

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-1077; FRL-8873-1]

Carbon Dioxide; 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 carbon dioxide (CAS Reg. No. 124-38-9) when used as an inert ingredient as a propellant in pre-harvest and post-harvest applications and when applied to animals. Whitmire Micro-Gen Research Laboratories, Inc., c/o Landis International, Inc. 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 carbon dioxide.

DATES: This regulation is effective May 4, 2011. Objections and requests for hearings must be received on or before July 5, 2011, 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-2007-1077. 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: P. V. Shah, Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-1846; e-mail address: shah.pv@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 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, 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-2007-1077 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 July 5, 2011. 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-2007-1077, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (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. Petition for Exemption

In the **Federal Register** of December 22, 2010 (75 FR 80489) (FRL-8857-8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7811) by Whitmire Micro-Gen Research Laboratories, Inc., c/o Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603-5126. The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of carbon dioxide (CAS Reg. No. 124-38-9) when used as an inert ingredient as a propellant in pesticide formulations applied pre-harvest and post-harvest under 40 CFR 180.910 and applied to animals under 40 CFR 180.930. That notice referenced a summary of the petition prepared by Whitmire Micro-Gen Research Laboratories, Inc., c/o Landis International, Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. (Docket ID number EPA-HQ-OPP-2007-1077). There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are

not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

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 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. * * *

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will

result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for carbon dioxide including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with carbon dioxide follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data for carbon dioxide and considered their validity, completeness, and reliability, as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The primary sources of data for this assessment are the U.S. EPA’s 1991, Reregistration Eligibility Decision document (RED) that included carbon dioxide (US EPA RED, 1991), and the Report of the FQPA Tolerance Reassessment Progress and Risk Management Decision (TRED) for Carbon Dioxide issued by EPA in 2004. The Agency has not found any more recent information that would change the conclusions found in these documents. Therefore, these documents are being used to evaluate the proposed exemption from the requirement of a tolerance for use as an inert ingredient as a propellant applied pre-harvest and post-harvest under 40 CFR 180.910 and applied to animals under 40 CFR 180.930. Specific information on the studies received and the nature of the adverse effects caused by carbon dioxide can be found in these documents at <http://www.regulations.gov>, “Reregistration Eligibility Document (RED) for Carbon and Carbon Dioxide”, “Lower Risk Pesticide Chemical Focus Group’s Assessment for Carbon Dioxide Tolerance Reassessment (TRED)”, and “PC code 800029; Decision Document for Pesticide Petition 0E7811; Carbon Dioxide (CAS Reg. No. 124–38–9) for Use as an Inert Ingredient as a Propellant Applied Pre-Harvest and Post-Harvest Under 40 CFR 180.910 and For Use on Animals Under 40 CFR 180.930.” found in docket ID number EPA–HQ–OPP–2007–1077.

The toxicology data for carbon dioxide are all derived from inhalation studies using high concentrations of carbon dioxide. Although these data show carbon dioxide does pose some hazard at concentrations well above normal atmospheric levels, these data have limited relevance to evaluating the safety of carbon dioxide residues in food. Because it is a gas, carbon dioxide would be expected to leave little or no residues on plant commodities, and, to the extent carbon dioxide is absorbed by the plant, it would likely be converted by the photosynthesis process into sugars and other organic compounds that are not of toxicological concern.

In evaluating the human toxicity of carbon dioxide, it is relevant to consider that “carbon dioxide is produced by the body’s metabolism and is always present in the body at about 6 percent concentration. An average adult human will produce more than 500g of carbon dioxide daily under resting conditions, and will produce much more when active.” (US EPA RED, 1991). It is on this basis that the Food and Drug Administration has classified carbon dioxide as Generally Recognized As Safe (21 CFR 184.1240) as a direct food additive. As the discussion in Unit IV.D. on exposure reveals, even worst case theoretical levels of carbon dioxide residues in food would be dwarfed by normal body levels of carbon dioxide.

B. Toxicological Points of Departure/ Levels of Concern

Considering its presence in the environment and in the human body, the additional toxicological contribution of carbon dioxide through the proposed use is expected to be minimal. Therefore, the Agency has determined that a qualitative assessment for all pathways of human exposure to carbon dioxide (food, drinking water, and residential) is appropriate.

C. Aggregate Exposures

1. *Dietary exposures (from food and drinking water).* In evaluating dietary exposure to carbon dioxide, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from carbon dioxide in food and drinking water as follows:

No residue data were submitted for carbon dioxide; however, carbon dioxide is not expected to accumulate in treated raw agricultural commodities, rather, it will diffuse into the atmosphere following application due to its physical and chemical properties. In the absence of reliable data regarding dietary exposures to carbon dioxide, the

Agency assessed dietary exposure using its highly conservative Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03). This approach uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738.

The Agency believes the assumptions used to estimate dietary exposures led to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. For example, the model assumes that the inert ingredients are used on all commodities and that residues will be present for every consumed commodity at the highest tolerance level residue for all food forms (including meat, milk, poultry, and eggs), using default processing factors for dried commodities and assuming that 100% of all crops are "treated" with the inert ingredient. In addition, a default concentration of 100 parts per billion (ppb) was assumed for the inert ingredient residues in drinking water. Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data. Even with the extremely conservative nature of this screening level model, the estimated dietary (food and drinking water) exposures from carbon dioxide when used in pesticide formulations are 10,000 fold less than the amount of carbon dioxide naturally produced by the human body each day.

2. *Non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Obviously, humans are exposed through respiration to carbon dioxide in the atmosphere. Dietary exposure from

naturally-carbonated and artificially-carbonated beverages is also ubiquitous. The discussion in this Unit focuses on additional exposures from use of carbon dioxide as a propellant in pesticide products.

i. *Dermal exposure.* In evaluating the potential for exposure from the use of carbon dioxide in residential pesticide products, dermal exposures of concern are not anticipated due to its physical and chemical properties and dissipating nature.

ii. *Inhalation exposures.* Inhalation is the primary route of exposure from carbon dioxide because of its high vapor pressure. Because of the potential increased risk to acute inhalation exposure from indoor uses, EPA used its conservative Exposure and Fate Assessment Screening Tool (E-FAST v.2.0) screening level model to estimate the potential for inhalation exposures from indoor uses of carbon dioxide as a propellant in residential pesticide products. E-Fast was developed by EPA's Office of Pollution, Prevention and Toxics as a tool to estimate concentrations of chemicals released from consumer products. Modeled estimates of concentrations and doses are designed to significantly overestimate exposures for use in a screening level assessment. For carbon dioxide, E-FAST's aerosol paint scenario was selected because it potentially resembles a use of a residential pesticide product using carbon dioxide as a propellant. This scenario estimates potential acute inhalation exposure over 20 minutes of aerosol paint use in an enclosed utility room. The Agency considers an acute inhalation exposure to be a single event occurring over a period of less than 24 hours. In this case, the E-FAST model generated estimates of exposure are expected to be greater than what is reasonably anticipated from the use of carbon dioxide as an inert ingredient in residential-use pesticide products. The concentration of carbon dioxide in aerosol paint products used in the E-FAST model was 100%. The results of the conservative E-FAST modeling show a peak concentration potential of 4,923 parts per million (ppm) (8,860 mg/m³). EPA does not expect actual exposure from residential use of carbon dioxide as a propellant as an inert ingredient in pesticide products to exceed these modeling estimates (peak concentration potential of 4,923 ppm (8,860 mg/m³)) and expects that outdoor exposure concentrations would also be lower.

3. *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."

EPA has not found carbon dioxide to share a common mechanism of toxicity with any other substances, and carbon dioxide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that carbon dioxide does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA has not used a quantitative risk assessment approach based on safety factors for carbon dioxide residues given that normal atmospheric levels of carbon dioxide do not pose a hazard, carbon dioxide is necessary to the proper functioning of the human body, and exposure to carbon dioxide residues from use in pesticide products is miniscule compared to existing environmental levels. For the same reasons, an additional safety factor to protect children is not needed.

E. Aggregate Risks and Determination of Safety

EPA expects aggregate exposure to carbon dioxide residues to pose no appreciable risk to human health given that normal atmospheric levels of carbon dioxide do not pose a hazard. Carbon dioxide is necessary to the proper functioning of the human body, and it is unlikely that the use of carbon

dioxide as an inert ingredient as a propellant in pesticide products will result in residues in food that measurably add to carbon dioxide exposure. Even potential non-dietary acute inhalation exposure from indoor uses was conducted using the extremely conservative E-FAST screening level model (described under Unit IV.C.2b), showed maximum levels of exposure of 4,923 ppm, well below the maximum permitted exposure limits established as safe by Office of Safety Health Administration (OSHA) or National Institute of Occupational and Health (NIOSH) (30,000 ppm).

Taking into consideration all available information on carbon dioxide, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to carbon dioxide under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance for residues of carbon dioxide (CAS Reg. No. 124–38–9) when used as an inert ingredient as a propellant in pesticide formulations applied pre- and post-harvest under 40 CFR 180.910 and when applied to animals under 40 CFR 180.930 is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

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.

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. 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 carbon dioxide.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 40 CFR 180.930 for residues of carbon dioxide (CAS Reg. No. 124–38–9) when used as an inert ingredient in pesticide formulations as a propellant in pre- and post-harvest applications under 40 CFR 180.910 and when applied to animals under 40 CFR 180.930.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 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, nor does this action 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) (Pub. L. 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).

VIII. 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 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 26, 2011.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * *		
Carbon Dioxide (CAS Reg. No. 124–38–9)	None	Propellant.
* * * * *		

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * *		
Carbon Dioxide (CAS Reg. No. 124–38–9)	None	Propellant.
* * * * *		

[FR Doc. 2011–10889 Filed 5–3–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0771; FRL–8873–3]

Clothianidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clothianidin in or on mustard, seed. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 4, 2011. Objections and requests for hearings must be received on or before July 5, 2011, 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–2008–0771. 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: Marianne Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8043; e-mail address: lewis.marianne@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 those engaged in the following activities:

- 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 to provide 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?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

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. 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–2008–0771 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 as required by 40 CFR part 178 on or before July 5, 2011.

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 this copy, identified by docket ID number EPA–