his or her designated representatives, no person or vessel is allowed within 100 yards of the Hawaii Superferry when it is underway, moored, position-keeping, or at anchor, unless authorized by the Captain of the Port or his or her designated representatives.

(4) Persons desiring to transit the security zone in this section may contact the Captain of the Port at telephone number (808) 927–0865 or on VHF channel 12 to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or his or her designated representatives. When conditions permit, the Captain of the Port, or his or her designated representatives, may permit vessels that are at anchor, restricted in their ability to maneuver, or constrained by draft to remain within the security zone in order to ensure navigational safety.

(e) *Enforcement.* Any Coast Guard commissioned, warrant, or petty officer, and any other Captain of the Port representative permitted by law, may enforce this temporary security zone.

Dated: November 21, 2007.

**Sally Brice-O'Hara,**

*Rear Admiral, U.S. Coast Guard, Commander, Fourteenth Coast Guard District.*

[FR Doc. 07–5872 Filed 11–26–07; 1:53 pm]

**BILLING CODE 4910–15–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2007–0105; FRL–8340–6]**

## Acetamiprid; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of acetamiprid in or on almond, hulls; fruit, stone, group 12, except plum, prune; nut, tree, group 14; pea and bean, succulent shelled, subgroup 6B; pistachio; plum, prune, dried; plum, prune, fresh; vegetable, cucurbit, group 9; and vegetable, legume, edible podded, subgroup 6A. Nippon Soda Co., Ltd. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective November 28, 2007. Objections and requests for hearings must be received on or before January 28, 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–2007–0105. 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:** Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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–2007–0105 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 January 28, 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–2007–0105, 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 September 15, 2004 (69 FR 55625) (FRL–7674–9), 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 4F6833) by Nippon Soda Co., Ltd., c/o Nisso America Inc., 220 East 42nd Street, Suite 3002, New York, NY, 10017. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on the cucurbit crop group at 0.5 parts per million (ppm); the stone fruit crop group, except plum, prune, fresh and dried at 1.2 ppm; plum, prune, fresh and dried at 0.3 ppm; the tree nut crop group, except almond hulls at 0.1 ppm; and almond hulls at 5.0 ppm. That notice included a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA–HQ–OPP–2004–0223, *http://www.regulations.gov*. Comments were received on the notice of filing from a private citizen. EPA's response to these comments is discussed in Unit IV.C below.

In the **Federal Register** of September 22, 2006 (71 FR 55468) (FRL–8091–9), 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 6F7051) by Nippon Soda Co., Ltd., c/o Nisso America Inc., 45 Broadway, Suite 2120, New York, NY, 10006. The petition requested that 40 CFR 180.578 be amended by establishing tolerances for residues of the insecticide acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on bulb vegetables crop group 3 at 3 ppm; edible podded legume vegetables, crop subgroup 6a at 0.5 ppm; succulent shelled pea and beans, crop subgroup 6b, at 0.5 ppm; and berries, crop group 13 at 1 ppm. The notice also announced the filing of amended pesticide petition 4F6833, requesting a tolerance for residues of acetamiprid in or on pistachio at 0.1 ppm in addition to the tolerances described in the preceding paragraph. That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available to the public in the docket ID Number EPA–HQ–OPP–2006–0733, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA is deferring to a later date the decision regarding the proposed tolerances for residues of acetamiprid on bulb vegetables crop group 3 and berry crop group 13. Based upon review of the data supporting the petitions, EPA has modified the tolerance levels and/or commodity terms for several of the other proposed tolerances. The reasons for these changes are explained in Unit V.

## 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 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 tolerance for residues of acetamiprid on Almond, hulls at 5.0 ppm; Fruit, stone, group 12, except plum, prune at 1.20 ppm; Nut, tree, group 14 at 0.10 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.40 ppm; Pistachio at 0.10 ppm; Plum, prune, dried at 0.40 ppm; Plum, prune, fresh at 0.20 ppm; Vegetable, cucurbit, group 9 at 0.50 ppm; and Vegetable, legume, edible podded, subgroup 6A at 0.60 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the 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 Stone Fruits, Cucurbit Vegetables, Tree Nuts, Berries, Strawberries, Bulb Vegetables, Legumes (Peas and Beans) and for Residential/Commercial Insecticide/Termiticide Uses*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as document ID number EPA–HQ–OPP–2007–0105–0003 in that docket.

The toxicity database for acetamiprid is complete. The acute toxicity data indicate that acetamiprid is moderately toxic via the oral route and is minimally toxic via the dermal and inhalation routes. Acetamiprid is not an eye or skin irritant, and it is not a dermal sensitizer. Based on subchronic, chronic, developmental and reproductive studies in rats, rabbits, and dogs, acetamiprid does not appear to have specific target organ toxicity. Generalized nonspecific toxicity was observed as decreases in body weight, body weight gain, food consumption and food efficiency when determined. Generalized effects were also observed in the liver in the form of hepatocellular hypertrophy in both mice and rats and hepatocellular vacuolation in the rat. The hepatocellular hypertrophy in mice is considered to be adaptive; it is likely that the

vacuolization in rats is more related to liver activity in response to the presence of the chemical rather than frank toxicity. Neurotoxicity was observed in the form of decreased locomotor activity in the acute neurotoxicity study in rats and as decreased auditory startle response in the developmental neurotoxicity study in rats.

Developmental studies showed no evidence of either quantitative or qualitative susceptibility of the rat or rabbit fetuses from *in utero* exposure. However, both the developmental neurotoxicity (DNT) study and the multi-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 early pup viability and weaning indices; offspring effects observed in the DNT study included decreased body weight and body weight gains, decreased early 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.

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.

*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/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* at pages 21–22 in the document *Acetamiprid: Human Health Risk Assessment for Proposed Food Uses on Stone Fruits, Cucurbit Vegetables, Tree Nuts, Berries, Strawberries, Bulb Vegetables, Legumes (Peas and Beans) and for Residential/Commercial Insecticide/Termiticide Uses* in docket ID number EPA–HQ–OPP–2007–0105.

*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 to acetamiprid, 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 relied upon anticipated residues derived from field trial data for certain commodities (apples; broccoli; cabbage, celery; grapefruit; grapes; lettuce; oranges; pears; peppers; spinach; tomatoes; stone fruits; and cucurbits) and assumed residues were present at tolerance levels in all other commodities. EPA also relied on percent crop treated (PCT) information for some of the currently registered commodities (apples, broccoli , celery, lettuce, pears, grapefruit, grapes, oranges, peppers, spinach and tomatoes) but assumed 100 PCT for all of the new 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 assumed all foods for which there are tolerances or for which tolerances are being established contain tolerance-level residues. EPA relied on PCT information for two currently registered crops (apples and oranges) but assumed 100 PCT for all other commodities.

iii. *Cancer.* As noted above, EPA has determined that acetamiprid is not likely to be carcinogenic to humans. Therefore, an exposure assessment for use in a quantitative cancer risk assessment 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 pursuant to section 408(f)(1) of FFDCA 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 section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

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:

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 such pesticide residue.

b. The exposure estimate does not underestimate exposure for any significant subpopulation group.

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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

For the acute assessment, maximum PCT estimates were used for the following commodities: Apples (15%),

broccoli (5%), celery (15%), lettuce (10%), pears (25%), and grapefruit, grapes, oranges, peppers, spinach and tomatoes, each at 2.5%.

For the chronic assessment, average PCT estimates were used for the following commodities: Apples (10%) and oranges (1%).

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available Federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of 5% except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available Federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of 5%. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed in this unit 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 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 lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for acetamiprid 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 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 environmental concentrations (EECs) of acetamiprid for acute exposures are estimated to be 20.1 parts per billion (ppb) for surface water and 1.6 ppb for ground water. The EECs for chronic exposures are estimated to be 4.9 ppb for surface water and 1.6 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 20.1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 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 the following residential non-dietary sites: As a pre- and post-construction termiticide/insecticide for use in subterranean or hard-to-reach structure components and building perimeters; and as a crack, crevice or spot application using gel bait formulations for control of ants and cockroaches in residential settings. EPA assessed residential exposure using the following assumptions: The pre- and post-construction termiticide/insecticide uses of acetamiprid are limited to licensed Pest Control Operators (PCOs); therefore, homeowner handler exposures are not expected to occur. Nor are post-application exposures of adults or children expected as a result of these uses, since applications are limited to subterranean or hard-to-reach structure components and building perimeters. EPA has determined that short-term and intermediate-term dermal exposure of residential handlers may occur from use of the gel bait formulations in residential settings; however, due to the low vapor pressure of acetamiprid and its formulation as a gel, inhalation exposure of handlers is not expected. Post-application exposures of adults and children from this use are expected to be negligible for the following reasons: (i) Homeowners are unlikely to revisit the crack, crevice or spot where the gel bait has been applied, thereby minimizing potential exposure; (ii) inhalation exposure is expected to be minimal due to acetamiprid's low vapor pressure and its formulation as a gel; and (iii) the gel bait products contain a bittering agent which is used to prevent ingestion by children and animals, thereby further reducing potential for incidental oral exposures of children. For these reasons, EPA assessed only residential handler dermal exposures from the gel bait uses of acetamiprid.

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 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. 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. 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 more 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 EPA's website at *http://www.epa.gov/pesticides/cumulative*.

*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*. The pre- 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 multi-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 early pup viability and weaning indices; offspring effects observed in the DNT study included decreased body weight and body weight gains, decreased early 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.

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, the toxicology database is complete, 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 even 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 intermediate-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 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.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for acetamiprid is complete.

ii. There is no evidence that acetamiprid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. Although there is qualitative evidence of increased susceptibility in the multi-generation reproduction study and in the DNT study, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of acetamiprid. The degree of concern for pre- and/or postnatal toxicity is low.

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 assessment were derived from valid, reliable Federal and private market survey data and are unlikely to be exceeded. Conservative ground and surface water modeling estimates were used to assess exposures to acetamiprid from drinking water; and residential, non-dietary exposure of infants and children to acetamiprid is not expected to occur. EPA believes these assessments will not underestimate the exposure and risks posed by acetamiprid.

*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 acetamiprid will occupy 35% 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 exposure to acetamiprid from food and water will utilize 35% of the cPAD for children 1 to 2 years old, the population group with greatest exposure. Based on the use pattern, chronic residential exposure to residues of acetamiprid is not expected.

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

Acetamiprid is currently registered for use 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 acetamiprid. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 900 for adults 20 to 49 years old and 930 for adults 50 years and older who apply gel bait acetamiprid products for ant and cockroach control.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Acetamiprid is currently registered for use that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for acetamiprid. Since the short-term and intermediate-term dermal exposures and endpoints for acetamiprid are the same, intermediate-term aggregate MOEs for adult residential handlers are the same as the short-term aggregate MOEs reported above (900 to 930).

5. *Aggregate cancer risk for U.S. population*. EPA has classified acetamiprid as ''Not likely to be carcinogenic to humans. Acetamiprid is not expected to pose a cancer risk.

6. *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*

Adequate residue analytical methods are available for the enforcement of established and new tolerances for plant commodities (gas chromotography /electron capture detector and high performance liquid chromotography/ ultra violet detection (GC/ECD and HPLC/UV) and animal commodities (HPLC/UV)). 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, Canadian or Mexican maximum residue levels (MRLs) established on the commodities associated with these petitions.

### *C. Response to Comments*

Comments were received from a private citizen objecting to establishing these tolerances or any exemptions for acetamiprid or approval of its sale. The commenter objected to acetamiprid residues in food as well as EPA's reliance on animal testing on the basis that animal tests are inhumane and not relevant to human toxicity. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to **Federal Register** 70 FR 37686 (June 30, 2005), 70 FR 1354 (January 7, 2005), and 69 FR 63096 (October 29, 2004) for the Agency's response to these objections.

## V. Conclusion

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as follows: (1) PP 4F6833: Modified the commodity terms for stone fruit, tree nuts and cucurbit vegetables to agree with recommended commodity terms in the Office of Pesticide Program's Food and Feed Commodity Vocabulary (Fruit, stone, group 12, except plum, prune; Nut, tree, group 14; and Vegetable, cucurbit, group 9); and modified the commodity terms and established separate tolerances for Plum, prune, dried at 0.40 ppm and Plum, prune, fresh at 0.20 ppm (fresh) based on the field trial results showing different residues in the dried and fresh forms. (2) PP 6F7051: Revised the commodity terms and tolerance levels for edible podded legumes and succulent shelled peas and beans to read ''Vegetable, legume, edible podded, subgroup 6A'' at 0.60 ppm and ''Pea and bean, succulent shelled, subgroup 6B'' at 0.40 ppm. EPA revised these tolerance levels based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP).

EPA is deferring to a later date the decision regarding the proposed tolerances for residues of acetamiprid on bulb vegetables crop group 3 and berry crop group 13.

Therefore, tolerances are established for residues of acetamiprid, N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine, in or on Almond, hulls at 5.0 ppm; Fruit, stone, group 12, except plum, prune at 1.20 ppm; Nut, tree, group 14 at 0.10 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.40 ppm; Pistachio at 0.10 ppm; Plum, prune, dried at 0.40 ppm; Plum, prune, fresh at 0.20 ppm; Vegetable, cucurbit, group 9 at 0.50 ppm; and Vegetable, legume, edible podded, subgroup 6A at 0.60 ppm.

## VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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: November 14, 2007.

**Donald R. Stubbs,**

*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 alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

**§ 180.578 Acetamiprid; tolerances for residues.**

(a) *General.* * * *

(1) * * *

| Commodity | Parts per million |
|---|---|
| Almond, hulls | 5.0 |
| * * * | * * |
| Fruit, stone, group 12, except plum, prune | 1.20 |
| * * * | * * |
| Nut, tree, group 14 | 0.10 |
| Pea and bean, succulent shelled, subgroup 6B | 0.40 |
| Pistachio | 0.10 |
| Plum, prune, dried | 0.40 |
| Plum, prune, fresh | 0.20 |
| * * * | * * |
| Vegetable, cucurbit, group 9 | 0.50 |
| * * * | * * |
| Vegetable, legume, edible podded, subgroup 6A | 0.60 |
| * * * | * * |

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