

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 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 a MRL for chlorfenapyr in or on tea, dried.

C. Revisions to Petitioned-for Tolerances

EPA is establishing a tolerance for “tea, dried”, as opposed to “tea” as requested by the petitioner, for consistency with the Agency’s food and feed commodity vocabulary. In addition, EPA is amending the introductory text of paragraph (a)(1) to be consistent with the Agency’s policy for drafting the tolerance expression. These revisions reflect the language in FFDCA section 408(a)(3), which includes metabolites and degradates of a pesticide chemical under the same tolerance unless otherwise excluded, as well as providing greater clarity for measuring residues to determine compliance. These revisions do not substantively change the existing tolerances in paragraph (a)(3).

V. Conclusion

Therefore, a tolerance is established without U.S. registrations for residues of chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, in or on tea, dried at 70 parts per million.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA 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); Executive Order 13045, entitled “Protection of

Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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 FFDCA 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: December 18, 2017.

Michael Goodis,

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 § 180.513, revise paragraph (a)(1) to read as follows:

§ 180.513 Chlorfenapyr; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of chlorfenapyr, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only chlorfenapyr, 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile, in or on the commodity.

Commodity	Parts per million
Tea, dried ¹	70
Vegetable, fruiting, group 8–10 ..	1.0

¹ There are no U.S. registrations for Tea, dried as of January 26, 2018.

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[FR Doc. 2018–01487 Filed 1–25–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0498; FRL–9971–94]

Flonicamid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of

flonicamid in or on prickly pear, fruit and prickly pear, pads.

This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on prickly pear, fruit and prickly pear, pads. This regulation establishes a maximum permissible level for residues of flonicamid in or on these commodities. The time-limited tolerances expire on December 31, 2020.

DATES: This regulation is effective January 26, 2018. Objections and requests for hearings must be received on or before March 27, 2018, 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-2017-0498, 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: RDfRNtices@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. To access the OCSPP test guidelines referenced in this document electronically, please go to <https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp> and select "Test Methods and Guidelines."

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 EPA-HQ-OPP-2017-0498 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 March 27, 2018. 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-2017-0498, 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 <https://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(1)(6), is establishing time-limited tolerances for residues of insecticide flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG (N-(4-trifluoromethylnicotinoyl)glycine), calculated as the stoichiometric equivalent of flonicamid, in or on prickly pear, fruit at 1.5 parts per million (ppm) and prickly pear, pads at 1.5 ppm. These time-limited tolerances expire on December 31, 2020.

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 granted by EPA 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 Flonicamid on Prickly Pear, Fruit and Prickly Pear, Pads and FFDCA Tolerances

The California Department of Pesticide Regulation (DPR) requested a specific emergency exemption for the use of flonicamid on prickly pear cactus fruit (*Opuntia spp.*) and nopalitos (pads) to control cochineal (*Dactylopius opuntiae*) in Monterey County, California. Cochineal insects are sap-sucking, aggressive scale insects that are considered to be a major pest for prickly pear cactus. These insects damage the cactus plant by inserting their mouth parts into the cactus and feeding on the plant’s sap. The feeding site of the cactus begins to swell and discolor. Eventually, the outer pads of the plant will fall off and the entire cactus plant dies. Cochineal colonies were first observed in the Salinas Valley cactus plantations in 2003. Birds heavily feed on cactus fruit, and while feeding on cochineal infected plants, the birds can pick up the nymphs on their feet and aid in spreading of the population. In 2013 and 2015 reduced amounts of precipitation in Salinas, California caused the cochineal population to flourish and build to uncontrollable levels. Even though 2016 and 2017 received normal levels of rain, cochineal infestations have not been inhibited due to the amount of cochineal present and the ineffective control from registered alternatives. As a result, growers are experiencing significant damage to their prickly pear cactus crops.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of flonicamid on prickly pear, fruit and prickly pear, pads for control of cochineal in California.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of flonicamid in or on prickly pear, fruit and prickly pear, pads. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances 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, 2020, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on prickly pear, fruit and prickly pear, pads 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 flonicamid meets FIFRA’s registration requirements for use on prickly pear, fruit and prickly pear, pads 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 flonicamid by a State for special local needs under FIFRA section 24(c), nor does this tolerance by itself serve as the authority for persons in any State other than California 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 flonicamid, 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 flonicamid on prickly pear, fruit at 1.5 ppm and prickly pear, pads at 1.5 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>.

A summary of the toxicological endpoints for flonicamid used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 14, 2012 (77 FR 67771) (FRL-9368-7).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flonicamid, EPA considered exposure expected under the time-limited tolerances established by this action as well as all existing flonicamid tolerances in 40 CFR 180.613. EPA assessed dietary exposures from flonicamid in food as follows:

i. *Acute exposure.* No acute effects were observed at doses well above those

likely to be encountered; therefore, an endpoint was not selected, and a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA Survey. For the proposed section 18 use of flonicamid on prickly pear, fruit and pads, a dietary exposure assessment was not performed because there was no consumption reported for either commodity in NHANES/WWEIA. Due to the limited production and availability of prickly pear commodities, any increase in flonicamid dietary exposure from consumption of prickly pear commodities is expected to be insignificant compared to the flonicamid exposures pursuant to existing tolerances for flonicamid on various fruits and vegetables (40 CFR 180.613) which are produced in significantly greater quantities than prickly pear. These existing flonicamid tolerances are based on conservative (protective) exposure assumptions including use of tolerance level residues for all crops and 100% of the crops were treated. Therefore, any additional chronic risks from exposures of residues of flonicamid on prickly pear would likely be accounted for through the conservative assumptions underlying the existing tolerances.

iii. *Cancer.* As discussed in Unit III.B. of the final rule published in the **Federal Register** of November 14, 2012 (77 FR 67771), EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to flonicamid. For the same reasons discussed in Unit IV.B.ii., regarding chronic exposure, EPA believes that any additional cancer risks from exposures of residues of flonicamid on prickly pear would likely be accounted for through the conservative assumptions underlying the existing tolerances.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flonicamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flonicamid. 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>.

Based on the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flonicamid for chronic exposures for non-cancer assessments are estimated to be 0.94 parts per billion (ppb) for surface water and 9.92 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 9.92 ppb was used as the flonicamid contribution from 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). Flonicamid is not registered for any specific use patterns that would result in residential exposure. 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 flonicamid to share a common mechanism of toxicity with any other substances, and flonicamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flonicamid 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 prenatal and postnatal toxicity database for flonicamid includes prenatal developmental toxicity studies in rats and rabbits and, a multi-generation reproduction toxicity study in rats. There is no evidence that flonicamid results in increased susceptibility (qualitative or quantitative) *in utero* in rats or rabbits in the prenatal developmental studies or in young rats in the multi-generation reproduction study. No developmental effects were seen in rabbits. In the multi-generation reproduction study, developmental delays in the offspring (decreased body weights, delayed sexual maturation) were seen only in the presence of prenatal toxicity (kidney and blood effects). Also, there are clear NOAELs and LOAELs for all effects. The degree of concern for prenatal and/or postnatal susceptibility is, therefore low due to the lack of evidence of qualitative and quantitative susceptibility.

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, except where assessing risk from inhalation exposure as discussed below. Those decisions are based on the following findings:

i. The toxicity database for flonicamid is essentially complete, except for an outstanding subchronic 28-day inhalation study. In the absence of a subchronic inhalation study, EPA has retained a 10X FQPA SF to assess risk from inhalation exposure, although at present, residential inhalation exposure is not expected from existing or pending uses of flonicamid.

ii. There is no indication that flonicamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that flonicamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessment was based on 100 PCT, tolerance-level residues and where applicable, default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to flonicamid in drinking water. These assessments will not underestimate the exposure and risks posed by flonicamid.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effects were observed to result from single oral exposures at doses well above those likely to be encountered, and therefore, flonicamid is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flonicamid from food and water will utilize 59% of the cPAD for (children 1–2 years old), the population group receiving the greatest exposure. There are no residential uses for flonicamid.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Flonicamid is not registered for any use patterns that would result in short term residential exposures.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Flonicamid is not registered for any use patterns that would result in intermediate-term residential exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the information referenced in Unit IV.A, EPA has

concluded that the cPAD is protective of possible cancer effects from flonicamid because, as noted in Unit IV.D.2, aggregate chronic exposure to flonicamid is below the cPAD.

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

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (FMC Method No. P–3561M, a liquid chromatography with tandem mass spectrometry (LC/MS/MS) method is available to enforce the tolerance expression for flonicamid and its metabolites in or on plant commodities. 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 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 a MRL for flonicamid.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG (N-(4-trifluoromethylnicotinoyl)glycine), calculated as the stoichiometric

equivalent of flonicamid, in or on prickly pear, fruit at 1.5 ppm and prickly pear, pads at 1.5 ppm. These tolerances expire on December 31, 2020.

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 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: December 28, 2017.

Michael L. Goodis,

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 § 180.613, revise paragraph (b) to read as follows:

§ 180.613 Flonicamid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide and its metabolites, TFNA (4-trifluoromethylnicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG (N-(4-trifluoromethylnicotinoyl)glycine), calculated as the stoichiometric equivalent of flonicamid, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Prickly pear, fruit	1.5	12/31/2020
Prickly pear, pads	1.5	12/31/2020

* * * * *

[FR Doc. 2018-01480 Filed 1-25-18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0254; FRL-9971-95]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of difenoconazole in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation removes several previously established tolerances that are superseded by this final rule. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). **DATES:** This regulation is effective January 26, 2018. Objections and requests for hearings must be received on or before March 27, 2018, 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-2016-0254, 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 Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC

20460-0001; 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 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 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-2016-0254 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 March 27, 2018. 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