PART 97—[AMENDED]

■ 28. The authority citation for part 97 continues to read as follows:

Authority: 42 U.S.C. 7401, 7403, 7410, 7426, 7601, and 7651, *et seq.*

§ 97.102 [Amended]

■ 29. Section 97.102 is amended as follows:
■ a. In the definition of ''Alternate CAIR designated representative'', by revising the words ''source in accordance'' to read ''source, in accordance''; and
■ b. In the definition of ''CAIR NO_X Ozone Season Trading Program'', by revising the words ''accordance with under subparts AAAA through IIII'' to read ''accordance with subparts AAAA through IIII of part 96''.

§ 97.113 [Amended]

■ 30. Section 97.113 is amended, in paragraph (a)(4)(iv), by revising the words ''(Where there are'' to read ''Where there are''.

§ 97.143 [Amended]

■ 31. Section 97.143 is amended, in paragraph (c) introductory text and paragraph (c)(2) introductory text, by revising the words ''CAIR NO_X emissions'' to read ''the CAIR NO_X emissions''.

§ 97.144 [Amended]

■ 32. Section 97.144 is amended, in paragraph (c)(2), by revising the words ''State(s compliance'' to read ''State's compliance''.

§ 97.184 [Amended]

■ 33. Section 97.184 is amended, in paragraph (c) introductory text, by revising the words ''heat rate'' to read ''heat input''.

§ 97.187 [Amended]

■ 34. Section 97.187 is amended, in paragraph (b)(2)(ii), by revising the words ''CAIR NO_X unit that'' to read ''CAIR NO_X opt-in unit that''.

§ 97.202 [Amended]

■ 35. Section 97.202 is amended as follows:
■ a. In the definition of ''Alternate CAIR designated representative'', by revising the words ''source in accordance'' to read ''source, in accordance'';
■ b. In the definition of ''CAIR NO_X Annual Trading Program'', by revising the word ''(§ 51.123(p)'' to read ''§ 51.123(p)''; and
■ c. In the definition of ''CAIR NO_X Ozone Season Trading Program'', by revising the word ''(§ 51.123(ee)'' to read ''§ 51.123(ee)'' and by revising the words ''accordance with under subparts AAAA through IIII'' to read ''accordance with subparts AAAA through IIII of part 96''.

§ 97.283 [Amended]

■ 36. Section 97.283 is amended as follows:
■ a. In paragraph (a)(2)(iii), by revising the words ''Is not, and'' to read ''Is not and,''; and
■ b. In paragraph (a)(2)(iv),by revising the words ''stack, and'' to read ''stack; and''.

§ 97.284 [Amended]

■ 37. Section 97.284 is amended as follows:
■ a. In paragraph (c) introductory text, by revising the words ''heat rate'' to read ''heat input'';
■ b. In paragraph (c)(2), by revising the words ''unit(s'' to read ''unit's''; and
■ c. In paragraph (d)(2), by revising the words ''and (b)(2)'' to read ''and (2)''.

§ 97.287 [Amended]

■ 38. Section 97.287 is amended, in paragraph (b)(2)(ii), by revising the words ''CAIR SO_2 unit that'' to read ''CAIR SO_2 opt-in unit that''.

§ 97.302 [Amended]

■ 39. Section 97.302 is amended as follows:
■ a. In the definition of ''Alternate CAIR designated representative'', by revising the words ''source in accordance'' to read ''source, in accordance'';
■ b. In the definition of ''CAIR NO_X Ozone Season Trading Program'', by revising the words ''accordance with under subparts AAAA through IIII'' to read ''accordance with subparts AAAA through IIII of part 96'';
■ c. In the definition of ''Reference method'', by revising the words ''(75.22'' to read ''§ 75.22''; and
■ d. In the definition of ''State'', by revising with words ''(52.35'' to read ''§ 52.35''.

§ 97.371 [Amended]

■ 40. Section 97.371 is amended, in paragraph (d)(2), by revising the words ''include: Replacement'' to read ''include: replacement''.

§ 97.384 [Amended]

■ 41. Section 97.384 is amended, in paragraph (c) introductory text, by revising the words ''heat rate'' to read ''heat input''.

§ 97.387 [Amended]

■ 42. Section 97.387 is amended, in paragraph (b)(2)(ii), by revising the words ''CAIR NO_X Ozone Season unit that'' to read ''CAIR NO_X Ozone Season opt-in unit that'' and by revising the words ''(97.304'' to read ''§ 97.304''.

[FR Doc. E6–21199 Filed 12–12–06; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0902; FRL–8105–5]

Clothianidin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clothianidin in or on sorghum (grain, forage, and stover) and cotton (undelinted and gin byproducts). Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, this establishes time-limited tolerances for residues of clothianidin, in or on beet, sugar, roots, and beet, sugar, tops. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugar beet seeds. This regulation establishes a maximum permissible level for residues of clothianidin in these food commodities. The tolerances for sugar beet commodities expire and are revoked on December 31, 2009. This regulation establishes tolerances for residues of clothianidin in or on grapes, potatoes, and potatoes, granules/flakes. Arvesta Corporation requested these tolerances under the FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective December 13, 2006. Objections and requests for hearings must be received on or before February 12, 2007, 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–2006–0902. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kable Bo Davis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0415; e-mail address: *Davis.Kable@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket 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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2006–0902. 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 on or before February 12, 2007.

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 your copies, identified by docket ID number EPA–HQ–OPP–2006–0902., 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 8, 2004 (69 FR 71036) (FRL–7687–4), 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 4F6869) by Arvesta Corporation, 15401 Weston PKWY Suite 150, Cary, North Carolina 27513. 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 grapes at 0.5 parts per million (ppm), raisins at 1.0 ppm, and potatoes at 0.1 ppm. That notice included a summary of the petition prepared by Arvesta Corporation, the registrant. There were no comments received in response to the notice of filing.

In the **Federal Register** of June 16, 2004 (69 FR 33635) (FRL–7350–6), 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 3F6792) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, North Carolina 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, in or on sorghum, grain at 0.01 ppm, sorghum, forage at 0.01 ppm, and sorghum, stover at 0.01 ppm. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

In the **Federal Register** of December 14, 2005 (70 FR 74003) (FRL–7747–4), 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 5F6908) by, Bayer CropScience, 2 T.W. Alexander Drive Research Triangle Park, North Carolina 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, in or on cotton, undelinted at 0.01 ppm, and cotton, gin byproducts at 0.01 ppm. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

Upon completing review of the current clothianidin database, the

Agency concluded that the appropriate tolerance levels for clothianidin residues in or on pending crops should be established as follows: Sorghum, grain at 0.01 ppm, sorghum, forage at 0.01 ppm, sorghum, stover at 0.01 ppm, cotton, undelinted seed at 0.01 ppm, cotton, gin byproducts at 0.01 ppm, grape at 0.60 ppm, potato at 0.05 ppm, and potato, granules/flakes at 0.08 ppm. In addition, the proposed tolerance for raisins was withdrawn because based on available processing data, a tolerance for this commodity is not needed.

EPA is also establishing time-limited tolerances for combined residues of the insecticide, clothianidin, in or on beet, sugar, roots, and beet, sugar, tops at 0.02 ppm. These tolerances expire and are revoked on December 31, 2009. The beet tolerances are being established in response to a regional crisis exemption request on behalf of Colorado, North Dakota, and Wyoming under FIFRA section 18 for the emergency use of clothianidin as a seed treatment on sugar beet seeds to control the beet leafhopper, which is a vector of the beet curly top virus in certain sugar beet growing regions throughout the western United States.

As part of its assessment of this emergency exemption request, EPA assessed the potential risks presented by residues of clothianidin in or on beet, sugar, roots, and beet, sugar, tops. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address the urgent non–routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing the tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances expire and are revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amount specified in the tolerances remaining in or on beet, sugar, roots, and beet, sugar, tops after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because the tolerances are being approved under emergency conditions, EPA has not made any decisions about whether clothianidin meets EPA's registration requirements for use on beet, sugar, roots, and beet, sugar, tops or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of clothianidin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any States other than Oregon, Colorado, North Dakota, and Wyoming to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for clothianidin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT.**

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA–PEST/1997/November/Day–26/p30948.htm.*

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for tolerances for residues of clothianidin (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on grapes at 0.60 ppm, potatoes at 0.05 ppm, potatoes, granules/flakes at 0.08 ppm, sorghum, grain at 0.01 ppm, sorghum, forage at 0.01 ppm, sorghum, stover at 0.01 ppm, cotton, undelinted at 0.01 ppm, and cotton, gin byproducts at 0.01 ppm, and beet, sugar, roots at 0.02 ppm, and beet, sugar, tops at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. Specific information on the studies received and the nature of the toxic 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.epa.gov/EPA-PEST/2003/May/Day-30/p13564.htm.*

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which the NOAEL are observed from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL of concern are identified is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm.*

A summary of the toxicological endpoints for clothianidin used for human risk assessment can be found at www.regulations.gov (pages 18–20) in Docket ID EPA–HQ–OPP–2006–0902. To locate this information on the regulations.gov website follow these steps:

1. Select ''Advanced Search'', then ''Docket Search''

2. In ''Keyword'' field type the chemical name or insert the applicable ''Docket ID number.'' (example: EPA–HQ–OPP–2005–9999).

3. Click the ''Submit'' button.

Follow the instructions on the regulations.gov website to view the index for the docket and access available documents.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.586) for the residues of clothianidin, in or on a variety of raw agricultural commodities. Tolerances have also been established for residues of clothianidin in milk. Risk assessments were conducted by EPA to assess 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 one–day or single exposure.

In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The acute dietary exposure assessment is based on maximum residues of clothianidin observed in clothianidin and thiamethoxam field trials and assumed 100 percent crop treated (%CT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic assessment is based on average residues from clothianidin field trials and also assumes 100% CT.

iii. *Cancer*. Because clothianidin has been classified as a ''not likely human carcinogen'', a cancer risk assessment is not required.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

The Agency used PCT information as follows:

The acute assessment is based on maximum residues of clothianidin observed in clothianidin field trials and assumes 100% CT. The chronic assessment is based on average residues from clothianidin field trials and also assumes 100% CT.

The Agency believes that the three conditions listed have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which clothianidin may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clothianidin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical 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 environmental concentrations (EECs) of clothianidin for acute exposures are 7.29 parts per billion (ppb) for surface water and 5.84 ppb for ground water. The EECs for chronic exposures are 1.35 ppb for surface water and 5.84 ppb for ground water.

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 the following residential non-dietary sites: Turfgrass. The risk assessment was conducted using the following residential exposure assumptions: The following exposure scenarios were assessed for residential post-application risks: toddlers playing on treated turf, adults performing yard work on treated turf, and adults and youths playing golf on treated turf. Additional information on residential exposure assumptions can be found at www.regulations.gov (Docket ID EPA–HQ–OPP–2006–0902, pages 27 through 29).

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the 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/*.

Note that because clothianidin is a major metabolite of thiamethoxam, EPA has combined exposure to clothianidin resulting both from thiamethoxam use and from use of clothianidin as an active ingredient and has compared this aggregate exposure estimate to relevant endpoints for clothianidin. EPA has taken the further conservative step of assuming that, in instances where both thiamethoxam and clothianidin are registered for use on a crop, both pesticides will, in fact, be used on that crop.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. In the developmental neurotoxicity study, toxicity in the offspring was observed at a lower dose level than the dose that caused toxicity in the maternal animals. Maternal effects included decreased body weights, body weight gains, and food consumption. Effects seen in the offspring included decreased body weights, body weight gains, motor activity, and acoustic startle response in the females. However, EPA determined that the degree of concern for the developmental neurotoxicity study is low and there are no residual uncertainties for prenatal and/or postnatal toxicity due to the results of the developmental neurotoxicity study because the observed effects are well characterized and there are clear NOAELs/LOAELs.

In the two-generation 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 lower dose than the dose that caused parental toxicity. Based on evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin data base and on evidence of increased quantitative susceptibility of juvenile rats, compared to adults, in the two-generation reproduction study to these effects. EPA has required that testing be conducted to assess immune system function in adults and in young animals following exposure during the period of organogenesis. No quantitative or qualitative susceptibility was observed in either of the developmental rat or rabbit studies. In the rat, no developmental toxicity was observed at the highest dose tested, although this dose level induced decreases in body weight gain and food consumption in the dams. In the rabbit, premature deliveries, decreased gravid uterine weights, an increase in litter incidence of a missing lobe of the lung, and a decrease in the litter average for ossified sternal centra per fetus were noted at a dose level in which maternal death, a decrease in food consumption, and clinical signs (scant feces and orange urine) were observed. Since the developmental effects observed in the rabbit study were seen in the presence of maternal toxicity, they are not considered to be qualitatively more severe than the maternal effects.

3. *Conclusion*. The exposure data for clothianidin are complete or are estimated based on data that reasonably accounts for potential exposures. The acute dietary exposure assessment is based on maximum residues of clothianidin observed in clothianidin and thiamethoxam field trials and assumes 100% CT. The chronic assessment is based on average residues from clothianidin and thiamethoxam field trials and also assumes 100% CT. For water, the highest acute estimate from conservative models was used for both the acute and the chronic dietary exposure analyses. By using these conservative assessments, acute and chronic exposures/risks will not be underestimated. The residential exposure assessment utilizes residential standard operation procedures (SOPs) to assess post-application exposure to children as well as incidental oral ingestion by toddlers. The residential SOPs are based on reasonable worst-case assumptions and will not likely underestimate exposure/risk. These assessments are unlikely to underestimate the potential exposure to

infants and children resulting from the use of clothianidin.

The toxicology data base for clothianidin, however, is not complete for FQPA purposes. A complete complement of acceptable developmental, reproduction, developmental neurotoxicity, mammalian neurotoxicity and special neurotoxicity studies are available; however, due to evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin data base, and because juvenile rats in the two-generation reproduction study appear to be more susceptible to these effects, EPA has determined that testing should be conducted to assess immune system function in adults and in young animals following developmental exposures. Given the levels at which this testing should be conducted it could result in selection of a more protective (i.e., lower) regulatory endpoint.

Due to the uncertainty with regard to potential effects on immune system function in young animals, EPA cannot conclude that there are reliable data supporting selection of a children's safety factor different from the presumptive 10X factor. Therefore, the 10X FQPA children's safety factor will be retained. This safety factor will be in the form of a database uncertainty factor to account for the lack of the testing with regard to immune system function with clothianidin.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to clothianidin will occupy 11% of the acute population adjusted dose (aPAD) for the U.S. population, 8% of the aPAD for females 13-49 years, 31% of the aPAD for all infants (<1 year old), and 45% of the aPAD for children 1-2 years old. The acute aggregate risks associated with the registered and proposed uses of clothianidin do not exceed the Agency's level of concern for the general U.S. population or any population subgroup.

2. *Chronic risk*. For the chronic exposure assessments the residues of concern are clothianidin. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clothianidin from food and water will utilize 5% of the chronic population adjusted dose (cPAD) for the U.S. population, 13% of the cPAD for all infants (< 1 year old), and 16% of the cPAD for children 1-2 years old. Based on the use pattern, chronic residential exposure to residues of clothianidin is not expected. The long-term aggregate risks associated with clothianidin exposure resulting from the registered and proposed uses of clothianidin and from the registered uses of thiamethoxam do not exceed the Agency's level of concern for the general U.S. population or any population subgroup.

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

Clothianidin is currently registered for use that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for clothianidin.

EPA has determined that, for clothianidin, the toxicological effects are the same across oral, dermal, and inhalation routes of exposure and has selected the same endpoint and dose for short-term and intermediate-term exposure scenarios. Therefore, the exposures are simply summed (combined/aggregated) for use in risk calculations. Short-term and intermediate aggregate risk estimates range from an MOE of 1,100 for toddlers (food + water + treated turf + treated soil + dermal) to 22,000 for youth golfers (food + water + post-application treated turf). The short-term and intermediate-term aggregate risks associated with the registered and proposed uses of clothianidin do not exceed the Agency's level of concern for the general U.S. population or any population subgroup.

4. *Aggregate cancer risk for U.S. population*. Clothianidin has been classified as a ''not likely human carcinogen.'' It is not expected to pose a cancer risk.

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, and to infants and children from aggregate exposure to clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate LC/MS/MS methods are available for both collecting data and enforcing tolerances for clothianidin residues in plant (Bayer Methods 00552 and 109240–1) and animal (Bayer Method 00624) commodities. The validated limit of quantitation (LOQ) for clothianidin in plant commodities is 0.010 ppm, except for wheat straw (0.020 ppm), and the validated LOQs are 0.010 ppm in milk and 0.020 ppm in animal tissues. All three of these methods have been approved for tolerance enforcement, and forwarded to FDA for inclusion in PAM Volume II.

In addition, Arvesta has submitted another LC/MS/MS method (Morse Method #Meth-164) for enforcing tolerances and collecting data on residues of clothianidin and TMG in grape and potato commodities. This newer method is similar to Method 00552 and involves extraction of residues with acetonitrile/water, cleanup using solid phase extraction (SPE) cartridges, and the separate analysis of clothianidin and *N*-(2-chloro-5-thiazolymethyl)-*N'*-methylguanidine (TMG) by LC/MS/MS. The validated LOQ for each analyte is 0.020 ppm in all grape and potato matrices, except for potato chips and raisins (with LOQs of 0.040 ppm). The method was adequately validated in conjunction with the field trials and processing studies and has undergone a successful independent laboratory validation (ILV) trial.

B. International Residue Limits

Canadian maximum residue limits (MRLs) have been established for residues of clothianidin at 0.01 milligram/kilogram (mg/kg) in milk, corn and canola. As of February 2006, there are no Canadian, Mexican, or Codex MRLs or tolerances for cotton, sorghum, grapes, or potatoes.

C. Response to Comments

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

V. Conclusion

Therefore, the tolerances are established for residues of clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on grapes at 0.60 ppm, potatoes at 0.05 ppm, potatoes, granules/flakes at 0.08 ppm, sorghum (grain, forage, and stover) at 0.01 ppm, and cotton (undelinted and gin byproducts) at 0.01 ppm. Time-limited tolerances are also established for residues of clothianidin in or on beet, sugar, roots, and beet, sugar, tops at 0.02 ppm.

VI. Statutory and Executive Order Reviews

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

October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA or are established under section 408(1)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this 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: december 1, 2006.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.586 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows, and by revising paragraph (b) as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cotton, gin byproducts	0.01
Cotton, undelinted seed	0.01
* * *	* *
Grape	0.60
* * *	* *
Potato	0.05
Potato, granules/flakes	0.08
Sorghum, forage, grain, stover	0.01

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. 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	December 31, 2009
Beet, sugar, tops	0.02	December 31, 2009

* * * * *

[FR Doc. E6–20898 Filed 12–12–06; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2002–0043; FRL–8064–3]

Pesticide Tolerance Nomenclature Changes; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct Final rule; technical amendment.

SUMMARY: This document makes minor revisions to the terminology of certain commodity terms listed under 40 CFR part 180, subpart C. EPA is taking this action to establish a uniform listing of commodity terms.

DATES: This Direct Final Rule is effective on February 26, 2007 without notice, unless EPA receives adverse comment by February 12, 2007. If EPA receives adverse comments, EPA will publish a **Federal Register** document to withdraw the direct final rule before the effective date.

If this Direct Final Rule becomes effective any person may file objections and request for hearings on those objections. Objections and requests for hearing must be filed with 60 days of issuance of the final rule. For direct final rules, the date of issuance is considered to be the effective date. Objections and requests for hearings must be received on or before April 27, 2007, 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–2002–0043. All documents in the docket are listed in the index for the docket. 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 availablein hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Stephen Schaible, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9362; e-mail address: schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturer (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturer (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

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

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket 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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at http://www.gpoaccess.gov/ecfr. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm.*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2002–0043 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 on or before February 12, 2007.

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 your copies, identified by docket ID number EPA–HQ–OPP–2002–0043, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305–5805.

II. Background

EPA's Office of Pesticide Programs (OPP) has developed a commodity vocabulary data base entitled ''Food and Feed Commodity Vocabulary.'' The data base was developed to consolidate all the major OPP commodity vocabularies