ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0403; FRL–9340–7]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acetamiprid in or on food/feed handling establishments and soybeans. Nippon Soda Co., Ltd., c/o Nisso America, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 28, 2012. Objections and requests for hearings must be received on or before May 29, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0403. 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: Jennifer Urbanski, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0156; email address: *urbanski.jennifer@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 site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2011–0403 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 29, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0403, 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. Summary of Petitioned-For Tolerance

EPA has received two petitions for tolerances for the insecticide acetamiprid. In the **Federal Register** of March 29, 2011 (76 FR 17374) (FRL–8867–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7812) 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 acetamiprid, N 1-[(6-chloro-3-pyridyl)methyl]-N 2-cyano-N 1-methylacetamidine, including its metabolites and degradates, in or on food/feed handling establishments at 0.05 parts per million (ppm). That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

In the **Federal Register** of July 6, 2011 (76 FR 39358) (FRL–8875–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7844) 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 acetamiprid, N 1-[(6-chloro-3-pyridyl)methyl]-N 2-cyano-N 1-methylacetamidine, in or on soybean, seed at 0.02 ppm and soybean, hulls at 0.04 ppm. That notice referenced a summary of the petition prepared by

Nippon Soda Co., Ltd., the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petitions, EPA has revised the tolerance associated with use in food handling establishments to 0.01 ppm in all food/feed items other than those covered by a higher tolerance from use on growing crops. EPA has also revised the tolerance to 0.03 ppm in soybean, seed and has added a tolerance of 5.0 ppm for grain, aspirated fractions. The reason for this change is explained in Unit IV.D.

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 acetamiprid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acetamiprid 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 and vaginal opening 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.

In 4-week immunotoxicity studies performed in both sexes of rats and mice, no effects on the immune system were observed up to the highest dose, although significant reductions in body weight and body weight gain were noted at that dose.

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 New Uses on Soybean and in Food/Feed Handling Establishments'' at pages 29–34 in docket ID number EPA–HQ–OPP–2011–0403.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for acetamiprid human risk assessment is shown in Table 1 of this unit.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.10 mg/kg/day aPAD = 0.10 mg/kg/day	Developmental Neurotoxicity in Rat LOAEL = 45 mg/kg/day based on decreased early pup survival on PND 0–1, and decreased startle response on PND 20/60 in males. Acute Neurotoxicity Study in Rat. LOAEL = 30 mg/kg/day based on decreased locomotor activity.
Chronic dietary (All populations).	NOAEL= 7.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.071 mg/kg/day cPAD = 0.071 mg/kg/day	Chronic Toxicity/Oncogenicity Study in Rats. LOAEL = 17.5 mg/kg/day based on decreased body weight and body weight gains in females and hepatocellular vacuolation in males.
Incidental oral short- and intermediate-term (1 to 30 days and 1 to 6 months).	NOAEL = 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Neurotoxicity in Rat. LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0–1, and decreased startle response on PND 20/60 in males.
Dermal short- and intermediate-term (1 to 30 days and 1 to 6 months).	Dermal (or oral) study NOAEL = 10 mg/kg/day (dermal absorption rate = 10% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Neurotoxicity in Rat. LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0–1, and decreased startle response on PND 20/60 in males.
Inhalation short- and intermediate-term (1 to 30 days and 1 to 6 months).	Inhalation (or oral) study NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental Neurotoxicity in Rat. LOAEL = 45 mg/kg/day based on decreased body weight and body weight gains in offspring, decreased early pup survival on PND 0–1, and decreased startle response on PND 20/60 in males.
Cancer (Oral, dermal, inhalation).	Not likely to be carcinogenic to humans (2005 revised Agency cancer guidelines).		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 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. Such effects were identified for acetamiprid.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA performed acute analyses based on tolerance level residues and assumed 100% crop treated. Empirical processing factors were used for processed commodities unless such data were not available, in which case DEEM™ default processing factors from Version 7.81 were used.

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 performed chronic analyses based on tolerance level residues and assumed 100% crop treated. Empirical processing factors were used for processed commodities unless such data were not available, in which case DEEM™ default processing factors from Version 7.81 were used.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that acetamiprid does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for acetamiprid. Tolerance level residues and/or 100% CT were assumed for all food commodities.

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 95.2 parts per billion (ppb) for acute exposures and 26.6 ppb for chronic exposure. For ground water, the EDWC is 0.035 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 95.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 26.6 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 uses that could result in residential exposures: Indoor and outdoor residential settings, including crack and crevice and spray applications. Mattress treatments were also assessed as there is a pending application for this use. EPA assessed the following residential exposure scenarios: Exposure for adults (from short-term dermal and inhalation exposure) applying crack and crevice and mattress treatments; and postapplication exposure for adults (from short- and intermediate-term dermal and inhalation exposure) and for children 3–6 years old (from short- and intermediate-term dermal, inhalation and hand-to-mouth exposure) following crack and crevice and mattress treatments. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* 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 and vaginal opening, 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. With the exception of a subchronic inhalation study, the toxicity database for acetamiprid is complete. Currently, inhalation exposure is being assessed by

using hazard information from the developmental neurotoxicity study, which is an oral study. The inhalation risks estimated by this approach are very low. Application of a 10-fold factor to account for the uncertainty associated with this approach would not result in risk estimates of concern.

ii. Acetamiprid produced signs of neurotoxicity in the high dose groups in the acute and developmental neurotoxicity studies in rats. 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. However, no neurotoxic findings were reported in the subchronic neurotoxicity study. There was a decrease in the auditory startle response in the male rats in the DNT. Tremors in the high dose female mice in the subchronic feeding study were the only other potentially neurotoxic effects observed in the other studies. EPA has selected doses and endpoints for risk assessment that account for these neurological effects; therefore, the Agency has no residual concern regarding neurotoxicity with respect to being protective of human health.

iii. EPA determined that neither quantitative nor qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to acetamiprid was observed in either the developmental toxicity study in rat or rabbit. However, in the 2-generation reproduction study, qualitative evidence of increased susceptibility of rat pups was observed. While parental and offspring NOAELs and LOAELs are set at the same doses, the effects in the offspring (including decreased viability) are considered to be more severe than those observed in the parents (decreased body weight and decreased weight gain). In the DNT study, maternal and offspring effects were observed at the same dose. However, the offspring effects included decreased pup viability which is considered to be more severe than the maternal body weight effects. Therefore, EPA concluded that there was evidence of increased qualitative susceptibility to fetuses exposed *in utero* and/or during lactation in the DNT study. Quantitative evidence of increased susceptibility was not observed in any study.

Since there is evidence of increased qualitative susceptibility of the young following *in utero* exposure to acetamiprid in the rat reproduction study, and increased qualitative susceptibility to pups in the DNT study, 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.

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 study as low, noting that there is a clear NOAEL for the offspring effects and regulatory doses were selected to be protective of these effects. No other residual uncertainties were identified. EPA believes that the endpoints and doses selected for acetamiprid are protective of adverse effects in both offspring and adults.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure assessments were based on tolerance level residues and assumed 100% crop treated. Empirical processing factors were used for processed commodities unless such data were not available, in which case DEEM™ default processing factors from Version 7.81 were used. EPA made conservative (protective) assumptions in the ground water 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetamiprid will occupy 50% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water will utilize 33% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of acetamiprid is not expected.

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

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 350 for adults and 160 for children aged 3–5 years. Because EPA's level of concern for acetamiprid is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, 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

Adequate enforcement methodology (LC–MS/MS, Method #KP–216R0 and its variant #KP–216R1) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural

practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for acetamiprid.

C. Response to Comments

An anonymous citizen objected to the presence of any pesticide residues on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the FFDCA contemplates that tolerances greater than zero may be set when persons seeking such or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA has determined that the requested tolerance (0.02 ppm) for soybean seed is too low. Residues in field trials (maximum = 0.025 ppm) exceed the requested tolerance level and therefore the Agency has established a tolerance of 0.03 ppm for soybean seed using the Organization for Economic Cooperation and Development tolerance calculation procedures. Although there was no petitioned-for tolerance for aspirated grain fractions and residue data was not provided for this commodity, EPA determined that such a tolerance is needed. In processing studies, residues concentrated in soybean hulls by 1.65X, indicating the potential for concentration into aspirated grain fractions. In lieu of empirical data, the Agency used a theoretical concentration factor of 200X to derive a tolerance level for aspirated grain fractions of 5.0 ppm. EPA is establishing a tolerance at that level. The petitioned-for tolerance for food-feed handling establishments (0.05 ppm) has the potential to confound enforcement actions for field crops that have a tolerance for residues of acetamiprid of less than 0.05 ppm. Given the residue levels observed in the food-feed handling establishment study in conjunction with the exaggerated application rate in that study, residues of acetamiprid are not expected to exceed 0.01 ppm as a result of the requested use in such facilities. Therefore, the Agency has established a tolerance of 0.01 ppm in all food/feed items other than those covered by a higher tolerance from use on growing crops. EPA has also revised the tolerance expression in paragraphs (a)(1), (a)(2) and (c) to correct the name of the chemical to (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N*′-cyano-*N*-methylethanimidamide.

V. Conclusion

Therefore, tolerances are established for residues of acetamiprid, (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N*′-cyano-*N*-methylethanimidamide, in or on soybean, seed at 0.03 ppm; soybean, hulls at 0.04 ppm; grain, aspirated fractions at 5.0 ppm; and commodities treated in food/feed handling establishments at 0.01 ppm.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: March 16, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.578 is amended as follows:

■ i. Revising the introductory text of paragraphs (a)(1), (a)(2), and (c).

■ ii. Adding alphabetically the commodities ''Grain, aspirated fractions'', ''Soybean, hulls'' and ''Soybean, seed'' to the table in paragraph (a)(1).

■ iii. Adding paragraph (a)(3).

§ 180.578 Acetamiprid; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide acetamiprid (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, 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
* * * * *	
Grain, aspirated fractions	5.0
* * * * *	
Soybean, hulls	0.04
Soybean, seed	0.03
* * * * *	

* * * * *

(2) Tolerances are established for residues of the insecticide acetamiprid (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, 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 (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-ethanimidamide in or on the following commodities.

* * * * *

(3) A tolerances of 0.01 ppm is established for residues of the insecticide acetamiprid, including its metabolites and degradates, in or on all food/feed items (other than those covered by a higher tolerance in paragraph (a)(1) or (a)(2) of this section as a result of the use on growing crops) as a result of the application of acetamiprid in food/feed handling establishments. Compliance with the 0.01 ppm tolerance level is to be determined by measuring only acetamiprid (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide in or on the commodities.

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the insecticide acetamiprid (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, 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.

* * * * *

[FR Doc. 2012–7461 Filed 3–27–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Part 1572

[Amendment No. 1572–9]

Transportation Security Administration Postal Zip Code Change; Technical Amendment

AGENCY: Transportation Security Administration, DHS.

ACTION: Final rule.

SUMMARY: This rule is a technical change to correct a regulatory reference to TSA's postal zip code. This rule revises existing regulations to reflect organizational changes and it has no substantive effect on the public.

DATES: Effective March 28, 2012.

FOR FURTHER INFORMATION CONTACT: Devara Achuko, Office of the Chief Counsel, TSA–2, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6002; telephone (571) 227–2649; facsimile (571) 227–1378; email *devara.achuko@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Justification for Immediate Adoption

This action is being taken without providing the opportunity for notice and comment, and it provides for an effective date less than 30 days after publication in the **Federal Register**.

This rule relates only to agency organization, procedure, and practice. Therefore, under 5 U.S.C. 553(b)(3)(A), this rule is exempt from notice and comment rulemaking requirements. The changes made by the rule will have no substantive effect on the public; therefore, under 5 U.S.C. 553(d), this rule may become effective less than 30 days after publication in the **Federal Register**.

Background

Beginning December 17, 2008, the postal zip codes for TSA headquarters facilities in Virginia and Maryland changed to new zip codes that are unique to TSA to enhance the safety and security of incoming mail to the Department of Homeland Security (DHS) and its components. The physical locations of TSA's facilities, however, did not change. The new TSA zip code for Virginia addresses changed to 20598 and for Maryland addresses changed to 20588. TSA locations in Washington, DC continued to use their existing zip codes. In addition, the last four digits of the new zip code format (zip + 4) now represent an office's routing symbol.

Since 2008, through other rulemaking actions, TSA revised most sections of TSA regulations (chapter XII of title 49, Transportation, of the Code of Federal Regulations, parts 1500–1699) that contain TSA mailing addresses with outdated postal zip codes. The only remaining zip code that is out of date is § 1572.5(e)(2).

Technical Amendment

This document amends section 1572.5(e)(2) in order to make this editorial change to the zip code from ''22202–4220'' to ''20598–6019''. TSA makes no other changes to the section.

List of Subjects in 49 CFR Part 1572

Appeals, Commercial driver's license, Criminal history background checks, Explosives, Facilities, Hazardous materials, Incorporation by reference, Maritime security, Motor carriers, Motor vehicle carriers, Ports, Seamen, Security measures, Security threat assessment, Vessels, Waivers.

The Amendment

For the reasons set forth in the preamble, the Transportation Security Administration amends part 1572 of