ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0923; FRL–8809–4]

Exemption from the Requirement of a Tolerance; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical amendmemt.

SUMMARY: EPA issued a final rule in the **Federal Register** of June 3, 2009, concerning minor technical revisions of certain commodity terms listed under 40 CFR part 180, subpart D. The fungal active ingredient *Aspergillus flavus* NRRL 21882 was inadvertently revised. This document is being issued to amend the section to include text that was omitted.

DATES: This final rule is effective February 10, 2010.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008-0923. All documents in the docket are listed in the docket index available in *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: *For 40 CFR 180.1254 only contact:* Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460–0001; telephone number: (703) 308–8097; fax number: (703) 308–7026; e-mail address: *bacchus.shanaz@epa.gov*.

For other matters regarding EPA–HQ–OPP–2008–0923: Stephen Morrill, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460–0001; telephone number: (703) 308–8319; fax number: (703) 308–7026; e-mail address: *morrill.stephen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What Does this Technical Amendment Do?

This technical amendment revises § 180.1254 to reinstate text that was inadvertently omitted in a final rule that was published in the **Federal Register** of June 3, 2009 (74 FR 26527) (FRL–8417–9). The June 3, 2009 final rule revised § 180.1254, however; the revision omitted text which which had been added as paragraph (b) in a final rule published in the **Federal Register** on October 1, 2008 (73 FR 56995).

III. Why is this Technical Amendment Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), (5 U.S.C. 553(b)(3)(B)), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical correction final without prior proposal and opportunity for comment, because the omission was the result of clerical error and was neither proposed nor commented upon. Notice and comment is therefore unnecessary.

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

No. This action only corrects the omission for a previously published final rule and does not impose any new requirements. EPA's compliance with the statutes and Executive orders for the underlying rule is discussed in Unit III. of the final rule published on June 3, 2009 (74 FR 26527).

V. 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 21, 2010.

Keith A. Matthews,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

■ Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

Authority: 321(q), 346a and 371.

■ 2. Section 180.1254 is revised to read as follows:

§ 180.1254 Aspergillus flavus NRRL 21882; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* NRRL 21882 on peanut; peanut, hay; peanut, meal; and peanut, refined oil.

(b) An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* NRRL 21882 on corn, field, forage; corn, field, grain; corn, field, stover; corn, field, aspirated grain fractions; corn, sweet, kernel plus cob with husk removed; corn, sweet, forage; corn, sweet, stover; corn, pop, grain; and corn, pop, stover.

[FR Doc. 2010–2655 Filed 2–9–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0289; FRL–8809–9]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetamiprid in

or on fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; and tea, dried. It additionally establishes tolerances with regional registrations on clover, forage and clover, hay. Finally, this regulation deletes an existing individual tolerance in or on grape, as it will be superseded by inclusion in subgroup 13-07F. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 10, 2010. Objections and requests for hearings must be received on or before April 12, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0289. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access electronically the OPPTS harmonized test guidelines referred in this document, please go to *http//www.epa.gov/oppts* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0289 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 12, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0289, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of August 19, 2009 (74 FR 41898) (FRL–8426–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7544) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.578 be amended by establishing a tolerance for residues of the insecticide acetamiprid, *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine, in or on fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.35 parts per million (ppm); and tolerances with regional restrictions in or on clover, forage at 0.10 ppm; clover, hay at 0.01 ppm; and tea at 50 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Nippon Soda Co., Ltd., 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.

Based upon review of the data supporting the petition, EPA has determined that the petitioned-for tolerance with regional registrations on tea should be established as a tolerance with no U.S. registrations. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is

reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of acetamiprid on fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.35 ppm; tea, dried at 50.0 ppm; clover, forage at 0.10 ppm; and clover, hay at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acetamiprid is moderately toxic via the oral route of exposure and is minimally toxic via the dermal and inhalation routes of exposure. It is not an eye or skin irritant, nor is it a dermal sensitizer. Acetamiprid does not appear to have specific target organ toxicity. Generalized toxicity was observed as decreases in body weight, body weight gain, food consumption and food efficiency in all species tested. Generalized liver effects were also observed in mice and rats (hepatocellular vacuolation in rats and hepatocellular hypertrophy in mice and rats).

In the rat developmental study, fetal shortening of the 13th rib was observed at the same dose level that produced maternal effects (reduced body weight and body weight gain and increased liver weights). No developmental effects were observed in the rabbit at doses that reduced maternal body weight and food consumption. Effects in pups in the 2-generation rat reproduction study included delays in preputial separation, vaginal opening and pinna unfolding as well as reduced litter size, decreased pup viability and weaning indices; offspring effects observed in the developmental neurotoxicity (DNT) study included decreased body weight and body weight gains, decreased pup viability and decreased maximum auditory startle response in males. These effects were seen in the presence of less severe effects (decreased body weight and body weight gain) in the maternal animals.

In the acute neurotoxicity study, male and female rats displayed decreased motor activity, tremors, walking and posture abnormalities, dilated pupils, coldness to the touch and decreased grip strength and foot splay at the highest dose tested (HDT). There was a decrease in the auditory startle response in male rats at the HDT in the DNT; additionally, tremors were noted in female mice at the HDT in the subchronic feeding study.

Based on acceptable carcinogenicity studies in rats and mice, EPA has determined that acetamiprid is "not likely to be carcinogenic to humans." This determination is based on the absence of a dose-response or statistical significance for the increased incidence in mammary adenocarcinomas observed in the rat carcinogenicity study, as well as the lack of evidence of carcinogenic effects in the mouse cancer study. Acetamiprid tested positive as a clastogen in an *in vitro* mammalian chromosome aberration assay in Chinese hamster ovary cells. There was no sign of mutagenicity in other mutagenicity studies for acetamiprid.

Specific information on the studies received and the nature of the adverse effects caused by acetamiprid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "*Acetamiprid*: *Human Health Risk Assessment for Proposed Food Uses on Clover Grown for Seed, Small Vine Climbing Fruits, except Kiwifruit, Subgroup 13-07F, Greenhouse Grown Tomatoes and Tea*," at pages 57-61 in docket ID number EPA–HQ–OPP–2009–0289.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for acetamiprid used for human risk assessment can be found at *http://www.regulations.gov* in the document "*Acetamiprid: Human Health Risk Assessment for Proposed Food Uses on Clover Grown for Seed, Small Vine Climbing Fruits, except Kiwifruit, Subgroup 13-07F, Greenhouse Grown Tomatoes and Tea*," at pages 25-26 in docket ID number EPA–HQ–OPP–2009–0289.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to acetamiprid, EPA considered exposure under the petitioned-for tolerances as well as all existing acetamiprid tolerances in 40 CFR 180.578. EPA assessed dietary exposures from acetamiprid in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the

possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA utilized maximum percent crop treated (PCT) data for several commodities and 100 PCT for all proposed uses; anticipated residues derived from field trial data for apples, broccoli, cabbage, celery, grapefruit, grapes, lettuce, oranges, pears, peppers, spinach, tomatoes, stone fruit and cucurbit vegetables; tolerance-level residues for livestock commodities; and empirical processing factors for apple juice, orange juice, grapefruit juice, raisins, dried prunes, tomato paste and tomato puree. Dietary Exposure Evaluation Model (DEEM) default processing factors were used for all other processed commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA utilized average PCT data for several commodities and 100 PCT for all proposed uses, tolerance-level residues for all commodities and empirical processing data for grape juice and raisins. DEEM default processing factors were used for all other processed commodities.

iii. *Cancer*. Based on the evidence discussed in Unit III.A., EPA has determined that acetamiprid is "not likely to be carcinogenic to humans." Therefore, a quantitative exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and 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 require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute assessment, EPA used maximum PCT information as follows:

Apples at 30%; broccoli at 15%; cabbage at 10%; cauliflower at 15%; celery at 45%; cotton at 5%; grapefruit at 5%; lettuce at 20%; oranges at 5%; peaches at 2.5%; pears at 60%; peppers at 5%; potatoes at 2.5%; pumpkins at 2.5%; spinach at 15%; and squash at 2.5%.

For the chronic assessment, EPA used average PCT information as follows:

Apples at 20%; broccoli at 5%; cabbage at 5%; cauliflower at 10%; celery at 25%; cotton at 5%; grapefruit at 2.5%; lemons at 5%; lettuce at 10%; oranges at 2.5%; peaches at 1%; pears at 35%; peppers at 2.5%; potatoes at 2.5; pumpkins at 1%; spinach at 5%; and squash at 2.5%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, 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 b and c, 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 reliable information on the regional consumption of food to which acetamiprid may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetamiprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetamiprid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of acetamiprid for surface water are estimated to be 20.1 parts per billion (ppb) for acute exposures and 4.9 ppb for chronic exposure. For ground water, the EDWC is 0.0016 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 20.1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of 4.9 ppb was used to assess 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).

Acetamiprid is currently registered for use in indoor and outdoor residential settings, including crack and crevice applications on carpet and hard surfaces and applications to residential turf. EPA assessed residential exposures for adults applying bait and gel products; for postapplication exposure for adults (from short-term dermal exposure) and toddlers (from short-term dermal and incidental exposure) following indoor crack and crevice treatments; and postapplication exposure for adults (from short- and intermediate-term dermal exposure) and toddlers (from short-term and intermediate-term dermal and incidental oral exposures, including hand-to-mouth, object-to-mouth and incidental ingestion of soil) following treatments on turf.

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

Acetamiprid is a member of the neonicotinoid class of pesticides which also includes thiamethoxam, clothianidin, imidacloprid and several other active ingredients. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events. Although the neonicotinoids bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) 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 nAChRs, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including aphids and leafhoppers, compared to mammals. 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 imidacloprid). 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. In addition, acetamiprid does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of this tolerance action, EPA has not assumed that acetamiprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism released by EPA's Office of Pesticide Programs on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safty factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for acetamiprid includes rat and rabbit developmental toxicity studies, a 2-generation reproduction toxicity study in rats and a DNT study in rats. There was no evidence of quantitative or qualitative susceptibility of rat or rabbit fetuses following *in utero* exposure to acetamiprid in the developmental toxicity studies. However, both the DNT and 2-generation reproduction studies showed an increase in qualitative susceptibility of pups. Effects in pups in the reproduction study included delays in preputial separation, vaginal opening and pinna unfolding, as well as reduced litter size, decreased pup viability and weaning indices; offspring effects observed in the DNT study included decreased body weight and body weight gains, decreased pup viability and decreased maximum auditory startle response in males. These effects were seen in the presence of decreased body weight and body weight gain in the maternal animals, indicating increased qualitative susceptibility of fetuses and offspring to acetamiprid. Quantitative evidence of increased susceptibility was not observed in any study.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for acetamiprid is complete except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (OPPTS Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. Acetamiprid does not show any evidence of treatment-related effects on the immune system and the overall weight of evidence suggests that this chemical does not directly target the immune system. Therefore, EPA does not believe that conducting the immunotoxicity study will result in a dose less than the point of departure currently used for overall risk assessment, and an additional database uncertainty factor for potential immunotoxicity does not need to be applied.

ii. There is evidence of increased qualitative susceptibility of the young following *in utero* exposure to acetamiprid in the rat reproduction study. Additionally, a rat DNT study is available that shows evidence of increased qualitative susceptibility of offspring (a decrease in the auditory startle response in male rats) at the HDT. Therefore, EPA performed a degree of concern analysis to determine the level of concern for the effects observed when considered in the context of all available toxicity data, and to identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the acetamiprid risk assessment.

In considering the overall toxicity profile and the endpoints and doses selected for the acetamiprid risk assessment, EPA characterized the

degree of concern for the effects observed in the acetamiprid DNT and the 2-generation reproduction study as low, noting that there is a clear NOAEL for the offspring effects in both studies, and regulatory doses were selected to be protective of potential offspring effects in both the DNT and the 2-generation study. No other residual uncertainties were identified. Based on the available data, EPA determined that changes in motor activity, auditory startle reflex, learning and memory assessments and changes in the brain morphometrics can occur as the result of a single exposure at a critical junction during pregnancy or from multiple exposures throughout pregnancy and lactation. Therefore, the NOAEL for offspring effects observed in the DNT was selected as the dose for acute dietary exposures (co-critical with the acute neurotoxicity study), as well as short-term and long-term non-dietary risk assessment. Use of the DNT NOAEL is protective of effects seen in the 2-generation study (the NOAEL from the DNT is 10.0 milligrams/kilogram/day (mg/kg/day) and the NOAEL from the 2-generation study is 17.9 mg/kg/day). The chronic dietary study in rats yielded a lower long-term NOAEL (7.1 mg/kg/day) and was, therefore, used for assessing chronic dietary risk. EPA believes that the endpoints and doses selected for acetamiprid are protective of adverse effects in both offspring and adults; therefore, there are no residual concerns regarding effects in the young.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance-level residues or anticipated residues derived from reliable field trial data. The PCT estimates used in the dietary assessments were derived from valid and reliable data and are unlikely to be exceeded. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acetamiprid in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by acetamiprid.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetamiprid will occupy 43% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water will utilize 15% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of acetamiprid is not expected.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acetamiprid is currently registered for uses that could result in short-term and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to acetamiprid.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded that the combined short-term and intermediate-term food, water, and residential exposures aggregated result in an aggregate MOE of 270 for toddlers, the population group receiving the greatest combined short-term and intermediate-term risk (from the combined dermal and incidental oral postapplication exposures following indoor crack and crevice treatments). As the aggregate MOEs for short-term and intermediate-term exposure are greater than 100 (the LOC) for all population subgroups assessed, short-term and intermediate-term aggregate exposures to acetamiprid are not of concern to EPA.

4. *Aggregate cancer risk for U.S. population*. Based on the adequate cancer studies in rats and mice, EPA has concluded that acetamiprid is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The following adequate enforcement methodologies are available to enforce the tolerance expression: A gas chromatography with electron capture detection (GC/ECD) method and a high performance liquid chromatography with ultraviolet detection (HPLC/UV) method. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex or Mexican maximum residue limits (MRLs) established for residues of acetamiprid on commodities associated with this petition. EPA is establishing a tolerance on tea, dried at 50.0 ppm, which will harmonize with a Japanese MRL established for tea at 50 ppm. Canada has established a MRL for acetamiprid residues on grape at 0.20 ppm; however, the tolerance for subgroup 13-07F (including grape) cannot be harmonized with the Canadian MRL on grape at this time because field trial data shows residue levels for grape that are higher than 0.20 ppm.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA has determined that the petitioned-for tolerance with regional registrations on tea at 50 ppm should be established as a tolerance with no U.S. registrations on tea, dried at 50.0 ppm. At least one U.S. residue field trial study is required to establish a domestic registration on tea; however, no U.S. residue field trial data were submitted in support of the use of acetamiprid on tea. Therefore, the Agency has established a tolerance with no U.S. registrations on tea, dried at 50.0 ppm. EPA has also revised the tolerance expression in paragraphs (a)(1), (a)(2) and (c) of §180.578 to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of

acetamiprid not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of acetamiprid, *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine, in or on fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.35 ppm; tea, dried at 50.0 ppm; clover, forage at 0.10 ppm; and clover, hay at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 1, 2010.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.578 is amended by revising the introductory text in paragraphs (a)(1) and (a)(2); removing the entry for "Grape" from the table in paragraph (a)(1); alphabetically adding "Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F" and "Tea, dried" to the table in paragraph (a)(1); and revising paragraph (c). The added and revised text reads as follows:

§ 180.578 Acetamiprid; tolerances for residues.

(a) * * *

(1) Tolerances are established for residues of the insecticide acetamiprid *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine, including its metabolites and degradates, in or on the commodities in the table below as a result of the application of acetamiprid. Compliance with the tolerance levels specified below is to be determined by measuring only acetamiprid in or on the following commodities.

Commodity	Parts per million
* * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.35
* * * * *	
Tea, dried[1]	50.0
* * * * *	

[1]There are no U.S. registrations as of February 10, 2010, for the use of acetamiprid on dried tea.

(2) Tolerances are established for residues of the insecticide acetamiprid *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine, including its metabolites and degradates, in or on the commodities in the table below as a result of the application of acetamiprid. Compliance with the tolerance levels specified below is to be determined by measuring acetamiprid and *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-acetamidine in or on the following commodities.

* * * * *

(c) *Tolerances with regional registrations*. Tolerances with regional registrations are established for residues of the insecticide acetamiprid *N*1-[(6-chloro-3-pyridyl)methyl]-*N*2- cyano-*N*1-methylacetamidine, including its metabolites and degradates, in or on the commodities in the table below as a result of the application of acetamiprid. Compliance with the tolerance levels specified below is to be determined by measuring only acetamiprid in or on the following commodities.

Commodity	Parts per million
Clover, forage	0.10
Clover, hay	0.01

* * * * *

[FR Doc. 2010–2803 Filed 2–9–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0480; FRL–8807–8]

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, polymer with 1, 1′-methylene-bis-[4-isocyanatocyclohexane]; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, polymer with 1, 1′-methylene-bis-[4-isocyanatocyclohexane]; when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. UDL Laboratories, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, polymer with 1, 1′-methylene-bis-[4-isocyanatocyclohexane] on food or feed commodities.

DATES: This regulation is effective February 10, 2010. Objections and requests for hearings must be received on or before April 12, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0480. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Elizabeth Fertich, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8560; e-mail address: *fertich.elizabeth@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather 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 Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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–2009–0480 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 April 12, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2009–0480, 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