B. Notice and Public Procedure

1. Executive Orders

The Commission is an independent regulatory agency under section 3(b) of Executive Order (''E.O.'') 12866 (Sept. 30, 1993), 58 FR 51735 (Oct. 4, 1993); E.O. 13563 (Jan. 18, 2011), 76 FR 3821 (Jan. 21, 2011); E.O. 13771 (Jan. 30, 2017), 82 FR 9339 (Feb. 3, 2017); E.O. 13777 (Feb. 24, 2017), 82 FR 12285 (Mar. 1, 2017); and E.O. 13132 (Aug. 4, 1999), 64 FR 43255 (Aug. 10, 1999).

The Commission has determined that this rulemaking does not have ''takings implications'' under E.O. 12630 (Mar. 15, 1988), 53 FR 8859 (Mar. 18, 1988).

The Commission has determined that these regulations meet all applicable standards set forth in E.O. 12988 (Feb. 5, 1996), 61 FR 4729 (Feb. 7, 1996).

2. Statutory Requirements

Although notice-and-comment rulemaking requirements under the Administrative Procedure Act (''APA'') do not apply to rules of agency procedure (5 U.S.C. 553(b)(3)(A)), the Commission invites members of the interested public to submit comments on this final rule. The Commission will accept public comment until December 9, 2019.

The Commission has determined that this rulemaking is exempt from the requirements of the Regulatory Flexibility Act (''RFA'') (5 U.S.C. 601 *et seq.*), because the proposed rule would not have a significant economic impact on a substantial number of small entities.

The Commission has determined that this rule is not a ''major rule'' under the Small Business Regulatory Enforcement Fairness Act (''SBREFA'') (5 U.S.C. 804(2)).

The Commission has determined that the Paperwork Reduction Act (''PRA'') (44 U.S.C. 3501 *et seq.*) does not apply because these rules do not contain any information collection requirements that require the approval of the OMB.

The Commission has determined that the Congressional Review Act (''CRA'') (5 U.S.C. 801 *et seq.*) does not apply because, pursuant to 5 U.S.C. 804(3)(C), these rules are rules of agency procedure or practice that do not substantially affect the rights or obligations of non-agency parties.

The Commission has determined that this rulemaking is not a major Federal action significantly affecting the quality of the human environment requiring an environmental assessment under the National Environmental Policy Act (''NEPA'') (42 U.S.C. 4321 *et seq.*).

The Commission is an independent regulatory agency, and as such, is not subject to the requirements of the Unfunded Mandates Reform Act (''UMRA'') (2 U.S.C. 1532 *et seq.*).

List of Subjects in 29 CFR Part 2700

Administrative practice and procedure, Mine safety and health, Penalties, Whistleblowing.

PART 2700—PROCEDURAL RULES

■ Accordingly, the interim rule amending 29 CFR part 2700, which was published at 78 FR 77354 on December 23, 2013, and corrected at 79 FR 3104 on January 17, 2014, is adopted as final without change.

Dated: November 1, 2019.

Marco M. Rajkovich, Jr.,

Chairman, Federal Mine Safety and Health Review Commission.

[FR Doc. 2019–24251 Filed 11–6–19; 8:45 am]

BILLING CODE 6735–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0357; FRL–10000–96]

Dinotefuran; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of dinotefuran in or on fuzzy kiwifruit. 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 fuzzy kiwifruit. This regulation establishes a maximum permissible level for residues of dinotefuran in or on this commodity. The time-limited tolerance expires on December 31, 2022.

DATES: This regulation is effective November 7, 2019. Objections and requests for hearings must be received on or before January 6, 2020 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–2019–0357, is available at *https://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 *https://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; 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 Publishing Office's e-CFR site at *https://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.*

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–2019–0357 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 January 6, 2020. 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–2019–0357, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://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 a time-limited tolerance for residues of dinotefuran, and its metabolites DN,1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, calculated as the stoichiometric equivalent of dinotefuran, in or on kiwifruit, fuzzy at 0.9 part per million (ppm). This time-limited tolerance expires on December 31, 2022.

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 Dinotefuran on Fuzzy Kiwifruit and FFDCA Tolerance

According to the Alabama Department of Agriculture and Industries (ADAI), in 2017 brown marmorated stink bug (BMSB) damage was observed in a small block of nursery stock plants. This observation alerted the staff at the kiwi nursery to the potential of BMSB for the 2018 crop season. ADAI claimed that in 2018, BMSB severely damaged the kiwifruit crop, making it unmarketable. ADAI estimated losses as high as 50% for 2018 and projected 2019 losses to be over $1.6 million without the use of this section 18 emergency exemption.

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 dinotefuran on fuzzy kiwifruit for control of brown marmorated stink bug in Alabama.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of dinotefuran in or on fuzzy kiwifruit. 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 this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2022, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on fuzzy kiwifruit 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 this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether dinotefuran meets FIFRA's registration requirements for use on fuzzy kiwifruit or whether a permanent tolerance 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 dinotefuran 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 Alabama to use this pesticide on the applicable crop under FIFRA section 18, absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for dinotefuran, 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 tolerance for residues of dinotefuran on kiwifruit, fuzzy at 0.9 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance 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 dinotefuran used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 10, 2013 (78 FR 21269) (FRL–9381–5).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dinotefuran, EPA considered exposure under the time-limited tolerance established by this action as well as all existing dinotefuran tolerances in 40 CFR 180.603. EPA assessed dietary exposures from dinotefuran in food as follows:

i. *Acute exposure.* Acute effects were identified for dinotefuran. 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 tolerance-level residues, corrected for additional residues which are of concern for risk assessment, default processing factors when appropriate, and 100% crop treated assumptions.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHANES/ WWEIA. As to residue levels in food, EPA assumed tolerance-level residues, corrected for additional residues which are of concern for the risk assessment, default processing factors when appropriate, and 100% crop treated assumptions.

iii. *Cancer.* Based on the data referenced in Unit IV.A., EPA has concluded that dinotefuran 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 dinotefuran. Tolerance level residues and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dinotefuran in drinking water. These simulation models take into account data on the physical, chemical, and fate/ transport characteristics of dinotefuran. 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 Tier 1 Rice Model, the estimated drinking water concentrations (EDWCs) for surface water are 269 parts per billion (ppb) for acute exposure and 257 ppb for chronic exposure. Based on the use on turf, ornamentals, and Christmas trees, the EDWCs for ground water are 154 ppb for acute exposure and 132 ppb for chronic exposure.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 269 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 257 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).

Dinotefuran is currently registered for uses that could result in short-term residential exposures: (Turf, ornamentals, indoor foggers, indoor broadcast, spot-ons, crack and crevice). Dinotefuran is also used on dogs, cats, and horses (spot-on and/or spray). The only potential post-application exposure pathway that was quantitatively assessed is the incidental oral exposure pathway for children 1 to less than 2 years old due to currently registered uses. The resulting margins of exposure (MOEs) range from 1,200 to 5,500,000 and are significantly greater than EPA's level of concern (LOC = 100). Residential exposure is not anticipated from the proposed use on kiwifruit; therefore, an updated residential exposure assessment was not conducted.

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 made a common mechanism of toxicity finding as to dinotefuran and any other substances and dinotefuran does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dinotefuran 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.* There was no evidence (qualitative or quantitative) of increased susceptibility of the young following *in utero* exposures to rats and rabbits and following pre- and post-natal exposure to rats for 2-generations.

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 dinotefuran is complete.

ii. The neurotoxic potential of dinotefuran has been adequately considered. Dinotefuran is a neonicotinoid and has a neurotoxic mode of pesticidal action. Consistent with the mode of action, changes in motor activity were seen in repeat-dose studies, including the subchronic neurotoxicity study. Additionally, decreased grip strength and brain weight were observed in the offspring of a multi-generation reproduction study albeit at doses close to the limit dose. For these reasons, a developmental neurotoxicity (DNT) study was required. The DNT study did not show evidence of a unique sensitivity of the developing nervous system; no effects on neurobehavioral parameters were seen in the offspring at any dose, including the limit dose.

iii. There is no evidence that dinotefuran 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 dietary food exposure assessments were performed based on 100% CT and tolerance-level residues corrected for additional residues of concern for risk assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dinotefuran in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by dinotefuran.

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 dinotefuran will occupy 11% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dinotefuran from food and water will utilize 5.2% of the cPAD for (children 1 to 2 years old) the population group receiving the greatest exposure. Based on the explanation in the unit regarding residential use patterns, chronic residential exposure to residues of dinotefuran is not expected.

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). Dinotefuran is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to dinotefuran.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 720 for children 1 to less than 2 years old from post-application hand-to-mouth exposures from fogger applications in indoor rooms or areas to control fleas. Although adults are expected to have short-term handler and post-application exposures to dinotefuran due to registered residential use patterns, quantitative dermal and inhalation assessments are not required since there was no dermal and inhalation hazard identified in the toxicity database. Therefore, the short-term aggregate assessment for adults is equivalent to the chronic dietary exposure and risk estimate for the most highly exposed adult population subgroup, adults 20 to 49 years old, and is not of concern (1.4% cPAD). Because EPA's level of concern for dinotefuran is an MOE of 100 or below, these MOEs are not of concern.

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).

Dinotefuran is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to dinotefuran.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 1,400 for children 1 to less than 2 years old. The recommended residential exposure estimates for use in the children 1 to less than 2 years old intermediate- and chronic/long-term aggregate assessment reflects post-application hand-to-mouth exposures from pet spot-on applications to small dogs. Although adults are expected to also have long-term post-application exposures to dinotefuran due to the pet spot-on treatments, quantitative dermal and inhalation assessments are not required since there was no dermal and inhalation hazard identified in the toxicity database and oral exposure is not anticipated for adults. Therefore, the intermediate- and chronic/long-term aggregate assessment for adults is equivalent to the chronic dietary exposure and risk estimate for the most highly exposed adult population subgroup, adults 20 to 49 years old, and is not of concern (1.4% cPAD). Because EPA's level of concern for dinotefuran is an MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of

evidence of carcinogenicity in two adequate rodent carcinogenicity studies, dinotefuran is not expected to pose a cancer risk to humans.

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 dinotefuran residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies (high performance liquid chromatography/tandem mass spectrometry (HPLC/MS/MS method for the determination of residues of dinotefuran, and the metabolites DN, and UF; an HPLC/ultraviolet (UV) detection method for the determination of residues of dinotefuran; and HPLC/MS and HPLC/MS/MS methods for the determination of DN and UF) are available to enforce the tolerance expression.

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 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 an MRL for residues of dinotefuran on kiwifruit, fuzzy.

VI. Conclusion

Therefore, a time-limited tolerance is established for residues of dinotefuran and its metabolites DN,1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, calculated as the stoichiometric equivalent of dinotefuran, in or on kiwifruit, fuzzy at 0.9 ppm. This tolerance expires on December 31, 2022.

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), nor is it considered a regulatory action under 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 in accordance with FFDCA sections 408(e) and 408(l)(6), 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).

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: October 25, 2019.

Daniel 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 § 180.603, add alphabetically an entry for ''Kiwifruit, fuzzy'' to the table in paragraph (b) to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration date
* * * * *		
Kiwifruit, fuzzy ...	0.9	12/31/2022
* * * * *		

[FR Doc. 2019–24268 Filed 11–6–19; 8:45 am]

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