

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 a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: July 12, 2011.

Lois Rossi,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredients to read as follows:

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

* * * * *

| Inert ingredients | Limits | Uses |
|--|--------------------------|--------------------------------|
| * * * * * | * * * * * | * * * * * |
| Carboxymethyl guar gum sodium salt (CAS Reg. No. 39346-76-4) | Without limitation | Thicker/drift reduction agent. |
| * * * * * | * * * * * | * * * * * |
| Carboxymethyl-hydroxypropyl guar (CAS Reg. No. 68130-15-4) | Without limitation | Thicker/drift reduction agent. |
| * * * * * | * * * * * | * * * * * |

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0888; FRL-8875-5]

Chlorantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of chlorantraniliprole in or on multiple commodities which are identified and discussed later in this document. This regulation additionally amends previously established tolerances in or on multiple commodities and deletes tolerances in or on several commodities that will be superceded by inclusion in crop group tolerances. E. I. du Pont de Nemours and Company, DuPont Crop Protection, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 27, 2011. Objections and requests for hearings must be received on or before September 26, 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-2010-0888. 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: Rita Kumar, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8291; e-mail address: kumar.rita@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 get electronic access to other related information?

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 site at <http://ecfr.gpoaccess.gov/cgi/t/>

[text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/?text=text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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-2010-0888 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 September 26, 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-2010-0888, 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. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 25, 2011 (76 FR 10584) (FRL-8863-3), 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 petition (PP 0F7763) by, E. I. du Pont de Nemours and Company, DuPont Crop Protection, 1700 Market

St., Wilmington, DE 19898. The petition requested that 40 CFR 180.628 be amended by establishing tolerances for residues of the insecticide chlorantraniliprole, 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, in or on bushberry, subgroup 13-07B at 2.5 parts per million (ppm); large shrub/tree berry, subgroup 13-07C at 2.5 ppm; low growing berry, subgroup 13-07G at 2.5 ppm; ti palm, roots at 0.35 ppm; ti palm, leaves at 13 ppm; root and tuber vegetables, group 1 at 0.35 ppm; leaves of root and tuber vegetables, group 2 at 40 ppm; sugar beet molasses at 11 ppm; onion, bulb, subgroup 3-07A at 0.35 ppm; peanut, nutmeat at 0.35 ppm; peanut, hay at 90 ppm; tea, dried leaves at 50 ppm; and to increase tolerances in or on fruiting vegetables (except cucurbits), group 8 from 0.7 ppm to 0.90 ppm; cucurbit vegetables, group 9 from 0.25 ppm to 0.30 ppm; and okra from 0.70 ppm to 0.90 ppm. That notice referenced a summary of the petition prepared by E. I. du Pont de Nemours and Company, DuPont Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerances for some of the petitioned commodities. Additionally, the Agency is revising tolerances for several proposed individual and group commodities and is revoking multiple established tolerances. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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. * * *

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Sufficient toxicology information exists for chlorantraniliprole for selecting doses and endpoints needed for assessing its risk to humans when used as an insecticide. Chlorantraniliprole is not genotoxic, neurotoxic, immunotoxic, carcinogenic,

or developmentally toxic. Chlorantraniliprole is not acutely toxic via oral, dermal or inhalation routes of exposure. Neither is chlorantraniliprole an eye or skin irritant nor a dermal sensitizer. There was only one animal toxicity study (18-month carcinogenicity study in mice) in the toxicology database which evidenced any adverse effect of chlorantraniliprole exposure. This study was used to establish a point of departure (POD), based on hepatocellular effects, for the chronic dietary exposure scenario.

Specific information on the studies received and the nature of the adverse effects caused by chlorantraniliprole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "Human Health Risk Assessment for Proposed Label Amendments to Remove Adjuvant Restrictions with Concomitant Increase in Tolerance for Fruiting and Leafy Vegetables and to Add Oilseed Rotational Crops," at page 22 in docket ID number EPA-HQ-OPP-2010-0888.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in

evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for chlorantraniliprole used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CHLORANTRANILIPROLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

| Exposure/Scenario | Point of departure and uncertainty/Safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|---|---|---|--|
| Acute dietary (All populations) | Not Applicable (N/A) | N/A | No acute hazard attributable to a single dose was identified; therefore, an acute dietary endpoint was not selected for quantitative risk assessment. |
| Chronic dietary (All populations) | NOAEL = 158 milligrams/kilogram/day (mg/kg/day). UF _A = 10x UF _H = 10 x FQPA SF = 1x | Chronic RfD = 1.58 mg/kg/day cPAD = 1.58 mg/kg/day | 18-Month Oral (feeding)/mouse LOAEL = 935 mg/kg/day based on eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight (males only). |
| Incidental oral short/intermediate-term (1 to 30 days). | N/A | N/A | There was no hazard identified via the oral route over the short- and intermediate-term and therefore, no endpoint was selected for quantitative risk assessment. |
| Dermal short/intermediate-term | N/A | N/A | There was no hazard identified via the dermal route (and no concerns for developmental, reproductive or neurotoxic effects) and therefore, no dermal endpoint was selected for quantitative risk assessment. |

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CHLORANTRANILIPROLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

| Exposure/Scenario | Point of departure and uncertainty/Safety factors | RfD, PAD, LOC for risk assessment | Study and toxicological effects |
|--------------------------------------|--|-----------------------------------|---|
| Inhalation short/intermediate-term | N/A | N/A | Based on the lack of hazard identified in the acute inhalation study, lack of acute irritation, and extremely low oral toxicity—no inhalation endpoint was selected for quantitative risk assessment. |
| Cancer (Oral, dermal, inhalation) .. | Classification: “Not likely to be Carcinogenic to Humans” based on weight of evidence of data: no treatment-related tumors reported in the submitted chronic and oncogenicity studies in rats and mice, sub-chronic studies in mice, dogs and rats and that no mutagenic concern was reported in the genotoxicity studies. | | |

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population-adjusted dose (a= acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to chlorantraniliprole, EPA considered exposure under the petitioned-for tolerances as well as all existing chlorantraniliprole tolerances in 40 CFR 180.628. EPA assessed dietary exposures from chlorantraniliprole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for chlorantraniliprole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Survey of Food Intake by Individual (CSFII). As to residue levels in food, EPA assumed recommended and/or established tolerance level residues and 100 percent crop treated (PCT). DEEM default processing factors were used.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that chlorantraniliprole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for chlorantraniliprole. Tolerance level

residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for chlorantraniliprole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of chlorantraniliprole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST), Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the acute and chronic estimated drinking water concentrations (EDWCs) of chlorantraniliprole were 55.30 parts per billion (ppb) and 39.87 ppb, respectively.

The surface water concentration of 39.87 ppb was used for chronic exposure for the chronic, non-cancer dietary risk assessment.

No acute dietary risk assessment was performed because no acute hazard was identified.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Chlorantraniliprole is currently registered for the following uses that could result in residential exposures: Turfgrass and ornamental plants. Residential exposure could occur for short-term and intermediate-term

exposures however, due to the lack of toxicity identified for short- and intermediate-term durations via relevant routes of exposure, no risk is expected from these exposures. Additional information on residential exposure assumptions can be found at <http://www.regulations.gov> (Docket ID EPA–HQ–OPP–2010–0888, “Human Health Risk Assessment for Proposed Label Amendments to Remove Adjuvant Restrictions with Concomitant Increase in Tolerance for Fruiting and Leafy Vegetables and to Add Oilseed Rotational crops”, page 37).

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *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 chlorantraniliprole to share a common mechanism of toxicity with any other substances, and chlorantraniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlorantraniliprole 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

1. *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 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.

2. *Prenatal and postnatal sensitivity.* There were no effects on fetal growth or postnatal development up to the limit dose of 1,000 mg/kg/day in rats or rabbits in the developmental or 2-generation reproduction studies. Additionally, there were no treatment related effects on the numbers of litters, fetuses (live or dead), resorptions, sex ratio, or post-implantation loss and no effects on fetal body weights, skeletal ossification, and external, visceral, or skeletal malformations or variations.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for chlorantraniliprole is complete, and considered adequate for this risk assessment (including 40 CFR 158.500 requirements for dermal toxicity, immunotoxicity, and acute/subchronic neurotoxicity effective December 26, 2007).

ii. There is no indication that chlorantraniliprole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that chlorantraniliprole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water

modeling used to assess exposure to chlorantraniliprole in drinking water. Due to the lack of toxicity via the dermal route, as well as the lack of toxicity over the acute-, short- and intermediate-term via the oral route—no risk is expected from postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by chlorantraniliprole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, chlorantraniliprole is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to chlorantraniliprole from food and water will utilize 6% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of chlorantraniliprole is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Although short-term residential exposure could occur with the use of chlorantraniliprole, no toxicological effects resulting from short-term dosing were observed. Therefore, the aggregate risk is the sum of the risk from food and water and will not be greater than the chronic aggregate risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Although intermediate-term residential exposure could result from the use of chlorantraniliprole, no toxicological effects resulting from intermediate-term dosing were observed. Therefore, the aggregate risk is the sum of the risk from food and water and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two rodent carcinogenicity studies, chlorantraniliprole is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

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 and Canada have established maximum residue levels (MRLs) for chlorantraniliprole in or on a number of crops and animal commodities. These MRLs are different than the tolerances established for chlorantraniliprole in the United States. There are no Mexican MRLs for chlorantraniliprole as Mexico adopts

Codex or US standards for its export purposes. Refer to the International Residue Limit Status appended at the end of the document "Human Health Risk Assessment for Proposed Label Amendments to Remove Adjuvant Restrictions with Concomitant Increase in Tolerance for Fruiting and Leafy Vegetables and to Add Oilseed Rotational Crops," pages 52–53, and an addendum to this risk assessment, at <http://www.regulations.gov> (Docket ID EPA–HQ–OPP–2010–0888).

Although the tolerance expression achieved harmonization, harmonized MRLs were only achieved for a few commodities. This is the result of differences in crop grouping and removing the adjuvant restriction in the United States. To allow for the use of adjuvant in the United States it was necessary to adjust the tolerances by a factor of two for some crop groups after reviewing bridging residue data. This causes disharmony with Codex MRLs for berries, cucurbits, fruiting vegetable, root and tuber vegetables, and leaves of root and tuber vegetables; and with Canada MRLs for cucurbit vegetables and fruiting vegetables.

C. Response to Comments

There were no comments received in response to the notice of filing.

D. Revisions to Petitioned-For Tolerances

Based on residue data submitted with this petition, several petitioned-for tolerances were revised. The revisions include: increases for fruiting vegetables except cucurbits from 0.9 to 1.4 ppm, and cucurbits from 0.3 to 0.5 ppm; decreases in low growing berries from 2.5 to 1.0 ppm, onions, bulb from 0.35 to 0.30 ppm, beet, sugar, molasses from 11 to 9 ppm, Ti, root from 0.35 to 0.30 ppm, and root and tuber vegetables from 0.35 to 0.30 ppm.

Tolerances for okra, strawberry, and vegetables, tuberous and corm, subgroup 1C were deleted as these commodities are now covered by fruiting vegetables crop group 8–10, berry, low-growing subgroup 13–07G, and vegetable, root and tuber, group 1, respectively.

The proposed tolerances for peanut hay and peanut nutmeat are not being established at this time. More residue data are needed.

In § 180.628(d), the tolerance for vegetables, leaves of root and tuber, group 2 was replaced by the tolerance for this crop group in § 180.628(a). The tolerance for shallot, fresh leaves was added to § 180.628(d).

V. Conclusion

Therefore, tolerances are established for residues of chlorantraniliprole, including its metabolites and degradates, in or on the commodities listed in § 180.368. Compliance with the tolerance levels specified below is to be determined by measuring only chlorantraniliprole, 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide. 3-bromo-N-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide. Tolerances are established in or on the following commodities: Bushberry, subgroup 13–07B at 2.5 ppm; Vegetable, cucurbit, group 9 at 0.5 ppm; vegetable fruiting, group 8–10 at 1.4 ppm; Berry, large shrub/tree, subgroup 13–07C at 2.5 ppm; Vegetable, leaves of root and tuber, group 2 at 40 ppm; Berry, low growing subgroup 13–07G at 1.0 ppm; Onion, bulb, subgroup 3–07A at 0.30 ppm; Vegetable, root and tuber, group 1 at 0.30 ppm; Beet, sugar, molasses at 9 ppm; Tea, dried at 50 ppm; Ti, leaves, at 13 ppm; and Ti, root, at 0.30 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances 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).

VII. 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 180

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

Dated: July 12, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.628 is amended as follows:

■ i. Add alphabetically tolerances for beet, sugar, molasses; berry large shrub/tree, subgroup 13–07C; berry, low growing, subgroup at 13–07G; onion, bulb, subgroup 3–07A; tea, dried; Ti, leaves; Ti, root; vegetable, leaves of root and tuber, group 2; vegetable, root and tuber, group 1; to the table in paragraph (a);

■ ii. Revise the tolerances for vegetable, cucurbit, group 9; and vegetable, fruiting, group 8–10 in the table to paragraph (a);

■ iii. Remove the entries for okra, strawberry, and vegetable, tuberous and corm, subgroup 1C from the table in paragraph (a);

■ iv. Remove the entries for shallot and vegetables, leaves of root and tuber, group 2 from paragraph (d); and

■ v. Add alphabetically an entry for shallot, green leaves to the table in paragraph (d).

The added and revised text read as follows:

§ 180.628 Chlorantraniliprole; tolerances for residues.

(a) * * *

| Commodity | Parts per million |
|--|-------------------|
| Beet, sugar, molasses | 9.0 |
| Berry, large shrub/tree, subgroup 13–07C | 2.5 |
| Berry, low growing, subgroup 13–07G | 1.0 |
| Onion, bulb, subgroup 3–07A | 0.30 |
| Tea, dried | 50.0 |
| Ti, leaves | 13.0 |
| Ti, root | 0.3 |
| Vegetable, cucurbit, group 9 | 0.5 |
| Vegetable, fruiting, group 8–10 | 1.4 |

| Commodity | Parts per million |
|--|-------------------|
| Vegetable, leaves of root and tuber, group 2 | 40.0 |
| Vegetable, root and tuber, group 1 | 0.30 |

(d) * * *

| Commodity | Parts per million | Expiration/revocation date |
|------------------------------|-------------------|----------------------------|
| Shallots, fresh leaves | 0.20 | 04/10/14 |

[FR Doc. 2011–18708 Filed 7–26–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MB Docket No. 03–185; FCC 11–110]

Digital Low Power Television, Television Translator, and Television Booster Stations and To Amend Rules for Digital Class A Television Stations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In the *Second Report and Order*, the Commission takes steps to resolve the remaining issues in this proceeding in order to allow a timely and successful completion of the low power television digital transition. Although Congress established a hard deadline of June 12, 2009 for full power stations to cease analog operations and begin operating only in digital, the statutory deadline did not apply to low power television stations. Therefore, while all full power television stations have ceased over-the-air analog broadcasting, many low power television stations are continuing to transmit analog signals.

DATES: Effective August 26, 2011, except for the amendment to 47 CFR 73.624(g), which contains information collection requirements that have not been approved by the Office of Management and Budget (“OMB”). The Federal Communications Commission will publish a separate document in the

Federal Register announcing the effective date.

FOR FURTHER INFORMATION CONTACT: Shaun Maher, Shan.Maher@fcc.gov of the Media Bureau, Video Division, (202) 418–1600. For additional information concerning the information collection requirement contained in this *Second Report and Order*, contact the Office of Managing Director (“OMD”), Performance Evaluation & Records Management (“PERM”), Cathy Williams, Cathy.Williams@fcc.gov, at 202–418–2918.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s *Second Report and Order*, FCC 11–110, adopted on July 15, 2011, and released on July 15, 2011. The full text of the *Second Report and Order* is available for inspection and copying during regular business hours in the FCC Reference Center, 445 Twelfth Street, SW., Room CY–A257, Portals II, Washington, DC 20554, and may also be purchased from the Commission’s copy contractor, BCPI, Inc., Portals II, 445 Twelfth Street, SW., Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. via their Web site, <http://www.bcpi.com>, or call 1–800–378–3160. This document is available in alternative formats (computer diskette, large print, audio record, and Braille). Persons with disabilities who need documents in these formats may contact the FCC by *e-mail*: FCC504@fcc.gov or *phone*: 202–418–0530 or *TTY*: 202–418–0432.

Executive Summary

In the *Second Report and Order*, the Commission takes steps to resolve the remaining issues in this proceeding in order to allow a timely and successful completion of the low power television digital transition. Specifically, in order to ensure a timely and successful completion to the low power television digital transition, the Commission takes the following steps: (1) Adopts a hard deadline of September 1, 2015 for the termination of all analog low power television facilities; (2) establishes rules permitting those stations needing additional time to complete their digital transition to obtain a “last minute” extension; (3) requires existing analog and digital low power television stations in the 700 MHz band (channels 52–69) to submit displacement applications by September 1, 2011, and to cease operations in the 700 MHz band by December 31, 2011; (4) increases the power limits for VHF low power television channels to 3 kilowatts (the current analog power limit); (5) delegates to the Media Bureau the