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: August 17, 2012.

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 180.361 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.361 Pendimethalin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Brassica, leafy greens, subgroup 5B	0.20
* * * * *	
Fruit, small vine climbing, except grape, subgroup 13–07E	0.10
* * * * *	
Lettuce, leaf	4.0
Melon subgroup 9A	0.10
* * * * *	
Turnip greens	0.20
* * * * *	
Vegetable, soybean, succulent	0.10
* * * * *	

* * * * *

[FR Doc. 2012–21361 Filed 8–28–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0217; FRL–9360–4]

Clothianidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clothianidin in or on rice, grain at 0.01 ppm. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 29, 2012. Objections and requests for hearings must be received on or before October 29, 2012, 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–2010–0217, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Marianne Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8043; email address: *lewis.marianne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

B. How can I access electronic copies of this document?

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–2010–0217 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 October 29, 2012.

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–2010–0217, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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. Petition for Tolerance

In the **Federal Register** of May 6, 2011 (76 FR 26291) (FRL–8870–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7832) 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 rice, grain at 0.01 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.* There were no comments received in response to the notice of filing.

Valent U.S.A. Corporation requested tolerances for residues of clothianidin to support rice, grain uses.

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 in or on rice, grain at 0.01 ppm. EPA's assessment of exposures and risks associated with clothianidin 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 used for risk assessment are well below the 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 mouse and the TMG metabolite in rat 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 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.'' in docket ID number EPA–HQ–OPP–2010–0217.

B. Toxicological Endpoints

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 shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CLOTHIANIDIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	NOAEL = 25 milligrams/kilograms/day (mg/kg/day) $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	Acute RfD = 0.25 mg/kg/day aPAD = 0.25mg/kg/day	Rabbit developmental study LOAEL = 75 mg/kg/day based on increased litter incidence of a missing lobe of the lung
Acute dietary (General population)	NOAEL = 25 mg/kg/day $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	Acute RfD = 0.25 mg/kg/day aPAD = 0.25 mg/kg/day	Special neurotoxicity/pharmacological study in mice LOAEL = 50 mg/kg/day based on transient signs of decreased spontaneous motor activity, tremors and deep respirations
Chronic dietary (All populations including infants and children).	NOAEL= 9.8 mg/kg/day $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	Chronic RfD = 0.098 mg/kg/day cPAD = 0.098 mg/kg/day	2-Generation reproduction study LOAEL = 31.2 mg/kg/day based on decreased body weight gains and delayed sexual maturation, decreased absolute thymus weights in F1 pups and increased stillbirths in both generations
Incidental oral (Short and intermediate term).	NOAEL= 9.8 mg/kg/day $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	LOC for MOE = 100	2-Generation reproduction study LOAEL = 31.2 mg/kg/day based on decreased body weight gains and delayed sexual maturation, decreased absolute thymus weights in F1 pups and increased stillbirths in both generations
Dermal (All durations)	Oral study NOAEL = 9.8 mg/kg/day (dermal absorption rate = 1%) $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	LOC for MOE = 100	2-Generation reproduction study LOAEL = 31.2 mg/kg/day based on decreased body weight gains and delayed sexual maturation, decreased absolute thymus weights in F1 pups and increased stillbirths in both generations

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CLOTHIANIDIN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation (All durations)	Oral study NOAEL= 9.8 mg/kg/day (inhalation absorption rate = 100%) $UF_A = 10_X$ $UF_H = 10_X$ FQPA SF = 1_X	LOC for MOE = 100	2-Generation reproduction study LOAEL = 31.2 mg/kg/day based on decreased body weight gains and delayed sexual maturation, decreased absolute thymus weights in F1 pups and increased stillbirths in both generations
Cancer (Oral, dermal, inhalation)	"Not likely to be Carcinogenic to Humans"		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to clothianidin, EPA considered exposure from 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) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food from use of clothianidin, 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 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 and 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 10-fold 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 percent crop treated (PCT) information.*

For food with thiamethoxam tolerances but without clothianidin tolerances, maximum residues of clothianidin observed in thiamethoxam field trials have been used in these assessments. For all commodities, 100 PCT was assumed.

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 72 parts per billion (ppb) for acute exposures and <72 ppb for chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The EDWC of 72 ppb was used to account for residues of clothianidin in both the acute and chronic dietary risk assessments.

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 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 still births. 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 indication of increased quantitative or qualitative susceptibility, as compared to adults, of rat and rabbit fetuses following *in utero* exposure to clothianidin 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 two-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 two-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:

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.

i. There are no residual concerns regarding potential pre- 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 pre- 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.

ii. 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 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. 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 appropriate POD 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 24% 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 21% 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.

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 result in aggregate MOEs of greater than 450 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 enforcement methodology is available to enforce the tolerance expression. This method involves extraction of residues with acetonitrile/water, cleanup using solid phase extraction (SPE) cartridges, and analysis of clothianidin by LC/MS/MS. 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; 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 U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for clothianidin in/on rice, grain.

C. Revisions to Petitioned-For Tolerances

The tolerance is considered appropriate as proposed; therefore, no revisions were needed.

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 rice, grain at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under

Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 17, 2012.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.586 is amended by revising paragraph (a)(1) introductory text, and by alphabetically adding the commodity ''rice, grain'' in the table in paragraph (a)(1) to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) *General.* (1) 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*)-*N*-[(2-Chloro-5-thiazolyl)methyl]-*N*′ -methyl-*N*″ -nitroguanidine, in or on the following raw agricultural commodities:

Commodity	Parts per million
* * * * * * *	
Rice, grain	0.01
* * * * * * *	

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 201 and 212

RIN 0750–AH65

Defense Federal Acquisition Regulation Supplement: Inflation Adjustment of Threshold for Acquisition of Right-Hand Drive Passenger Sedans (DFARS Case 2012–D016)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is adopting as final, without change, an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2012 that requires adjustment of the statutory dollar limitation on the acquisition of right-hand drive passenger sedans.

DATES: *Effective Date:* August 29, 2012.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION: