Dated: November 24, 2009.

S.E. Englebert,

Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.

[FR Doc. E9–29355 Filed 12–8–09; 8:45 am]

BILLING CODE 9910–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0945; FRL–8793–6]

Clothianidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clothianidin in or on multiple commodities which are identified and discussed later in this document. This regulation additionally increases established tolerances in or on cotton, gin byproducts; cotton, undelinted seed and potato, granules/flakes and deletes tolerances in or on several commodities that will be superseded by this action. Valent U.S.A. Corporation, Bayer CropScience and Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 9, 2009. Objections and requests for hearings must be received on or before February 8, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0945. 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0945 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 8, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0945, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of September 5, 2008 (73 FR 51817) (FRL–8380–4), 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 8F7395) by Valent U.S.A. Corporation, P.O. Box 8025, Walnut Creek, CA 94596. The petition 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 almond, hull at 1.5 parts per million (ppm); cotton, seed at 0.25 ppm; cotton, gin trash at 4.5 ppm; cotton, meal at 0.25 ppm; cotton, hull at 0.25 ppm; cotton, refined oil at 0.01 ppm; soybean, seed at 0.03 ppm; soybean, hull at 0.35 ppm; soybean, meal at 0.07 ppm; soybean, oil at 0.01 ppm; tomato, paste at 0.08 ppm; tomato, puree at 0.07 ppm; nut, tree, group 14 at 0.01 ppm;

vegetable, cucurbit, group 9 at 0.05 ppm; and vegetable, fruiting, group 8 at 0.25 ppm. The petition additionally requested to establish tolerances for residues of clothianidin and its metabolite TMG, N-(2-chlorothiazol-5-ylmethyl)-N'-methylguanidine, in or on vegetable, leafy, *brassica*, group 5 at 3.0 ppm; and vegetable, leafy, except *brassica*, group 4 at 3.5 ppm. That notice referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. This petition was assigned Docket No. OPP–2008–0646. There were no comments received in response to the notice of filing.

In the **Federal Register** of December 3, 2008 (73 FR 73640) (FRL–8390–4), 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 8F7413) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition 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 and its metabolite TMG, N-(2-chloro-5-thiazolylmethyl)-N-'-methylguanidine, in or on vegetable, root, except sugar beet, subgroup 1B at 0.6 ppm; vegetable, tuberous and corm, subgroup 1C at 0.2 ppm; vegetable, bulb, group 3 at 0.2 ppm; vegetable, leafy greens, except *brassica*, subgroup 4A at 1.1 ppm; and vegetable, *brassica*, leafy, group 5 at 0.35 ppm. The petition additionally requested to establish tolerances for residues of clothianidin in or on vegetable, fruiting, group 8 at 0.01 ppm; vegetable, cucurbit, group 9 at 0.01 ppm; grain, cereal, except rice, group 15 at 0.01 ppm, wheat, forage at 0.35 ppm, wheat, hay at 0.07 ppm and wheat, straw at 0.04 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. This petition was assigned Docket No. OPP–2008–0771. There were no comments received in response to the notice of filing.

In the **Federal Register** of April 13, 2009 (74 FR 16866) (FRL–8396–6), 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 8E7460) by Interregional Research Project Number 4 (IR-4), 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition 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 berry, low growing, subgroup 13-07H, except strawberry at 0.01 ppm; peach at 0.70 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.05 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Valent U.S.A. Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. This petition was assigned Docket No. OPP–2008–0945. There were no comments received in response to the notice of filing.

In the **Federal Register** of April 13, 2009 (74 FR 16866) (FRL–8396–6), 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 8F7416) by Bayer CropScience, P.O. Box 12014, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.586 be amended by increasing the tolerance for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine and its metabolite TMG, N-(2-chloro-5-thiazolylmethyl)-N-'-methylguanidine, in or on potato from 0.05 ppm to 0.6 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. This petition was assigned Docket No. OPP–2008–0771. There were no comments received in response to the notice of filing.

In the **Federal Register** of May 6, 2009 (74 FR 20947) (FRL–8412–7), 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 9F7530) by Valent U.S.A. Corporation, P.O. Box 8025, Walnut Creek, CA 94596. The petition 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 fig at 0.05 ppm and pomegranate at 0.2 ppm. That notice referenced a summary of the petition prepared by Valent, U.S.A. Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. This petition was assigned Docket No. OPP–2009–0262. There were no comments received in response to the notice of filing.

Bayer CropScience requested tolerances for residues of clothianidin to support seed treatment uses, whereas Valent U.S.A. Corporation and IR-4 requested tolerances to support foliar applications. Typically, foliar applications will result in higher residues than seed treatment uses. In cases where both use patterns were requested for the use of clothianidin on the same commodity, tolerance levels are being established at the higher level proposed; however, based upon review of the data supporting the petitions, EPA has revised the proposed foliar application tolerance levels for leafy vegetable, except *brassica*, crop group 4; *brassica* leafy vegetable, crop group 5; fruiting vegetable, crop group 8; and cucurbit vegetable, crop group 9. The Agency is also revising tolerances for several other proposed individual and group commodities.

EPA has determined that the proposed tolerance in or on bulb onion group 3 should be established on bulb onion, group 3-07. The Agency has also determined that tolerances are not required for several petitioned-for commodities. EPA is establishing tolerances on several commodities that were not proposed and is deleting several existing tolerances. Finally, the Agency is amending an established tolerance on potato granules/flakes that was not proposed. The reasons for these changes are explained in Unit IV.C.

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 the petitioned-for

tolerances for residues of clothianidin on almond hulls at 1.5 ppm; low-growing berry, subgroup 13-07H, except strawberry at 0.01 ppm; cotton, gin byproducts at 4.5 ppm; cotton undelinted seed at 0.20 ppm; fig at 0.05; cereal grain, forage, fodder and straw, group 16, except rice, forage at 0.35 ppm; cereal grain, forage, fodder and straw, group 16, except rice, hay at 0.07 ppm; cereal grain, forage, fodder and straw, group 16, except rice, stover at 0.1 ppm; cereal grain, forage, fodder and straw, group 16, except rice, straw at 0.05 ppm; cereal grain, group 15, except rice at 0.01 ppm; tree nut, group 14 at 0.01 ppm; peach at 0.80 ppm; pomegranate at 0.20 ppm; potato chips at 0.6 ppm; potato, granules/flakes at 1.5 ppm; soybean seed at 0.02 ppm; leafy brassica vegetable, group 5 at 1.9 ppm; bulb vegetable, group 3-07 at 0.45 ppm; cucurbit vegetable, group 9 at 0.06 ppm; fruiting vegetable, group 8 at 0.20 ppm; leafy vegetable except brassica, group 4 at 3.0 ppm; root vegetable except sugar beet, subgroup 1B at 0.8 ppm; and tuberous and corm vegetable, subgroup 1C at 0.3 ppm. EPA's assessment of exposures and risks associated with establishing tolerances 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.

EPA considered the toxicity of clothianidin as well as several metabolites and degradates in conducting this risk assessment. Metabolites/degradates of concern in plants include parent and TMG for leafy and root and tuber vegetables; parent-only for other crops; and parent, TZNG and MNG for rotational crops. For livestock commodities, the metabolites/degradates of concern include: Parent and TZU, TZG, TZNG and ATMG-pyruvate for ruminants; and parent and TZU, TZG, TZNG, and ATG-acetate for poultry. Acute toxicity and genotoxicity data are available for several metabolites/degradates of clothianidin. Given that the points of departure (POD) used for risk assessment are well below the lethal dose LD_{50} levels observed in the acute toxicology studies and that clothianidin and its metabolites/degradates of toxicological concern are similar in structure, EPA is assuming that these compounds are toxicologically equivalent to clothianidin with respect to the endpoints being used for risk assessment.

Clothianidin and its metabolites and degradates have relatively low acute toxicity via oral, dermal and inhalation routes of exposure; however, acute oral administration of clothianidin in mice and the TMG metabolite in rats showed evidence of increased relative toxicity. There is no evidence of dermal sensitization or eye irritation with the exception of the clothianidin-triazan intermediate, which is a dermal sensitizer. 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 the document ''*Clothianidin*: Human Health Risk Assessment for Proposed Uses on Berries (Group 13-07H), Brassica Vegetables (Group 5), Cotton, Cucurbit Vegetables (Group 9), Fig, Fruiting Vegetables (Group 8), Leafy Green Vegetables (Group 4A), Peach, Pomegranate, Soybean, Tree Nuts (Group 14), and Tuberous and Corm Vegetables (Group 1C),'' pages 46–54 in docket ID number EPA–HQ–OPP–2008–0945.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological POD is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the

extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in the document ''*Clothianidin*: Human Health Risk Assessment for Proposed Uses on Berries (Group 13-07H), Brassica Vegetables (Group 5), Cotton, Cucurbit Vegetables (Group 9), Fig, Fruiting Vegetables (Group 8), Leafy Green Vegetables (Group 4A), Peach, Pomegranate, Soybean, Tree Nuts (Group 14), and Tuberous and Corm Vegetables (Group 1C),'' page 23 in docket ID number EPA–HQ–OPP–2008–0945.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to clothianidin, EPA considered exposure under 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.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used tolerance-level residues, 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 from 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. These include meats, meat by-products, artichoke, tropical fruits, coffee, hop, mint, rice, and strawberry. The metabolism of clothianidin is complex, with a few major (> 10% of the total radioactive residues) and numerous minor metabolites. Metabolites/degradates of concern in plants include clothianidin and TMG for leafy, root and tuber vegetables; parent-only for other crops; and parent, TZNG and MNG for rotational crops. For livestock commodities, the metabolites of concern include: parent and TZU, TZG, TZNG, and ATMG-pyruvate for ruminants; and parent and TZU, TZG, TZNG, and ATG-acetate for poultry. For leafy vegetables the EPA required analysis for residues of TMG along with parent in field trial samples. Residues of TMG were shown to occur in leafy vegetables at levels approximately tenfold below those of clothianidin. EPA has not included these metabolites in the tolerance expression for plant or animal commodities because the metabolites are only found in certain commodities, including the metabolites would create tolerance harmonization issues with Canada, and monitoring residues of clothianidin based on parent only would be representative of total clothianidin residues and thus adequate for enforcement. Because the metabolites are not included in the tolerance expressions, an adjustment factor of 1.1 has been incorporated into the assessment for leafy vegetables to account for the presence of the metabolite TMG, and an adjustment factor of 1.5 has been incorporated for livestock-derived commodities (milk) to account for the presence of metabolites TZU, TZG, TZNG, ATMG-pyruvate and ATG-acetate. The 1.1 adjustment factor is based on field trial data showing TMG does not exceed 10% of the parent compound residue level in leafy vegetables and the 1.5 factor was based on metabolism data.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. 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 lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, EPA has classified clothianidin as ''not likely to be carcinogenic to humans.'' Therefore, a quantitative exposure assessment to evaluate 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 clothianidin. 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 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*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of clothianidin for surface water are estimated to be 7.29 parts per billion (ppb) for acute exposures and 1.35 ppb for chronic exposures. For ground water, the EDWC is estimated to be 5.88 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration value of 7.29 ppb was used to assess the contribution to drinking water for the acute dietary assessment. For chronic dietary risk assessment, the water concentration of value 5.88 ppb was used.

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 use on turf. Residential handler exposure is not expected from the currently registered or proposed uses of clothianidin since these products are to be applied by commercial applicators. Adult short- and intermediate-term postapplication exposures were assessed for dermal exposures from commercial applications (via granular push-type spreaders), dermal post-application contact and golfer postapplication contact. For toddlers, short- and intermediate-term postapplication incidental oral (hand-to-mouth and soil ingestion) and dermal risks were assessed for exposure to treated turf.

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 (EPA, 2002). 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 non competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, 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 still births. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (e.g., testicular tubular atrophy with thiamethoxam; 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 EPA's Office of Pesticide Programs on EPA's website 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 Food Quality Protection Act (FQPA) safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The toxicology data for clothianidin provide no indication of increased quantitative or qualitative susceptibility, as compared to adults, of rat and rabbit fetuses to *in utero* exposure in developmental studies. However, increased quantitative susceptibility was observed in both the developmental neurotoxicity and rat multi–generation reproduction studies. In the developmental neurotoxicity study, offspring toxicity (decreased body weight gains, motor activity and acoustic startle response) was seen at a lower dose than that which caused maternal toxicity. In the 2–generation rat reproduction study, offspring toxicity (decreased body weight gains, delayed sexual maturation in males, decreased absolute thymus weights in F1 pups of both sexes and an increase in stillbirths in both generations) was seen at a dose lower than that which caused parental toxicity.

3. *Conclusion*. In the final rule published in the **Federal Register** of February 6, 2008 (73 FR 6851) (FRL–8346–9), EPA had previously determined that the FQPA SF for clothianidin should be retained at 10X because EPA had required the submission of a developmental immunotoxicity study to address the combination of evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin data base, and evidence showing that juvenile rats in the 2–generation reproduction study appear to be more susceptible to these potential immunotoxic effects. In the absence of a developmental immunotoxicity study EPA concluded that there was sufficient uncertainty regarding immunotoxic effects in the young that the 10X FQPA factor should be retained as a database uncertainty factor. Since that determination, EPA has received and reviewed an acceptable/guideline developmental immunotoxicity study, which demonstrated no treatment-related effects. Taking the results of this study into account as well as the rest of the data on clothianidin, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF for clothianidin were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for clothianidin is complete. As noted, the prior data gap concerning developmental immunotoxicity has been addressed by the submission of an acceptable developmental immunotoxicity study.

ii. 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; therefore, there are no residual concerns regarding effects in the young.

iii. 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 and LOAEL have been selected 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 prenatal and postnatal toxicity after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for clothianidin.

iv. 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 tolerance-level residues, adjustment factors from metabolite data, empirical processing factors, and 100 PCT for all commodities. Additionally, EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to clothianidin in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children and adults as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by clothianidin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to clothianidin will occupy 23% of the aPAD for children 1 to 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 19% of the cPAD for children 1 to 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.

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).

Clothianidin is currently registered for use on turf that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to clothianidin. Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of greater than 380 for all population subgroups. As the aggregate MOEs are greater than 100 (the LOC) for all population subgroups, including infants and children, short- and intermediate-term aggregate exposures to clothianidin are not of concern to EPA.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in mice and rats at doses that were judged to be adequate to assess the carcinogenic potential, 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 liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) enforcement methodology is available to enforce the tolerance expression for both plant and animal commodities and has been forwarded to the Food and Drug Administration for inclusion in the Pesticide Analytical Manual (PAM), Volume II. 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 order to harmonize with Canadian maximum residue limits (MRLs) on potato tubers at 0.3 ppm; potato chips at 0.6 ppm and potato granules/flakes at 1.5 ppm, EPA has recommended the following tolerances: Vegetable, tuberous and corm, subgroup 1C (which includes potato) at 0.3 ppm; potato, chips at 0.6 ppm; and potato granules/flakes at 1.5 ppm. Additionally, Canada is currently reviewing a petition to establish a tolerance in or on the stone fruit (including peaches) crop group at 0.8 ppm. A tolerance on peach at 0.80 ppm is being recommended by EPA to harmonize with Canada's recommended stone fruit MRL. There are currently no Canadian MRLs established for residues of clothianidin in or on other commodities associated with these petitions. There are currently no Codex or Mexican MRLs established for residues of clothianidin in or on commodities associated with these petitions.

C. Revisions to Petitioned-For Tolerances

EPA has revised the proposed tolerance levels for foliar applications of clothianidin on the following commodities: Leafy vegetable, crop group 4 from 3.5 ppm to 3.0 ppm; *brassica* vegetable, crop group 5 from 3.0 ppm to 1.9 ppm; fruiting vegetable, crop group 8 from 0.25 to 0.20 ppm; and cucurbit vegetable, crop group 9 from 0.05 to 0.06 ppm. EPA has also revised the proposed tolerance levels in or on

soybean, seed from 0.03 ppm to 0.02 ppm; root vegetable, except sugar beet, subgroup 1B from 0.60 ppm to 0.8 ppm; bulb vegetable group 3-07 from 0.2 ppm to 0.45 ppm; and wheat, straw from 0.04 ppm to 0.05 ppm; and has revised the proposed tolerance amendment for cotton, undelinted seed (the preferred commodity definition for cotton, seed) from 0.25 to 0.20. EPA revised the tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data.

The Agency has also revised tolerances in order to harmonize U.S. MRLs with currently established or pending Canadian MRLs for peach from 0.7 ppm to 0.80 ppm; and for tuberous and corm vegetable, group 1C (based on the a seed piece treatment which results in the highest residue) from 0.2 ppm to 0.3 ppm. Additionally, the Agency has established a tolerance in or on potato, chips at 0.6 ppm; and has increased a currently-established tolerance in or on potato, granules/flakes from 0.08 to 1.5 ppm to harmonize with Canadian MRLs on the commodities.

EPA has also determined that individual tolerances are not necessary for several petitioned-for commodities. A request to increase an existing potato tolerance from 0.05 ppm to 0.6 ppm is not necessary because potato is superseded by inclusion in the tuberous and corm subgroup 1C; thus, the existing potato tolerance is being deleted. A proposed tolerance on vegetable, leafy greens, except *brassica*, subgroup 4A at 1.1 ppm is not necessary, as the subgroup tolerance is superseded by inclusion in the leafy vegetable except *brassica*, group 4. Separate tolerances in or on soybean, hulls; soybean, meal; and soybean, oil are not required because adequate soybean processing data indicate that quantifiable residues are unlikely to occur in soybean processed fractions; thus, only a soybean seed tolerance is being established. Separate tolerances in or on cotton, meal; cotton, hulls; and cotton, refined oil are not required because residues were reduced in these commodities; therefore, the existing cotton, undelinted seed (the preferred commodity term for cotton, seed) and cotton, gin byproducts (the preferred commodity term for cotton, gin trash) tolerances are being amended to reflect increased tolerances of 0.20 and 4.5 ppm, respectively. Finally, adequate processing data indicate that separate tolerances in or on tomato, paste at 0.08 ppm and tomato, puree at 0.07 ppm are not necessary; therefore, only a fruiting vegetable group 8 (including tomato) tolerance is required.

EPA has reviewed the available wheat, corn and sorghum data and has determined that sufficient data are available to establish the following group tolerances: Grain, cereal, forage, fodder and straw, group 16, except rice, forage at 0.35 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, hay at 0.07 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, stover at 0.1 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, straw at 0.05 ppm. The registrant petitioned for a crop group tolerance on the Cereal Grains Group (Crop Group 15) but only petitioned for individual tolerances in or on wheat, forage (at 0.35 ppm); wheat, hay (at 0.07 ppm); and wheat, straw (at 0.04); and not tolerances on the crop group covering Forage, Fodder, and Straw of the Cereal Grains (Crop Group 16). However, EPA has determined that tolerances for group 16 are appropriate because the petitioned-for wheat feed item tolerances when considered in conjunction with the existing feed item tolerances for corn and sorghum satisfied the requirements for establishment of Crop Group 16 tolerances. The Crop Group 16 tolerances are being limited like the Crop Group 15 tolerance to exclude rice. Additionally, the following established tolerances are being deleted because they are superseded by inclusion in group 16: corn, field, forage at 0.10 ppm; corn, field, stover at 0.10 ppm; corn, pop, stover at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, sweet, stover at 0.10; sorghum, forage and stover at 0.01 ppm; and grain, cereal, forage, fodder and straw, group 16 at 0.02 ppm (a tolerance resulting from indirect/inadvertent residues of clothianidin). Finally, tolerances of clothianidin in or on corn, field grain at 0.01 ppm; corn, pop, grain at 0.01 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; and sorghum, grain at 0.01 ppm are being deleted because they are being superseded by inclusion in the grain, cereal, group 15.

Additionally, a final rule published in the **Federal Register** of December 7, 2007 (72 FR 69150) (FRL–8343–1) that amended the existing bulb vegetable group 3 by adding several commodities; the updated group was renamed the bulb vegetable group 3-07. This rule, as well as the earlier May 23, 2007 proposed rule (72 FR 28920) (FRL–8126–1) stated that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA has assessed for and is establishing a tolerance for group 3-07 instead of the proposed bulb vegetable group 3.

Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of clothianidin not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

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 almond, hulls at 1.5 ppm; berry, low-growing, subgroup 13-07H, except strawberry at 0.01 ppm; fig at 0.05; grain, cereal, forage, fodder and straw, group 16, except rice, forage at 0.35 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, hay at 0.07 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, stover at 0.1 ppm; grain, cereal, forage, fodder and straw, group 16, except rice, straw at 0.05 ppm; grain, cereal, group 15, except rice at 0.01 ppm; nut, tree, group 14 at 0.01 ppm; peach at 0.80 ppm; pomegranate at 0.20 ppm; potato, chips at 0.6 ppm; soybean, seed at 0.02 ppm; vegetable, brassica, leafy, group 5 at 1.9 ppm; vegetable, bulb, group 3-07 at 0.45 ppm; vegetable, cucurbit, group 9 at 0.06 ppm; vegetable, fruiting, group 8 at 0.20 ppm; vegetable, leafy, except brassica, group 4 at 3.0 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.8 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.3 ppm. Additionally, tolerances are amended for residues of clothianidin in or on cotton, gin byproducts from 0.01 ppm to 4.5 ppm; cotton, undelinted seed from 0.01 ppm to 0.20 ppm; and potato, granules/flakes from 0.08 to 1.5 ppm. This regulation deletes a tolerance in or on potato at 0.05 ppm; corn, field, forage at 0.10 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.10 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.10 ppm; corn, sweet, forage at 0.10 ppm; corn, sweet, kernel plus cob with husk removed at 0.01 ppm; corn, sweet, stover at 0.10 ppm; and sorghum, forage, grain, stover at 0.01 ppm. Finally, this regulation deletes a tolerance for indirect/inadvertent residues of clothianidin in or on grain, cereal, forage, fodder and straw, group 16 at 0.02 ppm. Also, the introductory text in 40 CFR 180.586(a), (b) and (d), which includes the tolerance expression, are revised.

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) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

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: November 27, 2009.

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 revised to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide clothianidin, including its metabolites and degradates. Compliance with the tolerance levels specified below is to be determined by measuring only clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almond, hulls	1.5
Beet, sugar, dried pulp	0.03
Beet, sugar, molasses	0.05
Beet, sugar, roots	0.02
Berry, low-growing, subgroup 13-07H, except strawberry	0.01
Canola, seed	0.01
Cotton, gin byproducts	4.5
Cotton, undelinted seed	0.20
Fig	0.05
Fruit, pome	1.0
Grain, cereal, forage, fodder and straw, group 16, except rice, forage	0.35
Grain, cereal, forage, fodder and straw, group 16, except rice, hay	0.07
Grain, cereal, forage, fodder and straw, group 16, except rice, stover	0.1
Grain, cereal, forage, fodder and straw, group 16, except rice, straw	0.05
Grain, cereal, group 15, except rice	0.01
Grape	0.60
Milk	0.01
Nut, tree, group 14	0.01
Peach	0.80
Pomegranate	0.20
Potato, chips	0.6
Potato, granules/flakes	1.5
Soybean, seed	0.02
Vegetable, brassica, leafy, group 5	1.9
Vegetable, bulb, group 3-07	0.45
Vegetable, cucurbit, group 9	0.06
Vegetable, fruiting, group 8	0.20
Vegetable, leafy, except brassica, group 4	3.0
Vegetable, root, except sugar beet, subgroup 1B	0.8
Vegetable, tuberous and corm, subgroup 1C	0.3

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insecticide clothianidin, including its metabolites and degradates in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine. These tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Beet, sugar, roots	0.02	12/31/09

Commodity	Parts per million	Expiration/ revocation date
Beet, sugar, tops	0.02	12/31/09

(c) *Tolerances with regional registrations*. [Reserved]

(d) *Indirect and inadvertant residues*. Tolerances are established for the indirect or inadvertent residues of the insecticide clothianidin, including its metabolites and degradates. Compliance with the tolerance levels specified below is to be determined by measuring only clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on the following raw agricultural commodities when present therein as a result of the application of clothianidin to crops listed in paragraph (a) of this section:

Commodity	Parts per million
Animal feed, nongrass, group 18	0.02
Grass, forage, fodder and hay, group 17	0.02
Soybean, forage	0.02
Soybean, hay	0.02

[FR Doc. E9–29339 Filed 12–9–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0769; FRL–8799–6]

Novaluron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of novaluron in or on bushberry subgroup 13-07B; Brassica, leafy greens, subgroup 5B; turnip, greens; fruit, stone, group 12, except cherry; cherry; and plum, prune, dried. This regulation additionally revises an existing tolerance in or on egg and revises terminology for an existing tolerance. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 9, 2009. Objections and requests for hearings must be received on or before February 8, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0769. 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number (703) 305–7390; e-mail address: *nollen.laura.@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How Can I Access Electronic Copies of this Document?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Test Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/oppts* and select ''Test Methods & Guidelines'' on the left side navigation menu.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0769 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 8, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008-0769, 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.