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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0005; FRL-9959-90]

Acetamiprid; Pesticide Tolerances for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of acetamiprid in or on sugarcane, cane and sugarcane, molasses. This action is associated with the issuance of a crisis exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sugarcane. This regulation establishes maximum permissible levels for residues of acetamiprid in or on sugarcane, cane and sugarcane, molasses. The time-limited tolerances expire on December 31, 2019.

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-2017-0005, 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: Michael L. Goodis, 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: RDFRNotices@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 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 section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0005 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-2017-0005, 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, Environmental Protection Agency Docket Center (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/where-send-comments-epa-dockets>.

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(l)(6), is establishing time-limited tolerances for residues of acetamiprid, (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, in or on sugarcane, cane at 45 parts per million (ppm) and

sugarcane, molasses at 600 ppm. These time-limited tolerances expire on December 31, 2019.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption issued under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Acetamiprid on Sugarcane and FFDCA Tolerances

With EPA’s concurrence, the Louisiana Department of Agriculture and Forestry (LDAF) declared a crisis on June 17, 2016 necessitating the use of acetamiprid to control the West Indian canefly on sugarcane. At that time, LDAF stated that substantial yield losses had likely already occurred in sugarcane, and the West Indian canefly populations were moving into other crops nearby, posing significant risk to these crops as well.

The state agency asserted that an emergency condition exists in accordance with the criteria for approval of an emergency exemption, and issued a crisis exemption under FIFRA section 18 to allow the use of acetamiprid on sugarcane for control of West Indian canefly in Louisiana. After having reviewed the submission, EPA concurred that an emergency condition exists.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of acetamiprid in or on sugarcane cane and sugarcane molasses. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing

these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2019, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on sugarcane cane and sugarcane molasses after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether acetamiprid meets FIFRA's registration requirements for use on sugarcane, or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of acetamiprid by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons in any State other than Louisiana to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for acetamiprid, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with 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 expected as a result of this emergency exemption request and the time-limited tolerances for residues of acetamiprid on sugarcane, cane at 45 ppm and sugarcane, molasses at 600 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>.

The complete human health risk assessment for this action may be found at <http://www.regulations.gov> in the document “*Acetamiprid. Aggregate Human Health Risk Assessment for the Proposed FIFRA Section 18 Specific Exemption Use of the Insecticide on Sugarcane in Louisiana*” in the docket for ID number EPA-HQ-OPP-2017-0005. Additionally, 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 November 6, 2015 (80 FR 68772) (FRL-9936-12).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetamiprid, EPA considered exposure under the time-limited tolerances established by this action 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.* Acute effects were identified for acetamiprid. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey; What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed one hundred percent crop treated (PCT), and established and proposed tolerance level residues except as follows for sugarcane molasses. No residue data were available for sugarcane molasses, and residue data from sweet corn stover were used as a surrogate. The Agency determined it appropriate to translate corn stover data to

sugarcane, and the use patterns and maximum application rates for sweet corn and sugarcane are similar. The residue level of 240 ppm acetamiprid in sugarcane molasses and sugarcane molasses baby food was used for dietary risk assessment, which is less than the recommended tolerance of 600 parts per million (ppm). The 240 ppm level is based on the highest average field trial acetamiprid residue level of 20 ppm in sweet corn stover, multiplied by the average molasses processing factor of 12X. The average processing factor was derived from molasses processing data for 9 other pesticides, and results in a residue estimate that is more representative of potential levels which could occur in these commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA again used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. Residue levels in food were included as explained in Unit IV.B.1.i. of this document at tolerance-level residues for established and proposed tolerances and 240 ppm for sugarcane molasses and sugarcane molasses baby food. Additionally, 100 PCT was assumed.

iii. *Cancer.* Based on the data referenced in Unit IV.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. As detailed in the previous section, residues were estimated for sugarcane molasses and sugarcane molasses baby food based upon data for sweet corn and incorporating an

appropriate processing factor derived from processing data for 9 other pesticides in sugarcane. Tolerance level residues were used for the remainder of the commodities 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

EPA used the Food Quality Protection Act Index Reservoir Screening Tool and the Provisional Cranberry Model to generate 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 was used to generate groundwater EDWCs. The EDWCs of acetamiprid for acute exposures were estimated at 88.3 parts per billion (ppb) for surface water and 49.7 ppb for ground water. For chronic exposures (non-cancer assessment) the EDWCs were estimated at 32.2 ppb for surface water and 45.0 ppb for ground water. To assess dietary exposure contribution from drinking water, the higher acute EDWC of 88.3 ppb was used for acute assessment and for chronic exposures, the higher EDWC of 45 ppb was used. These modeled EDWCs were directly entered into the dietary exposure model.

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).

Residential exposures to acetamiprid could result from the currently registered uses of spot-on dog treatments, application to mattresses, and as crack and crevice treatments. For the dog spot-on products, EPA determined that short- and intermediate-term residential exposures may occur for residential (non-professional) applicators through dermal and inhalation routes; and short- intermediate- and long-term exposures may occur post-application for adults and children through dermal exposures, and also through incidental oral ingestion for children 1-2 years old. For the mattress, crack, and crevice treatments, short- and intermediate-term residential handler exposure may occur through dermal and inhalation routes; and short- and intermediate-term exposures may occur post application for adults and children through dermal and inhalation routes, and also through incidental oral ingestion for children 1-2 years old. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at:

<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

C. 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 SF 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 the second generation of 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 that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for acetamiprid is complete.
- ii. Although there was evidence of increased qualitative susceptibility of the young in the DNT and 2-generation reproduction studies in rats, 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. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in exposure assessments (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. These assessments will not underestimate the exposure and risks posed by acetamiprid.

D. 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 69% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Typically, EPA does not consider residential exposures when assessing

acute aggregate risk unless such exposures can be characterized as a series of single-day exposures. For acetamiprid, residential exposures are assessed as short- and intermediate-term exposures. Therefore, acute aggregate risk estimates for acetamiprid are equivalent to the acute dietary risk estimates which are not of concern.

2. *Chronic risk.* Using the exposure assumptions described in unit IV. for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water will utilize 62 % of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Dietary exposure from food and water, considered to be a background exposure level, is included in aggregate exposures for all population groups. Based on the explanation in Unit IV.B.3., adult aggregate chronic exposures also include long-term post-application dermal exposure from contact with dogs following spot-on treatment. For children 1 to 2 years old, aggregate chronic exposures also include long-term post-application dermal and incidental oral 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 390 and 100, respectively, and are above the level of concern of an MOE <100, indicating that risk estimates are not of concern. The chronic dietary exposure estimates are highly conservative, assuming tolerance-level residues for registered uses and 100 PCT for all commodities. Therefore, EPA also considers the aggregate MOEs to be conservative estimates.

3. Short- and Intermediate-term risk. **Acetamiprid** is currently registered for uses that could result in short/intermediate-term residential exposure. Short- (1 to 30 days) and intermediate-term (1-6 months) aggregate exposures take into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Toxicological endpoints and points of departure for assessing short- and intermediate-term risks (including oral, dermal, and inhalation routes of exposure) are identical for acetamiprid. Therefore, separate assessments were not conducted and one risk assessment addresses both of these durations. Using the exposure assumptions described in unit IV.B.3. for short/intermediate-term exposures, EPA has concluded the combined short/intermediate-term food, water, and residential exposures result in aggregate MOEs of 290 for adults and 110 for children. Because EPA's level of concern for acetamiprid is an MOE of <100, these MOEs do not indicate risks 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 classified as "not likely to be carcinogenic to humans" and is therefore 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.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression, including gas chromatography with electron capture detection (GC/ECD) for vegetables and non-citrus fruits, high performance liquid chromatography with ultraviolet detection (HPLC/UV) for citrus fruits only, and HPLC with tandem mass spectrometric detection (LC/MS/MS) for vegetables and non-citrus fruits.

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 FFDCA section 408(b)(4). The Codex 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 an MRL for acetamiprid on sugarcane.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of acetamiprid, (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, in or on sugarcane, cane at 45 ppm and sugarcane, molasses at 600 ppm. These tolerances expire on December 31, 2019.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA sections 408(e) and 408(l)(6). 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 in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This 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).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA submitted 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: March 16, 2017.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.578, revise paragraph (b) to read as follows:

§ 180.578 Acetamiprid; tolerances for residues.

* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the acetamiprid, (1E)-N-[(6-chloro-3-pyridinyl)methyl]-N'-cyano-N-methylethanimidamide, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified below is to be determined by measuring only acetamiprid. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Sugarcane, cane	45	12/31/2019
Sugarcane, molasses	600	12/31/2019

* * * *

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