safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 28, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: February 11, 2013.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 52.1870 is amended by adding paragraph (c)(157) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(157) On February 23, 2012, Ohio submitted revisions to Ohio Administrative Code Chapter 3745–17, Rule 3745–17–11. The revisions contain particulate matter restriction for industrial sources in the State of Ohio necessary to attain and maintain the 2006 24-hour $PM_{2.5}$, annual $PM_{2.5}$, and 24-hour PM_{10} NAAQS.

(i) Incorporation by reference.

(A) Ohio Administrative Code Rule 3745–17–11 ''Restrictions on particulate emissions from industrial processes'', effective December 23, 2011.

(B) December 13, 2011, ''Director's Final Findings and Orders'', signed by Scott J. Nally, Director, Ohio Environmental Protection Agency.

§ 52.1919 [Amended]

■ 3. Section 52.1919 is amended by removing paragraph (c).

[FR Doc. 2013–07259 Filed 3–28–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0860; FRL–9378–6]

Clothianidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of clothianidin in or on tea, dried and increases the tolerance level for pepper to support a shorter pre-harvest interval (PHI). These tolerances were requested by Interregional Research Project Number 4 (IR–4) and Valent U.S.A. Corporation, respectively, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 29, 2013. Objections and requests for hearings must be received on or before May 28, 2013, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0860, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; email address: *jackson.sidney@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

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.*

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–2011–0860 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 May 28, 2013. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0860, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 8, 2011 (76 FR 76674) (FRL–9328–8) and September 28, 2012 (77 FR 59578) (FRL–9364–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions ((PP) 1E7923 and 2F8008) by IR–4, IR–4 Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540 and Valent U.S.A. Corporation, P.O. Box 8025, Walnut Creek, CA 94596, respectively. The petitions requested that 40 CFR 180.586 be amended by establishing tolerances for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on fruit, citrus, group 10–10; citrus, dried pulp; pistachio; strawberry and tea, fresh at 0.60, 1.0, 0.01, 1.50 and 70 parts per million (ppm), respectively, 1E7923; and vegetable, fruiting group 8–10, except pepper/eggplant, subgroup 8–10B; and pepper/eggplant subgroup 8–10B at 0.20, and 0.7 ppm, respectively, 2F8008. In addition, PP 2F8008 requested that 40 CFR 180.586(a) be amended by deleting the tolerance for residues of clothianidin in or on the vegetable, fruiting group 8 at 0.2 ppm, upon approval of vegetables, fruiting, group 8–10, except pepper/eggplant subgroup 8–10B at 0.2 ppm; and replacing the tolerance for residues of clothianidin in or on fruit, pome at 1.0 ppm with fruit, pome group 11–10 at 1.0 ppm due to EPA expansion of the crop group. The above-mentioned **Federal Register** documents referenced a summary of the petition prepared by Valent U.S.A. Corporation, P.O. Box 8025, Walnut Creek, CA 94596, the registrant, which is available in the docket, *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

At this time, EPA is only establishing tolerances for tea, dried and is increasing the tolerance level for pepper to support PHI for an existing registration. In addition, EPA is re-defining the crop group tolerance expression ''vegetable, fruiting, group 8'' as ''vegetable, fruiting, group 8, except pepper.'' EPA is not prepared to establish tolerances for the remaining petitioned-for clothianidin tolerances until the potential ecological and environmental risks can be assessed. EPA will make a final determination on the other petitioned-for tolerances at a later date. The reasons 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 clothianidin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clothianidin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data 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.

EPA considered the toxicity of clothianidin as well as several metabolites and degradates in conducting this risk assessment. EPA assumed that clothianidin's metabolites/degradates that are similar in structure to clothianidin are toxicologically equivalent to clothianidin with respect to the endpoints being used for risk assessment.

The available data indicate that there are no consistent target organs in mammals; however, some effects noted in the liver, hematopoietic system and kidney are similar to effects from other neonicotinoid insecticides. In

subchronic oral studies, the dog seemed to be more sensitive to clothianidin than the rat. In addition to decreases in body weight and body weight gains observed in both animals, dogs also displayed decreased white blood cells, albumin and total protein, as well as some anemia. Long-term dietary administration of clothianidin did not result in a wider spectrum of effects in the dog; in contrast, the chronic feeding studies in rats showed additional effects in the liver, ovaries and kidneys. In the mouse chronic oral study, increases in vocalization and decreases in body weight and body weight gain were noted.

Based on the lack of significant tumor increases in two adequate rodent carcinogenicity studies, EPA has classified clothianidin as ''not likely to be carcinogenic to humans.'' A bone marrow micronucleus assay in mice showed that clothianidin is neither clastogenic nor aneugenic up to a toxic oral dose. Additionally, a study on the livers of Wistar male mice showed no induction of unscheduled DNA synthesis up to the limit dose; therefore, mutagenicity is not of concern.

Clinical signs of neurotoxicity were exhibited in both rats (decreased arousal, motor activity and locomotor activity) and mice (decreased spontaneous motor activity, tremors and deep respirations) in acute neurotoxicity studies following exposure by gavage; however, no indications of neurotoxicity were observed following dietary exposure in the subchronic neurotoxicity study in rats.

There was no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses following *in utero* exposure to clothianidin in developmental studies; however, increased quantitative susceptibility of rat pups was seen in both the reproduction and developmental neurotoxicity studies. In the rat reproduction study, offspring toxicity (decreased body weight gains and absolute thymus weights in pups, delayed sexual maturation and an increase in stillbirths) was observed in the absence of maternal effects. In the developmental neurotoxicity study in rats, offspring effects (decreased body weights, body weight gains, motor activity and acoustic startle response amplitude) were noted at doses lower than those resulting in maternal toxicity.

Decreased absolute and relative thymus and spleen weights were observed in multiple studies; these studies showed possible evidence of effects on the immune system. In addition, juvenile rats in the rat reproduction study appeared to be more susceptible to these effects. However, a guideline immunotoxicity study showed no evidence of clothianidin-mediated immunotoxicity in adult rats and a developmental immunotoxicity study demonstrated no increased susceptibility for offspring with regard to immunotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by clothianidin 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: ''Clothianidin—Aggregate Human Health Risk Assessment of New Uses on Strawberry, Pistachio, and Citrus; New Tolerance for Tea; and Revised PHI and Tolerance for Pepper and Eggplant (Crop Subgroup 8–10B),'' dated September 27, 2012 at page 32, and additional information on pome fruit can be found in document: ''Clothianidin—Human Health Risk Assessment for Requested Foliar Uses on Rice, Seed Treatment on Leafy Vegetables, Increased Application Rate for Vegetables, and Expanded Uses on Fruiting Vegetables and Pome Fruit,'' dated February 1, 2012, in docket ID number EPA–HQ–OPP–2011–0860.

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 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 clothianidin used for human risk assessment is discussed in Unit II of the final rule published in the **Federal Register** of August 29, 2012 (77 FR 52246) (FRL–9360–4).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to clothianidin, EPA considered exposure for all of the petitioned-for tolerances as well as all existing clothianidin tolerances in 40 CFR 180.586. EPA assessed dietary exposures from clothianidin 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.

Such effects were identified for clothianidin. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used maximum field trial values, empirical processing factors and assumed 100 percent crop treated (PCT) for all commodities. Clothianidin is a major metabolite of thiamethoxam, and there are a number of crops for which uses of both clothianidin and thiamethoxam have been registered. The labels for the various end-use products containing these active ingredients prohibit the application of both active ingredients to the same crop during a growing cycle. Due to that restriction and the assumption of 100 PCT, a single value reflecting the greatest clothianidin residue from either active ingredient has been used for crops listed for use with both active ingredients (versus combined estimates from clothianidin and thiamethoxam). Generally, this assessment uses the established or recommended clothianidin tolerance for crops having tolerances for both compounds (the exception being low-growing berry, subgroup 13–07G, which is based on observed clothianidin residues in thiamethoxam strawberry field trials). For foods with thiamethoxam tolerances but without clothianidin tolerances, maximum residues of clothianidin observed in thiamethoxam field trials have been used in these assessments. Foods falling

into this category include meats, meat by-products, artichoke, tropical fruits, coffee, hop, mint, and rice.

In relying on maximum field trial residues of clothianidin, EPA has adjusted the field trial values upward to account for metabolites of concern for leafy and root and tuber vegetables and for ruminants and poultry. Details on these adjustments are provided in document: ''Clothianidin—Human Health Risk Assessment for Requested Foliar Uses on Rice, Seed Treatment on Leafy Vegetables, Increased Application Rate for Vegetables, and Expanded Uses on Fruiting Vegetables and Pome Fruit,'' dated February 1, 2012, in docket ID number EPA–HQ–OPP–2011–0860.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA assessed chronic dietary exposure using the same residue information and assumptions regarding metabolites/degradates as in the acute exposure analysis.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that clothianidin 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 information.* EPA used anticipated residue (maximum field trial residues) in the dietary assessment for clothianidin.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for clothianidin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of clothianidin. 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.*

The Agency modeled estimated drinking water concentrations (EDWC) of clothianidin in surface and groundwater using the Tier 1 Rice Model, the Food Quality Protection Act (FQPA) Index Reservoir Screening Tool (FIRST), and the Screening Concentrations in Groundwater model (SCI–GROW). The Tier 1 Rice Model produced the greatest value of any of the models used to predict EDWCs for acute and chronic exposures. The Tier 1 Rice Model EDWC of 72 parts per billion (ppb) was entered directly into the dietary exposure model.

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).

Clothianidin is currently registered for the following uses that could result in residential exposures: Turf, ornamental plants, and/or indoor use to control bed bugs. EPA assessed residential exposure using the following assumptions: Exposures may occur during application of products containing clothianidin (handler exposure) as well as following application (post-application exposure) and are expected to be of short-term (1–30 days) duration.

Adults were assessed for potential short-term dermal and inhalation handler exposure from applying clothianidin to residential turf/home lawns and for short-term post-application dermal exposure from contact with treated residential and recreational turf home lawns and golf courses. There is also potential for post-application dermal and inhalation exposure for adults and children resulting from use of clothianidin on residential turf, ornamentals (*i.e.,* trees), and indoor surfaces, as well as, potential for incidental oral post-application exposure for children.

Although there is potential for adult exposure resulting from both applying the product and post-application activities, the Agency did not combine exposure estimates from adult handler and post-application activities because of the conservative assumptions and inputs within each exposure scenario. The children's combined exposure includes only the hand-to-mouth exposure for the incidental oral exposure component. To include exposure from object-to-mouth and soil ingestion in addition to hand-to-mouth would overestimate incidental oral exposures for purposes of estimating combined residential exposure. Further, because the level of concern for dermal exposures (MOEs less than 100) and inhalation exposure (MOEs less than 1,000) are different, a total aggregate risk index (ARI) approach was used instead of the MOE approach. ARIs of greater than 1 indicate risks are not of concern.

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.''

Clothianidin is a member of the neonicotinoid class of pesticides and is a metabolite of another neonicotinoid, thiamethoxam. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events. Although clothianidin and thiamethoxam bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for clothianidin, thiamethoxam, and the other neonicotinoids are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a noncompetitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nAChRs, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including aphids and leafhoppers, compared to mammals. While the insecticidal action of the neonicotinoids is neurotoxic, the most sensitive regulatory endpoint for clothianidin is based on unrelated effects in mammals, including changes in body and thymus weights, delays in sexual maturation,

and stillbirths. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (such as testicular tubular atrophy with thiamethoxam, and mineralized particles in thyroid colloid with imidaclopid). Thus, there is currently no evidence to indicate that neonicotinoids share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the neonicotinoids. 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 the policy statements concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism released by OPP on 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 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.

2. *Prenatal and postnatal sensitivity.* There is no residual concern for increased qualitative or quantitative susceptibility in the rat or rabbit developmental toxicity studies. Since there is evidence of increased quantitative susceptibility of the young following exposure to clothianidin in the rat reproduction study and the DNT study, EPA performed a degree of concern analysis to:

i. Determine the level of concern for the effects observed when considered in the context of all available toxicity data; and,

ii. Identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the clothianidin risk assessment.

Considering the overall toxicity profile and the endpoints and doses selected for the clothianidin risk assessment, EPA characterized the degree of concern for the effects observed in the clothianidin 2-generation reproduction and DNT studies as *low,* noting that there are clear NOAELs for the offspring effects and regulatory doses were selected to be protective of these effects. No other residual uncertainties were identified with respect to susceptibility.

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 in assessing risks from dermal and oral exposure pathways. However, EPA does not have reliable data to support reduction of the FQPA SF in assessing risks from the inhalation exposure pathway and thus is retaining the 10X FQPA SF for these assessments. That decision is based on the following findings:

i. The toxicity database for clothianidin is complete with the exception of a required 28-day inhalation study.

ii. There are no residual concerns regarding potential prenatal and postnatal toxicity in the young. A rat developmental neurotoxicity study is available and shows evidence of increased quantitative susceptibility of offspring. However, EPA considers the degree of concern for the developmental neurotoxicity study to be low for prenatal and postnatal toxicity because the NOAEL and LOAEL were well characterized, and the doses and endpoints selected for risk assessment are protective of the observed susceptibility. While the rat multi-generation reproduction study showed evidence of increased quantitative susceptibility of offspring compared to adults, the degree of concern is low because the study NOAEL has been selected as the POD for risk assessment purposes for relevant exposure routes and durations. In addition, the potential immunotoxic effects observed in the study have been further characterized with the submission of a developmental immunotoxicity study that showed no evidence of susceptibility. As a result, there are no concerns or residual uncertainties for pre- and postnatal toxicity after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for clothianidin.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on assumptions that were judged to be highly conservative and health-protective for all durations and population subgroups, including maximum field trial residues, adjustment factors from metabolism data, empirical processing factors, and 100 PCT for all commodities. The exposure databases (dietary food, drinking water, and residential) are complete. The risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate potential exposure and risk for infants or children. Additionally, EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to clothianidin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by clothianidin.

In conclusion, there are reliable data showing that, with the exception of scenarios involving inhalation exposure, the risk to infants and children can be safely assessed without an additional 10X safety factor. However, in the absence of the required inhalation toxicity study, EPA is retaining the 10X FQPA factor as a database uncertainty factor for assessing inhalation exposure and risk only, for both adults and children.

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 acute Population adjusted dose (aPAD) and chronic PAD (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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to clothianidin will occupy 28% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to clothianidin from food and water will utilize 28% 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 clothianidin is not expected;

therefore, the chronic aggregate risk estimates are equivalent to the dietary risk estimates and are below EPA's level of concern.

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

For purposes of performing an aggregate assessment, the EPA selected the worst-case adult and children exposure scenarios. The treatment of tree trunks using a manually-pressurized handwand presents the worst-case exposure estimate for adults, while the bed bug scenario presents the worst-case exposure estimates for children 1 to <2 yrs old.

For short- and intermediate-term ''worst-case'' aggregate exposure estimates, the ARI for adults is 6.5 and for children 1 to <2 years old, the ARI is estimated at 1.2. ARI estimated values greater than 1.0 indicate risks are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, clothianidin was classified as ''not likely to be carcinogenic to humans,'' and is not expected to pose a cancer risk to humans.

5. *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 clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies, based on solvent extraction and Liquid chromatography—mass spectrometry/mass spectrometry (LC–MS/MS) separation, identification, and quantification, are available for plant (Morse Method #Meth 164—modified, RM–39C–1, or Bayer Method 00552) and livestock (Bayer Method 00624) matrices. The (LOQ) for clothianidin in plant commodities is 0.01 ppm, except for wheat straw (0.02 ppm), and the validated LOQs are 0.01 ppm in milk and 0.02 ppm in animal tissues. Clothianidin and its major metabolites are not adequately recovered using any of the United States Food and Drug Administration (FDA) multiresidue methods.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email 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 United Nations 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 established MRLs for clothianidin in or on tea, fresh at 0.7 ppm and fruiting vegetables other than cucurbits at 0.050 ppm. The residue field trial submitted to support the U.S. tolerances results in higher clothianidin residues than the maximum residue levels established by Codex and therefore, the U.S. tolerances cannot be harmonized with the Codex MRLs.

C. Response to Comments

EPA received one comment on the notice of filing for petition, 1E7923, in which the commenter requested that EPA deny IR–4's petition to establish a tolerance for residues of clothianidin on food crops because it is toxic to humans.

When new or amended tolerances are requested for the presence of the residues of a pesticide and its toxicologically significant metabolite(s) in food or feed, the Agency, as is required by section 408 of the FFDCA, estimates the risk of the potential exposure to these residues by performing an aggregate risk assessment. As discussed in Unit III, EPA's assessment for clothianidin concludes that there is a reasonable certainty that no harm will result from exposure to clothianidin residues of interest. Therefore, the tolerances established by this action are found to be acceptable. The commenter submitted no evidence or argument that addresses this statutory finding.

D. Revisions to Petitioned-For Tolerances

In this action EPA is only establishing tolerances for tea, dried and pepper and will make a final determination on the remaining petitioned for tolerances at a later date. Though EPA is able to make the required safety finding under FFDCA and the human health risk assessments support all of the petitioned-for uses, what must still be considered for the additional uses to be registered in the United States are potential ecological and environmental risks associated with clothianidin. Therefore, at this time EPA is only prepared to establish a tolerance on dried tea (without a U.S. registration; *i.e.,* an ''import tolerance'') and to increase the tolerance on pepper to support a shorter pre-harvest interval (PHI).

EPA is still in the process of assessing the potential ecological concerns identified with the additional exposures expected from the registration of the proposed pome fruit group 11–10, pepper/eggplant subgroup 8–10B, citrus fruit group 10–10, pistachio, and strawberry uses. However, in order to support an effort to establish tolerances for residues of pesticides on tea, to ensure a safe supply of tea for the U.S. consumer, EPA has determined it will move forward with establishing the tolerance for clothianidin on tea prior to finalizing the decision on the remaining petitioned for uses. Additionally, there is an existing tolerance for residues of clothianidin on fruiting vegetable group 8 at 0.20 ppm and residue field trial data were submitted for pepper to support a lower PHI which results in a recommended higher tolerance. Though EPA is not prepared to allow the expansion of the Fruiting Vegetable Group 8 at this time to include the additional commodities in Pepper/eggplant Subgroup 8–10B, shortening the PHI on pepper is not expected to result in any additional environmental exposure. Therefore, the EPA has determined that it will establish a higher tolerance for clothianidin on pepper in this action and a final determination on the petition for the pepper/eggplant subgroup 8–10B tolerance will be made at a later date.

As to the tolerance levels, the proposed tea, fresh tolerance at 50 ppm will be established on tea, dried at 70 ppm. The commodity listing is changed from tea, fresh to tea, dried to reflect the commodity from which residue data were collected and to reflect the principal tea commodity that is in the channels of trade. The value of the tolerance is changed based on the

output from the Organisation for Economic Cooperation and Development (OECD) calculation procedures. EPA is also establishing the separate tolerance on pepper at 0.80 ppm which is different than the requested tolerance at 0.7 ppm for pepper/eggplant subgroup 8–10B. EPA based the 0.80 tolerance level on the non-bell-pepper residue data and OECD Calculation Procedures.

Finally, to account for the establishment of a ''separate'' pepper tolerance, EPA re-defined the existing crop group tolerance expression ''vegetable, fruiting, group 8'' as ''vegetable, fruiting, group 8, except pepper''.

V. Conclusion

Therefore, tolerances are established for residues of clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on tea, dried at 70 ppm, pepper at 0.80 ppm, and vegetable, fruiting, group 8, except pepper at 0.20 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). 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 FFDCA section 408(d), such as the tolerances 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 FFDCA section 408(n)(4). 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) (2 U.S.C. 1501 *et seq.*).

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) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: March 15, 2013.

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 180.586 is amended in paragraph (a)(1) by revising the commodity ''vegetable, fruiting, group 8'', by alphabetically adding the commodities ''pepper'' and ''tea, dried'', and by adding footnote 1 to the table to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
* * * * *	
Pepper	0.80
* * * * *	
Tea, dried [1]	70
* * * * *	
Vegetable, fruiting, group 8, except pepper	0.20
* * * * *	

[1] No U.S. registrations.

* * * * *

[FR Doc. 2013–07093 Filed 3–28–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 602

[Docket No. FTA–2013–0004]

RIN 2132–AB13

Emergency Relief Program

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: This action establishes procedures governing the implementation of the Federal Transit Administration's (FTA) Public Transportation Emergency Relief Program under 49 U.S.C. 5324, as authorized by the Moving Ahead for Progress in the 21st Century Act. FTA is issuing this interim final rule in order to comply with the Disaster Relief Appropriations Act of 2013. FTA will accept comments on the interim final rule and will publish a final rule after the comment period closes.

DATES: This interim final rule becomes effective on March 29, 2013. Comments on this interim final rule are due May 28, 2013. Late-filed comments will be considered to the extent practicable. In compliance with the Paperwork Reduction Act, FTA is also seeking