



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0740; FRL-9936-12]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises existing tolerances with regional restrictions for residues of acetamiprid in or on clover, forage and clover, hay. Interregional Research Project Number 4 (IR-4) requested this tolerance action under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0740, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDNRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCFA 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-2014-0740 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 [insert date 60 days after date of publication in the **Federal Register**]. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0740, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, EPA/DC, (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL-9921-94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8307) by IR-4, IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.578 be amended by revising (increasing) tolerances for residues of the insecticide, acetamiprid (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanamide, including its metabolites and degradates, in or on clover, forage from 0.10 to 0.3 parts per million (ppm) and clover, hay from 0.01 to 1.5 ppm. That document referenced a summary of the petition prepared by Nisso America Incorporated, the registrant, which is available in the docket, <http://www.regulations.gov>. A 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 petition, EPA has modified the tolerance for clover, hay from what was requested. 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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 in acute lethality studies 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); the effects were considered to be adaptive. Other effects observed in the oral studies include amyloidosis of multiple organs in the mouse oncogenicity study, tremors in high

dose females in the mouse subchronic study, and microconcretions in the kidney papilla and mammary hyperplasia in the rat chronic/oncogenicity study. No effects were observed in a dermal toxicity study in rabbits.

In the rat developmental study, fetal shortening of the 13th rib was observed in fetuses at the same dose level that produced maternal effects (reduced body weight and body weight gain and increased liver weights). In the developmental rabbit study, no developmental effects were observed in fetuses at doses that reduced maternal body weight and food consumption. In the reproduction study, decreased body weight, body weight gain, and food consumption were observed in parental animals while significant reductions in pup weights were seen in the offspring in both generations. Also observed were reductions in litter size, and viability and weaning indices among F₂ offspring as well as significant delays in the age to attain vaginal opening and preputial separation. In the developmental neurotoxicity study, parental effects were limited to decreased body weight and body weight gains, while the offspring effects noted were decreased body weights and body weight gains, decreased pre-weaning survival, and decreased maximum auditory startle response. 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 were clinical signs (decreases auditory startle, tremors) noted in rats and mice in the developmental neurotoxicity (DNT) and subchronic mouse studies. However, no neurotoxic effects were seen in the subchronic neurotoxicity study in rats. No neuropathology was observed in the toxicology studies.

In 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.” The classification is based on (1) the absence of an increase in the incidence of tumors in a mouse carcinogenicity study; and (2) in a rat chronic/carcinogenicity study, the absence of a dose-response and the lack of a statistically significant increase in the mammary adenocarcinoma incidence by pair-wise comparison of the mid- and high- dose groups with the controls. There was no clear evidence of a mutagenic effect. Acetamiprid tested positive as a clastogen in an *in vitro* study but not in an *in vivo* study.

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 document, “Subject: Acetamiprid. Human Health Risk Assessment.....for Use of the Insecticide on Clover.....Interval (Regional Registration)” dated September 2, 2015 at pp. 42 in docket ID number EPA-HQ-OPP-2014-0740.

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 the NOAEL and the LOAEL are identified. 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 used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of June 19, 2013 (78 FR 36671) (FRL-9391-2). However, in this tolerance rule, an additional new use is considered spot-on treatments for dogs. This newly proposed spot-on dog treatment to control fleas, ticks, and mosquitoes has potential for long-term exposure in residential indoor settings; therefore, the Agency selected additional endpoints and POD for the following exposure/scenarios: (1) Long-term (> 6 months) incidental oral (hand-to-mouth in children) and (2) Long-term (> 6 months) dermal. The endpoints/PODs selected were the same for both scenarios, based on effects observed in a rat chronic toxicity/oncogenicity study. In the study, at the LOAEL of 17.5 milligram/kilogram/day (mg/kg/day), decreased body weight and body weight gains were noted in females and hepatocellular vacuolation were noted in males. The NOAEL in the study is 7.1 mg/kg/day. The level of concern (LOC) is 100, based on an interspecies uncertainty factor of 10X, an intra-species uncertainty factor of 10X, and an Food Quality Protection Act (FQPA) safety factor of 1X.

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 the *Dietary Exposure Evaluation Model* software with the *Food Commodity Intake Database* (DEEM-FCID), Version 3.16. This software uses 2003-2008 food consumption data from the US Department of Agriculture's (USDA's) *National Health and Nutrition Examination Survey, What We Eat in America* (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues in the assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used DEEM-FCID, Version 3.16 and food consumption data from the 2003–2008 USDA NHANES/WWEIA. As to residue levels in food, EPA assumed 100 PCT and tolerance-level residues in the assessment.

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 PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for acetamiprid. Tolerance-level residues and 100 PCT 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>.

EPA used the Food Quality Protection Act Index Reservoir Screening Tool (FIRST) and the Provisional Cranberry Model to generate surface water Estimated Drinking Water Concentrations (EDWCs) for use in the human health dietary risk assessment, while the Pesticide Root Zone Model for Groundwater (PRZM-GW) was used to generate groundwater EDWCs. The EDWCs of acetamiprid for acute exposures are 88.3 parts per billion (ppb) for surface water and 49.7 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 32.2 ppb for surface water and 45.0 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 88.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 45 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: Controlling a wide variety of indoor and outdoor insect pests using insecticide traps, crack and crevice treatments, soil treatments, and sprays. There is also a proposal to register acetamiprid for use by homeowners and commercial applicators as a monthly topical spot-on product for dogs only (not cats) to provide continuous protection against fleas, ticks, and mosquitoes. Residential exposure from proposed dog spot-on product is anticipated to result in dermal exposures for adult handlers. In addition, residential post-application dermal exposures are expected for adults and children 1 to 2 years old, and incidental oral exposures for children 1 to 2 years old. Inhalation exposure from the use of the spot-on product is considered negligible. Therefore, only dermal and incidental oral exposure were assessed for the proposed product.

Residential post-application exposures are expected to be short- (1 to 30 days), intermediate- (1 to 6 months) for the indoor treatments, and long-term (greater than 6 months) in duration from pet spot-on products. Residential handler exposure is assumed to be short-term due to the intermittent nature of homeowner spot-on applications (once-monthly treatment).

EPA assessed all these uses and conducted an aggregate residential exposure using the following assumptions:

Residential handler exposures: The Agency used short-term and intermediate-term dermal and inhalation exposure estimates to adult applicators from applications to mattresses, cracks and crevices in the aggregate risk assessment.

Post-application exposures: The Agency used short-term and intermediate-term dermal and inhalation exposure estimates to adults and children 1 to 2 years old from indoor applications (mattress treatment and crack and crevice treatments) and long-term dermal exposure estimates to adults and children 1 to 2 years old from contact with spot-on treated pets. In addition, the

Agency used short-term and intermediate-term hand-to-mouth exposure estimates to children 1-2 years old from indoor applications and long-term hand-to-mouth exposure estimates from contact with spot-on treated pets.

EPA combines risk values resulting from separate routes of exposure when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population, and if the hazard associated with the PODs is similar across routes. Residential post-application inhalation exposure is expected to be negligible from the proposed spot-on product; therefore, a quantitative assessment was not performed.

For children 1 to 2 years old, post-application dermal and incidental oral (hand-to-mouth) exposures were combined for short-, intermediate-, and long-term durations.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at:

<http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

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.”

EPA has not found acetamiprid to share a common mechanism of toxicity with any other substances, and acetamiprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetamiprid does not have 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCFA 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 Food Quality Protection Act Safety Factor (FQPA 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 pre- and post-natal toxicity databases for acetamiprid include developmental toxicity studies in the rat and rabbit, developmental neurotoxicity (DNT) study in rats and a 2-generation reproduction toxicity study in rats. There was no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses following *in utero* exposure to acetamiprid in the developmental toxicity studies. In the DNT and 2-generation reproduction studies there was no evidence of quantitative increased susceptibility observed. However, there was evidence of increased qualitative susceptibility of rat pups seen in the studies. In the DNT study in rats, although both maternal and offspring effects were seen at the same dose level, offspring animals were more severely affected. Decreased pre-weaning survival, and decreased maximum auditory startle response were observed in the presence of limited maternal toxicity (body weight effects). In the 2-generation reproduction study, effects observed were a decrease in mean body weight, body weight gain, and food consumption in the

parental animals, and significant reductions in body weights in pups (both generations). Also, reduction in litter size and viability and weaning indices were seen among F₂ offspring, as well as significant delays in the age to attain vaginal opening and preputial separation. These offspring adverse effects were more severe than the parental effects.

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

- i. The toxicology database for acetamiprid is complete.
- ii. Although there was evidence of increased qualitative susceptibility of the young in the DNT and 2-generation reproduction studies, there are clear NOAELs identified for the effects observed in the toxicity studies. Also, there was no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses in the developmental toxicity studies.
- iii. Acetamiprid produced signs of neurotoxicity in the high dose groups in the acute and developmental neurotoxicity studies in rats and the subchronic toxicity study in mice. However, no neurotoxic findings were reported in the subchronic neurotoxicity study in rats. Additionally, there are clear NOAELs identified for the effects observed in the toxicity studies. The doses and endpoints selected for risk assessment are protective and account for all toxicological effects observed in the database, including neurotoxicity.
- iv. EPA has used conservative assumptions in the exposure (food, drinking water, and residential) assessment, including the use of 100 PCT assumptions, tolerance-level residue values, and upper-bound estimates of potential exposure through drinking water. In addition, the residential exposure assessment was conducted such that residential exposure and risk will not be underestimated. The aggregate exposure and risk estimates considered are expected to over-

estimate the actual exposure and risk anticipated, based on the current and proposed use patterns; no risk estimates of concern were identified.

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 67% of the aPAD for children 1–2 years old, the population subgroup receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions discussed in this unit for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water will utilize 61% of the cPAD for children 1-2 years old, the population subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3., adult aggregate exposures reflect background exposure from food and water, plus long-term post-application dermal exposure from contact with dogs following spot-on treatment. For children 1-2 years old, long-term aggregate assessment reflects post-application dermal and hand-to-mouth (incidental) exposures from contact with spot-on treated dogs. The chronic dietary exposure and post-application pet spot-on residential exposure were aggregated and compared to the long-term POD. Adult and children long-term aggregate MOEs were 570 and 100, respectively, are ≥ 100 , and indicate that risk estimates are not of concern. The chronic dietary exposure estimates are highly

conservative, assuming tolerance-level residues and 100 PCT for all commodities. Therefore, EPA also considers the aggregate MOEs to be conservative estimates.

3. *Short- and Intermediate-term risk.* Short-term and intermediate aggregate exposure take 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. Toxicological endpoints and POD for assessing short- and intermediate-term risks associated with exposure to acetamiprid are identical. Therefore, separate assessments are not being conducted for these durations. Using the exposure assumptions described in this unit for short- and intermediate-term exposures which represent the combined short- and intermediate-term food, water, and residential exposures aggregate. Additionally, for adults, reflect dermal and inhalation exposures from applications to mattresses, cracks and crevices, and for children 1-2 years old short- and intermediate- term aggregate assessment reflects dermal, inhalation, and hand-to-mouth exposures from post-application exposures following indoor applications.

EPA concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs of 300 for adults and 110 for children. Both short- and intermediate- term aggregate MOEs are ≥ 100 , and indicate that risks are not of concern. The chronic dietary exposure estimates are highly conservative, assuming tolerance-level residues and 100 PCT for all commodities. Therefore, EPA also considers the aggregate MOEs to be conservative estimates.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, acetaminophen is classified as “not likely to be carcinogenic to human” and 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 acetaminophen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression including; 1) gas chromatography with electron capture detection (GC/ECD) and 2) high-performance liquid chromatography (HPLC) with tandem mass spectrometric detection liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS).

The 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; 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 FFDCFA section 408(b)(4). The Codex Alimentarius is a joint United Nations 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 MRLs for acetamiprid in or on clover, forage or clover, hay.

C. Response to Comments

One comment expressed concern generally for pesticide residues remaining on harvested food crops and potential human health concerns. The commenter further states that “it is the responsibility of our government to protect American consumers for being harmed by the food they eat and that this action is a step in the right direction for establishing a safer, healthier food system....” The Agency agrees with these comments.

D. Revisions to Petitioned-For Tolerances

Available and relevant field trial data support a clover tolerance of 2.0 ppm, instead of the proposed tolerance of 1.5 ppm, in clover hay. The petitioner used residues in clover hay from all field trials which included pre-harvest intervals (PHIs) ranging from 27 to 63 days to calculate the proposed 1.5 ppm tolerance level. Since the proposed labeling stipulates a PHI of 30 days, EPA utilized only those residue data for clover hay collected at PHIs of 27-32 days as the input dataset for the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure, which yielded a clover hay tolerance level at 2.0 ppm.

In clover forage, the recommended tolerance level includes an additional significant figure (0.30 ppm rather than 0.3 ppm). This is in order to avoid the situation where rounding of a residue result to the level of precision of the tolerance expression would be considered non-violative (such as 0.34 ppm being rounded to 0.3 ppm).

V. Conclusion

Therefore, revised tolerances with regional restrictions 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 clover, forage at 0.30 ppm and clover, hay at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCFA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCFA section 408(d), 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 action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: October 29, 2015.

Susan Lewis,

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. In § 180.578, revise the tolerance for commodities in the table in paragraph (c) to read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

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(c) * * *

Commodity	Parts per million
Clover, forage	0.30
Clover, hay	2.0

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