that this regulation will not have a significant economic impact on a substantial number of small business entities. This rule imposes no new costs or burden on small entities. Rather, this rule adds Spain to the list of non-traditional countries permitted to export NRM to the United States, helping to ensure that United States importers and manufacturers will have access to, and be able to procure, supplies of NRM to meet legitimate United States medical, scientific, research, and industrial needs, to ensure maintenance of adequate reserve stocks, and to meet lawful export requirements. Additionally, this rule provides DEA registered importers with another source from which to purchase NRM which are utilized for the production of controlled substances used in the United States for medical purposes.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

Executive Order 12988

This rule meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rule does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR part 1312 is amended as follows:

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 952, 953, 954, 957, 958.

■ 2. Section 1312.13 is amended by revising paragraphs (f) and (g) to read as follows:

§ 1312.13 Issuance of import permit.

* * * * *

(f) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the Administrator shall permit, pursuant to section 1002(a)(1) or 1002(a)(2)(A) of the Act (21 U.S.C. 952(a)(1) or (a)(2)(A)), the importation of approved narcotic raw material (opium, poppy straw and concentrate of poppy straw) having as its source:

(1) Turkey,

(2) India,

(3) Spain,

(4) France,

(5) Poland,

(6) Hungary, and

(7) Australia.

(g) At least eighty (80) percent of the narcotic raw material imported into the United States shall have as its original source Turkey and India. Except under conditions of insufficient supplies of narcotic raw materials, not more than twenty (20) percent of the narcotic raw material imported into the United States annually shall have as its source Spain, France, Poland, Hungary and Australia.

Dated: January 30, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E8–2142 Filed 2–5–08; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0280; FRL–8346–9]

Clothianidin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of clothianidin in or on sugar beet roots, tops and molasses. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 6, 2008. Objections and requests for hearings must be received on or before April 7, 2008, 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–2007–0280. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: 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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 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 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 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0280 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 April 7, 2008.

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–2007–0280, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of April 30, 2007 (72 FR 21263) (FRL–8124–5), 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 6F7159) by Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.586 be amended by establishing a tolerance for residues of the insecticide clothianidin, (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on beet, sugar, root at 0.02 parts per million (ppm); beet, sugar, tops at 0.04 ppm; and beet, sugar, molasses at 0.06 ppm. That notice referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. 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: Beet, sugar, roots at 0.02 ppm, beet, sugar, molasses at 0.05 ppm and beet, sugar, dried pulp at 0.03 ppm. The Agency no longer considers sugar beet tops to be a significant livestock feedstuff; therefore, a separate tolerance for tops is not required.

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....'' These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of clothianidin on beet, sugar, roots at 0.02 ppm, beet, sugar, molasses at 0.05 ppm and beet, sugar, dried pulp at 0.03. 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 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*. The risk assessment is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA–HQ–OPP–2007–0280 in that docket.

Clothianidin does not appear to exhibit toxicity towards a consistent specific target organ. Decreases in body weight and body weight gain were observed in rats, dogs, and mice. In single-dose studies, mice (acute toxicity category II) appear more sensitive than rats (category IV). Clinical signs of neurotoxicity were exhibited in both mice (decreased motor activity, tremors, and deep respirations at 50 milligram/kilogram (mg/kg)) and rats (transient signs of decreased arousal, motor activity, and locomotor activity at 100 mg/kg) 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. In a developmental neurotoxicity study in rats, decreased body weights, body weight gains, motor activity, and acoustic startle response amplitude (females) were seen in offspring at doses lower than those resulting in maternal toxicity. Although the NOAELs were similar for the subchronic and chronic feeding studies in the rat, a greater spectrum of effects was observed in the chronic study (decreased body weight, body weight gain, and food consumption plus additional observations in the liver, ovary, and kidney) versus the subchronic study (effects only on body weight and food consumption). In the rat, administration via the oral route appears to be more toxic than via the dermal route. In longer term studies, dogs exhibited clinical signs of anemia. The only observed effects in mice following chronic dietary administration were increases in vocalization and decreases in body weight and body weight gain. Clothianidin has been classified as not likely to be carcinogenic to humans.

There was no evidence of increased quantitative or qualitative susceptibility of rat or rabbit offspring in developmental studies; however, increased quantitative susceptibility of rat pups was seen in both the reproduction and developmental neurotoxicity studies. The degree of concern for both of these studies is low because the observed effects are well characterized, and there are clear NOAELs and LOAELs. The NOAEL for the effects of concern identified in the reproduction study (decreased mean body weight gain and absolute thymus weights in pups, delayed sexual maturation, and an increase in still births) is the basis for the endpoint selected for the chronic dietary and short-term, intermediate-term and long-term non-dietary risk assessments.

In adult rats, a guideline immunotoxicity study shows no clothianidin-mediated immunotoxicity at doses lower than those resulting in generalized signs of toxicity (e.g., decreases in body weight); however, it cannot be concluded that a similar lack of effects will occur in offspring. 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 2–generation reproduction study to these effects, a developmental immunotoxicity (DIT) study has been required.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day–26/p30948.htm*.

A summary of the toxicological endpoints for clothianidin used for human risk assessment can be found at *http://www.regulations.gov* in document ''Clothianidin: Human Health Risk Assessment for Proposed Use on Sugar Beet'' at pages 18–20 in docket ID number EPA–HQ–OPP–2007–0280.

C. Exposure Assessment

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

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

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The acute assessment is based on maximum residues of clothianidin observed in clothianidin and thiamethoxam field trials and assumes 100 percent crop treated (%CT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. The chronic assessment is based on average residues from clothianidin and thiamethoxam field trials and assumes 100% CT.

iii. *Cancer*. Because clothianidin is not expected to pose a cancer risk, a quantitative dietary exposure assessment for the purposes of assessing cancer risk was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA 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. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of 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% crop treated. 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 in Unit III. 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 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 environmental fate 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 estimated to be 7.29 parts per billion (ppb) for surface water and 5.84 ppb for ground water. The EECs for chronic exposures are estimated to be 1.35 ppb for surface water and 5.84 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 7.29 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 5.84 ppb was used to access the contribution to drinking 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 the following residential non-dietary sites: Turfgrass. EPA assessed residential exposure using the following 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–2007–0280, pages 26 through 27).

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Clothianidin is a member of the neonicotinoid class of pesticides and is a metabolite of another neonicotinoid, thiamethoxam. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events (EPA, 2002). Although clothianidin and thiamethoxam bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for clothianidin, thiamethoxam, and the other neonicotinoids are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including aphids and leafhoppers, compared to mammals. While the insecticidal action of the neonicotinoids is neurotoxic, the most sensitive regulatory endpoint for clothianidin is based on unrelated effects in mammals, including changes in body and thymus weights, delays in sexual maturation, and still births. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (e.g., testicular tubular atrophy with thiamethoxam; mineralized particles in thyroid colloid with imidaclopid). Thus, there is currently no evidence to indicate that neonicotinoids share common mechanisms of toxicity, and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the neonicotinoids. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism released by EPA's Office of Pesticide Programs on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

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 (''10X'') 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 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. 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 FQPA safety factor value based on the use of traditional UFs 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 2–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 2–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 74,800 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 database, 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

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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 45% of the aPAD for the population group (children 1–2 years old) receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clothianidin from food and water will utilize 16% of the cPAD for the population group (children 1–2 years old). Based on the use pattern, chronic residential exposure to residues of clothianidin is not expected.

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

Clothianidin is currently registered for use(s) that could result in short-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- 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 LOC 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, or to infants and children from aggregate exposure to clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate liquid chromotography/mass spectrometry/mass spectrometry (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 reviewed by EPA's Analytical Chemistry Laboratory (ACL), approved for tolerance enforcement, and forwarded to FDA for inclusion in PAM Volume II.

B. International Residue Limits

There are no established or proposed Canadian, Mexican, or Codex maximum residue limits (MRLs) for clothianidin residues on sugar beet commodities.

V. Conclusion

Therefore, the tolerance is established for residues of (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, in or on beet, sugar, roots at 0.02 ppm, beet, sugar, molasses at 0.05 ppm and beet, sugar, dried pulp at 0.03.

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, 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) 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 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: January 22, 2008.

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 the following commodities to the table in paragraph (a) to read as follows:

§ 180.586 Clothianidin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Beet, sugar, dried pulp ...	0.03
Beet, sugar, molasses	0.05
Beet, sugar, roots	0.02
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