related clinical signs and no test material-related findings at necropsy. Since there were no significant differences between the test and control groups related to the oral administration of eCry3.1Ab-0208 test material, the eCry3.1Ab protein does not appear to cause any significant adverse effects at an exposure level of up to 2,000 mg/kg bwt and supports the finding that the eCry3.1Ab protein would be nontoxic to mammals.

When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels (Ref. 8). Therefore, since no acute effects were shown to be caused by eCry3.1Ab, even at relatively high dose levels, the eCry3.1Ab protein is not considered toxic. Further, amino acid sequence comparisons showed no similarities between the eCry3.1Ab protein and known toxic proteins in protein databases that would raise a safety concern.

Since eCry3.1Ab is a protein, allergenic sensitivities were considered. Currently, no definitive tests exist for determining the allergenic potential of novel proteins. Therefore, EPA uses a "weight-of-the-evidence" approach where the following factors are considered: Source of the trait; amino acid sequence similarity with known allergens; prevalence in food; and biochemical properties of the protein, including *in vitro* digestibility in simulated gastric fluid (SGF) and glycosylation (as recommended by *CAC* 2003, see Ref. 2). Current scientific knowledge suggests that common food allergens tend to be resistant to degradation by acid and proteases; may be glycosylated; and present at high concentrations in the food.

1. *Source of the trait. Bacillus thuringiensis* is not considered to be a source of allergenic proteins.

2. *Amino acid sequence*. A comparison of the amino acid sequence of eCry3.1Ab with known allergens showed no significant overall sequence similarity or identity at the level of eight contiguous amino acid residues. This is the appropriate level of sensitivity to detect possible IgE epitopes without high false positive rates.

3. *Prevalence in food*. Preliminary expression level analysis shows that the eCry.1Ab protein is present at relatively low levels. Dietary exposure is expected to be correspondingly low. Expression in Event 5307 leaf is 35 parts per million ppm; root is 6 ppm; and pollen is 0.15 ppm. Thus, the expression has been shown to be in the parts per million range.

4. *Digestibility*. The eCry3.1Ab protein was rapidly digested in simulated mammalian gastric fluid containing pepsin at a pH of 1.2 at 37°C. Theestimated degradation rate (DT50) is less than 1 minute for eCry3.1Ab protein.

5. *Glycosylation*. The eCry3.1Ab protein expressed in corn was shown not to be glycosylated.

6. *Conclusion*. Considering all of the available information, EPA has concluded that the potential for eCry3.1Ab to be a food allergen is minimal.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of 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. First, with respect to other related substances, the eCry3.1Ab protein is a chimeric *Bacillus thuringiensis* protein, composed of portions of Cry1Ab and mCry3A proteins both of which are registered PIPs that were previously assessed as having a lack of mammalian toxicity at high levels of exposure. Exemptions from the requirement of a tolerance have been established for Cry1Ab in food and

mCry3A in maize, (see 40 CFR 174.511, effective Apr. 25, 2007 and 40 CFR 174.505, effective Apr. 25, 2007, respectively). Second, and specific to the eCry3.1Ab protein, these considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the PIP chemical residue and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the PIP is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. The amino acid homology assessment included similarity to known aeroallergens. It has been demonstrated that there is no evidence of occupationally-related respiratory symptoms, based on a health survey on migrant workers after exposure to *Bt* pesticides (Ref. 1). Exposure via residential or lawn use to infants and children is also not expected because the use sites for the eCry3.1Ab 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 of 2 gm/kg showed no adverse effects. Furthermore, the expected dietary exposure from corn is several orders of magnitude lower than the amounts of eCry3.1Ab protein shown to have no toxicity. Therefore, even if negligible aggregate exposure should occur, the Agency concludes that such exposure would present no harm due to the lack of mammalian toxicity and the rapid digestibility demonstrated for the eCry3.1Ab protein.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of 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."

Since eCry3.1Ab is not considered toxic, EPA has not found eCry3.1Ab protein to share a common mechanism of toxicity with any other substances, and eCry3.1Ab protein does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that eCry3.1Ab protein does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with eCry3.1Ab that need to be considered. 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

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

The data submitted and cited regarding potential health effects for the eCry3.1Ab protein include the characterization of the expressed eCry3.1Ab protein in corn, as well as the acute oral toxicity, heat stability, and *in vitro* digestibility of the protein. The results of these studies were used to evaluate human risk, and the validity, completeness, and reliability of the available data from the studies were also considered.

As discussed more fully in Unit III. above, the acute oral toxicity data submitted supports the prediction that the eCry3.1Ab protein would be nontoxic to humans. Moreover, eCry3.1Ab showed no sequence similarity to any known toxin. Because of this lack of demonstrated mammalian toxicity, no protein residue chemistry data for eCry3.1Ab were required for a human health effects assessment. Even so, preliminary expression level analysis showed eCry3.1Ab protein is present at relatively low levels. Dietary exposure is expected to be correspondingly low.

In addition, since eCry3.1Ab is a protein, its potential allergenicity was also considered as part of the toxicity assessment. Data considered as part of the allergenicity assessment include that the eCry3.1Ab protein came from *Bacillus thuringiensis,* which is not a known allergenic source, showed no sequence similarity to known allergens, was readily degraded by pepsin, and was not glycosylated when expressed in the plant. Therefore, there is a reasonable certainty that eCry3.1Ab protein will not be an allergen.

Considered together, the lack of mammalian toxicity at high levels of exposure to the eCry3.1Ab protein and the minimal potential for that protein to be a food allergen demonstrate the safety of the product at levels well above possible maximum exposure levels anticipated in the crop.

Finally, and specifically in regards to infants and children, 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) 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.

Based on its review and consideration of all the available information, as discussed in more detail above, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of the eCry3.1Ab protein and the genetic material necessary for its production in corn. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has also concluded, again for the reasons discussed in more detail above, that there are no threshold effects of concern and, as a result, that an additional margin of safety for infants and children is unnecessary in this instance.

VII. Other Considerations

A. Analytical Enforcement Methodology

The Agency has determined that an analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Nonetheless, a method for extraction and two test strip commercial kits to detect eCry3.1Ab protein via enzyme-linked immunosorbent assay analysis in corn have been submitted and are under review by the Agency.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance

that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for eCry3.1Ab protein in corn.

C. Response to Comments

One comment was received from an anonymous individual who objected in general terms to EPA's registration of any pesticides and its approval of any tolerance or tolerance exemption, claiming that no safety testing is required or undertaken. While the Agency understands that some individuals are opposed to all pesticide use, relavant data (discussed above) did serve as the basis for EPA's conclusion in this instance that there is a reasonable certainty of no harm from residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn.

VIII. Conclusions

The Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of eCry3.1Ab protein in corn and the genetic material necessary for its production. Therefore, a temporary exemption is established for residues of *Bacillus thuringiensis* eCry3.1Ab protein in or on corn.

IX. References

1. Bernstein IL, Bernstein JA, Miller M, Tierzieva S, Bernstein DI., Lummus Z, Selgrade MK, Doerfler DL, Seligy VL. 1999. Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides. *Environmental Health Perspectives*. 107(7):575–82.

2. CAC. 2003. Alinorm 03/34: Joint FAO/WHO Food Standard Programme. Codex Alimentarius Commission, Twenty-Fifth Session, 30 July 2003. Rome, Italy. Appendix III: Guideline for Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants; Appendix IV: Annex on Assessment of Possible Allergenicity. Codex Alimentarius Commision, 47–60.

3. Ge A, Rivers D, Milne R, Dean DH. 1991. Functional Domains of *Bacillus thuringiensis* Insecticidal Crystal Proteins. Refinement of *Heliothis virescens* and *Trichoplusiani* Specificity Domains on Cry1A(c). *Journal of Biological Chemistry*. 266: 17954–17958.

4. Hofte H, Whitley HR. 1989. Insecticidal Crystal Proteins of *Bacillus thuringiensis*.. *Microbiology Review*. 53: 242–255.

5. Honee G, Convents D, Van Rie J, Jansens S, Peferoen M, Visser B. 1991. The C-Terminal Domain of the Toxic Fragment of a *Bacillus thuringiensis* Crystal Protein Determines Receptor Binding. *Molecular Microbiology*. 5: 2799–2806.

6. Li J, Carroll J, Ellar DJ. 1991. Crystal Structure of Insecticidal δ-Endotoxin from *Bacillus thuringiensis* at 2.5 A resolution. *Nature*. 353: 815–821.

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8. Sjoblad R D, McClintock JT, Engler R. 1992. Toxicological Considerations for Protein Components of Biological Pesticide Products. *Regulatory Toxicology and Pharmacology*. 15(1): 3–9.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under section 408(d) of 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not 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).

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).

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: June 1, 2010.

Steven Bradbury,

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

■ 2. Add § 174.532 to subpart W to read as follows:

§ 174.532 *Bacillus thuringiensis* **eCry3.1Ab protein in corn; temporary exemption from the requirement of a tolerance.**

Residues of *Bacillus thuringiensis* eCry3.1Ab protein in corn, in or on the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop are exempt temporarily from the requirement of a tolerance when *Bacillus thuringiensis* eCry3.1Ab protein in corn is used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit 67979-EUP-8. This temporary exemption from the requirement of a tolerance expires and is revoked on June 1, 2012.

[FR Doc. 2010–14330 Filed 6–15–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0739; FRL–8825–2]

Sodium 1,4-Dialkyl Sulfosuccinates; 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 sodium 1,4-dialkyl sulfosuccinates including sodium 1,4-dihexyl sulfosuccinate (CAS Reg. No. 3006–15–3); sodium 1,4-diisobutyl sulfosuccinate (CAS Reg. No. 127–39–9); and sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5) when used as an inert ingredient in pesticide formulations for pre-harvest and post-harvest uses, as well as, for application to animals under 40 CFR 180.910 and 40 CFR 180.930, respectively. The Joint Inerts Task Force (JITF), Cluster Support Team 13 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of the sodium 1,4-dialkyl sulfosuccinates.

DATES: This regulation is effective June 16, 2010. Objections and requests for hearings must be received on or before August 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0739. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Karen Samek, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8825; e-mail address: *samek.karen@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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0739 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 16, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number