

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: September 30, 2016.

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

#### § 180.681 Isofetamid; tolerances for residues.

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the fungicide, isofetamid (*N*-[1,1-dimethyl-2-[2-methyl-4-(1-methylethoxy)phenyl]-2-oxoethyl]-3-methyl-2-thiophenecarboxamide) 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
Caneberry sub-group 13-07A	4.0	12/31/2019
Bushberry sub-group 13-07B	5.0	12/31/2019

\* \* \* \* \*

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### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2015-0390; FRL-9951-92]

#### Pyridaben; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of the insecticide pyridaben in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 14, 2016. Objections and requests for hearings must be received on or before December 13, 2016, 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 HQ-EPA-OPP-2015-0390, 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; main telephone number: (703) 305-7090; email address: [RDfRNtices@epa.gov](mailto: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 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](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 HQ-EPA-OPP-2015-0390 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 December 13, 2016. 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 HQ-EPA-OPP-2015-0390, 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/contacts.html>.

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

## II. Summary of Petitioned-for Tolerance

In the **Federal Register** of Wednesday, August 26, 2015 (80 FR 51759) (FRL-9931-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E8363) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.494 be amended by establishing tolerances for residues of the insecticide pyridaben, [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] in or on

berry, low growing subgroup 13-07G, except cranberry at 2.5 ppm; cucumber at 0.5 ppm; fruit, citrus group 10-10 at 0.5 ppm; fruit, pome group 11-10 at 0.75 ppm; fruit, stone, group 12-12 at 2.5 ppm; fruit, small, vine climbing, subgroup 13-07F, except fuzzy kiwifruit at 1.5 ppm; and nut, tree, group 14-12 at 0.05 ppm. In addition, the petitioner requests removal of established tolerances under 40 CFR 180.494 in or on apple at 0.5 ppm; pear at 0.75 ppm; nut, tree, group 14 at 0.05 ppm; citrus (fruit) at 0.5 ppm; fruit, stone, group 12 at 2.5 ppm; pistachio at 0.05 ppm; grape at 1.5 ppm; and strawberry at 2.5 ppm upon approval of tolerances mentioned above and thereby eliminating redundancies. That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, <http://www.regulations.gov>. Two comments were received on the notice of filing in support of this action.

Based upon review of the data supporting the petition, EPA has revised certain proposed tolerance levels, corrected crops/crop group definitions, as needed, and modified the tolerance expression for pyridaben to comply with current EPA policies. The reason for these changes are explained in Unit IV.C.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of

and to make a determination on aggregate exposure for pyridaben including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyridaben follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity database and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In subchronic and chronic oral toxicity studies in rats and mice, the adverse effects were decreased body weight and food consumption; in dogs, toxicity consisted of increased incidences of clinical signs (*i.e.*, ptyalism) and decreased body weight. In the repeat dose dermal toxicity studies in rabbits, the adverse effect was decreased body weight. In the repeat dose inhalation toxicity study in rats, there were no adverse effects up to the highest dose tested. In all animals where toxicity was observed, body weight decreases became more pronounced as study duration increased while incidences of clinical signs of toxicity did not become more severe or more frequent as the study duration increased.

Susceptibility was observed in the rat prenatal developmental toxicity and rat developmental neurotoxicity studies. In the rat prenatal developmental toxicity study, fetal toxicity (*i.e.*, decreased bodyweight and incomplete ossification) occurred in the absence of maternal toxicity at the highest dose tested (HDT) of 30 mg/kg/day. In the rat developmental neurotoxicity study, offspring toxicity (*i.e.*, decreased bodyweight) occurred in the absence of maternal toxicity at the HDT of 8.4 mg/kg/day. In the rabbit prenatal developmental toxicity study, fetal and maternal toxicity consisted of abortions and occurred at the HDT of 15 mg/kg/day. There were no adverse effects observed in the rabbit dermal prenatal developmental toxicity study. In the rat reproduction and fertility effects study, parental and offspring toxicity (*i.e.*, decreased bodyweight) occurred at the HDT of 6.3 mg/kg/day.

In the acute neurotoxicity study in rats, animals had increased incidences of clinical signs (*i.e.*, piloerection, hypoactivity, tremors, and partially closed eyes). In the subchronic neurotoxicity study in rats, male animals had increased incidences of

impaired righting reflex. In the developmental neurotoxicity study in rats, there were no neurotoxicity effects up to the highest dose tested (17.7 mg/kg/day).

Pyridaben has been classified as “not likely to be carcinogenic in humans” based on the results from carcinogenicity studies in rats and mice. The mutagenicity studies do not indicate increased mutagenic potential in the battery of in vivo and in vitro assays.

Specific information on the studies received and the nature of the adverse effects caused by pyridaben as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Pyridaben—Human Health Risk Assessment for Proposed Uses on Greenhouse Cucumbers and Crop Group Expansions for Pome Fruit Group 11–10, Tree Nut Group 14–12, Stone Fruit

Group 12–12, Citrus Fruit Group 10–10, Small Fruit Vine Climbing (except Fuzzy Kiwifruit) Subgroup 13–07F, and Low Growing Berry Subgroup 13–07G (except Cranberry), dated June 21, 2016” at page 28 in docket ID number EPA–HQ–OPP–2015–0390.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern

are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

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

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

Exposure/Scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 44 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 0.44 mg/kg/day. aPAD = 0.44] mg/kg/day	<i>Acute Neurotoxicity Study in Rats:</i> LOAEL = 80 mg/kg/day based on increased incidences of clinical signs (i.e., piloerection, hypoactivity, tremors, and partially closed eyes).
Chronic dietary (All populations) .....	NOAEL= 2.2 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.022 mg/kg/day. cPAD = 0.022 mg/kg/day	<i>Reproduction and Fertility Effects in Rats</i> LOAEL = 6.3 mg/kg/day based on decreased parental and pup body weight.
Cancer (Oral, dermal, and inhalation)	Classification: “Not Likely to be Carcinogenic to Humans” based on the results of carcinogenicity studies in rats and mice.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyridaben, EPA considered exposure under the petitioned-for tolerances as well as all existing pyridaben tolerances in 40 CFR 180.494. EPA assessed dietary exposures from pyridaben in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for pyridaben. In estimating acute dietary exposure, EPA used the Dietary

Exposure Evaluation Model—Food Commodity Intake Database (DEEM–FCID™), Version 3.16, which incorporates 2003–2008 food consumption information from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used anticipated-residue estimates derived from proposed and established tolerance levels; DEEM–FCID™, Version 7.81 default processing factors were utilized for most processed commodities; and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM–FCID™, Version 3.16, which incorporates 2003–2008

food consumption data from the USDA’s NHANES/WWEIA. As to residue levels in food, the chronic dietary exposure assessment is partially refined, assuming anticipated residue estimates derived from proposed and established tolerance levels and percent crop treated estimates for most crops.

iii. *Cancer.* Pyridaben has been classified as not likely to be carcinogenic to humans. Based on the data summarized in Unit III.A., EPA has concluded that pyridaben 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.* Section 408(b)(2)(E) of FFDCA authorizes EPA

to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDC section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDC section 408(b)(2)(E) and authorized under FFDC section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDC states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDC section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for chronic exposure for existing uses as follows: almonds 2.5%; apples 20%; cherries 2.5%; grapefruit 35%; grapes 5%; lemons 2.5%; nectarines 2.5%; oranges 10%; peaches 10%; pears 35%; pecans 2.5%; plums/prunes 5%; tangelos 15%; tangerines 25%; tomatoes 2.5%; and walnuts 5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the

maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which pyridaben may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyridaben in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyridaben. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at: <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

The EPA's Tier II water models have been updated and applied in the drinking water analysis for total residues of concern (TRC) of pyridaben. The Pesticide Water Calculator (PWC), Ver.1.5001, has replaced the PE5 shell for the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) used previously to generate surface water estimated drinking water concentrations (EDWC) in dietary risk assessments. In addition, the PRZM-Ground Water (PRZM GW) model, version 1.07, has replaced Screening Concentration in Ground

Water (SCI-GROW), which was used to generate groundwater EDWCs. These latest versions of the PWC and PRZM-GW models not only analyze for pyridaben, but its two degradates PB-7 and P-9, residues of concern for drinking water.

Based on the PWC and PRZM GW, the maximum acute surface water EDWCs of pyridaben TRC for acute exposures are estimated to be 12 parts per billion (ppb) for surface water and an indeterminately low concentration for ground water.

For chronic exposures for non-cancer assessments are estimated to be 0.91 ppb for surface water and an indeterminately low concentration for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 12 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 0.91 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). Pyridaben 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: <http://www2.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 FFDC 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 pyridaben to share a common mechanism of toxicity with any other substances, and pyridaben does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyridaben 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 Web site at: <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There was no evidence for increased susceptibility to pyridaben following pre- or post-natal exposure in the rat reproduction and fertility effects study, notwithstanding the observed decreased pup body weight since that is not considered to be more severe than decreased parental body weight. Parental and offspring toxicity (*i.e.*, decreased bodyweight) occurred at the HDT of 6.3 mg/kg/day.

Increased susceptibility following prenatal exposure in the rat prenatal developmental toxicity studies was observed including fetal toxicity (*i.e.*, decreased bodyweight and incomplete ossification) occurring in the absence of maternal toxicity at the HDT of 30 mg/kg/day. In the rabbit prenatal developmental toxicity study, fetal and maternal toxicity consisted of abortions and occurred at the HDT of 15 mg/kg/day. There were no adverse effects observed in the rabbit dermal prenatal developmental toxicity study.

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

i. The toxicity database for pyridaben is complete.

ii. Although there are signs that pyridaben causes neurotoxic effects, a developmental neurotoxicity study in rats demonstrated no observed neurotoxicity effects in offspring up to the HDT of 17.7 mg/kg/day. Furthermore, the RfD of 0.44 mg/kg/day

for acute dietary exposures is protective of the HTD in the developmental neurotoxicity study. Additionally, the acute RfD is based on clinical signs (piloerection, hypoactivity, tremors and partially closed eyes) in adults that could be signs of neurotoxicity, however tissue analysis did not confirm neurotoxicity. Similarly, the chronic RfD of 0.022 mg/kg/day (based on parental and pup body weight decreases in a reproductive study) is protective of the impaired righting reflex observed in the subchronic neurotoxicity study at 8.5 mg/kg/day. There is no need to retain the FQPA 10X to account for any residual uncertainties concerning neurotoxicity.

iii. There is evidence that pyridaben results in increased susceptibility following prenatal exposure in the rat prenatal developmental toxicity and rat developmental neurotoxicity studies. There was no evidence for increased susceptibility following pre- or post-natal exposure in the rat reproduction and fertility effects study since the decreased pup body weight is not considered to be more severe than decreased parental body weight. EPA concluded that selected endpoints based on the rat reproduction and fertility effects study's NOAELs/LOAELs are protective of the susceptibility observed in the rat prenatal developmental toxicity and rat developmental neurotoxicity studies.

iv. There are no residual uncertainties identified in the exposure databases. The pyridaben exposure databases are complete or are estimated based on data that reasonably account for potential exposures. The chronic dietary food exposure assessment was based on anticipated residue estimates derived from proposed and established tolerance levels and PCT assumptions and conservative ground water drinking water modeling estimates. All of the exposure estimates are not likely to result in underestimated exposure and risks posed by pyridaben.

#### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyridaben will occupy 7.8% of the aPAD for the general U.S. population and 29% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyridaben from food and water will utilize 5% of the cPAD for the general U.S. Population and 20% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for pyridaben.

3. *Short-term and Intermediate-term risks.* Short-term and intermediate-term aggregate exposures take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyridaben is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, pyridaben is not expected to pose a cancer risk to humans.

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

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with mass spectrometry (GC/MS) detection using a modified version of BASF Method D9312A) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto: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.

There are no Codex maximum residue levels (MRLs) established for residues of pyridaben on the commodities for which tolerances are being established in this action.

### C. Revisions to Petitioned-for Tolerances

In order to harmonize tolerances with Canada and avoid trade irritants, EPA is establishing pyridaben tolerances as follows: (1) Fruit, stone, group 12–12 at 3.0 ppm, instead of at 2.5 ppm as requested; (2) Fruit, citrus, group 10–10 at 0.9 ppm, instead of at 0.5 ppm as requested; and (3) Fruit, small, vine climbing, except fuzzy kiwifruit subgroup 13–07F at 2.0 ppm, instead of at 1.5 ppm, as requested.

Finally, in accordance with EPA's policy to update its tolerance expressions where applicable, EPA is revising the tolerance expression to clarify that (1) as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of pyridaben not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

### V. Conclusion

Therefore, tolerances are established for residues of the insecticide pyridaben, [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] in or on berry, low growing subgroup 13–07G, except cranberry at 2.5 ppm; cucumber at 0.50 ppm; fruit, citrus group 10–10 at 0.9 ppm; fruit, pome group 11–10 at 0.75 ppm; fruit, stone, group 12–12 at 3.0 ppm; fruit, small, vine climbing except fuzzy kiwifruit subgroup 13–07F at 2.0 ppm; and nut, tree, group 14–12 at 0.05 ppm. Additionally, the existing tolerances in or on apple at 0.50 ppm; pear at 0.75 ppm; nut, tree, group 14 at 0.05 ppm; fruit, stone, group 12 at 2.5 ppm; citrus at 0.5 ppm; pistachio at 0.05 ppm; grape at 1.5 ppm; and strawberry at 2.5 ppm are being removed as a result of being

superseded by the new tolerances. Also, the tolerance expression is being updated to clarify that the tolerance covers metabolites and degradates of pyridaben not specifically mentioned and compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. Finally in order to correct a typographical error that was made in a previous action (**Federal Register** of July, 14, 2000 (65 FR 43704) (FRL–6593–1)), where a number was inadvertently dropped from the table in paragraph (a), the EPA is revising the goat fat tolerance from 0.0 ppm to 0.05 ppm in order to reinstate the original tolerance level published in the **Federal Register** of May 16, 1997 (62 FR 26954) (FRL–5178–4).

### VI. Statutory and Executive Order Reviews

This action establishes tolerances 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) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under 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: September 9, 2016.

**Michael L. Goodis,**

*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. Section 180.494 is amended by revising paragraphs (a) and (c) to read as follows:

**§ 180.494 Pyridaben; tolerance for residues.**

(a) *General.* Tolerances are established for residues of the insecticide pyridaben, including its metabolites and degradates, in or on the commodities as indicated in the following table. Compliance with the tolerance levels specified below for plant commodities is to be determined by measuring the insecticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] on the plant commodity. Compliance with the tolerance levels specified below for animal commodities is to be determined by measuring the insecticide pyridaben and its metabolites, [2-tert-butyl-5-(4-(1-carboxy-1-methylethyl) benzylthio)-4-chloropyridazin-3 (2H)one] and [2-tert-butyl-5-[4-(1, 1-dimethyl-2-hydroxyethyl)benzylthio-4-chloropyridazin-3(2H)one] on the animal commodity.

Commodity	Parts per million
Almond, hulls .....	4.0
Apple, wet pomace .....	0.75
Berry, low growing, subgroup 13-07G, except cranberry .....	2.5
Canistel .....	0.10
Cattle, fat .....	0.05
Cattle, meat .....	0.05
Cattle, meat byproducts .....	0.05
Citrus, dried pulp .....	1.5
Citrus, oil .....	10.0
Cucumber .....	0.50
Fruit, citrus group 10-10 .....	0.9
Fruit, pome group 11-10 .....	0.75
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F .....	2.0
Fruit, stone, group 12-12 .....	3.0
Goat, fat .....	0.05
Goat, meat .....	0.05
Goat, meat byproducts .....	0.05
Hog, fat .....	0.05
Hog, meat .....	0.05
Hog, meat byproducts .....	0.05
Hop, dried cones .....	10.0
Horse, fat .....	0.05
Horse, meat .....	0.05
Horse, meat byproducts .....	0.05
Mango .....	0.10
Milk .....	0.01
Nut, tree, group 14-12 .....	0.05
Papaya .....	0.10
Sapodilla .....	0.10
Sapote, black .....	0.10
Sapote, mamey .....	0.10
Sheep, fat .....	0.05
Sheep, meat .....	0.05
Sheep, meat byproducts .....	0.05
Star apple .....	0.10
Tomato .....	0.15

\* \* \* \* \*

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(m) are established for residues of the

insecticide pyridaben, 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 the insecticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] on the following plant commodity.

Commodity	Parts per million
Cranberry .....	0.5

\* \* \* \* \*

[FR Doc. 2016-24089 Filed 10-13-16; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 412**

[CMS-1659-CN]

RIN 0938-ZB26

**Medicare Program; Explanation of FY 2004 Outlier Fixed-Loss Threshold as Required by Court Rulings; Correction**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Clarification; correction.

**SUMMARY:** This document corrects a technical error that appeared in the document published in the **Federal Register** on January 22, 2016 entitled “Medicare Program; Explanation of FY 2004 Outlier Fixed-Loss Threshold as Required by Court Rulings.”

**DATES:** October 14, 2016.

**FOR FURTHER INFORMATION CONTACT:** Don Thompson, (410) 786-6504.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In FR Doc. 2016-01309 of January 22, 2016 (81 FR 3727), there was an error that is identified and corrected in the Correction of Errors section below. The provisions of this correction document are applicable as if they had been included in the document published January 22, 2016.

**II. Summary of Errors**

On page 3728, in our discussion of the cost-to-charge ratios estimates, we made an error regarding the fiscal year (FY).

**III. Correction of Errors**

In FR Doc. 2016-01309 of January 22, 2016 (81 FR 3727), make the following correction:

1. On page 3728, second column, first partial paragraph, line 12, the phrase “FY 2004 using actual market basket” is corrected to read “FY 2002 using actual market basket”.

Dated: October 6, 2016.

**Wilma Robinson,**

*Deputy Executive Secretary to the Department, Department of Health and Human Services.*

[FR Doc. 2016-24917 Filed 10-13-16; 8:45 am]

BILLING CODE 4120-01-P

**DEPARTMENT OF TRANSPORTATION**

**Pipeline and Hazardous Materials Safety Administration**

**49 CFR Part 190**

[Docket No. PHMSA-2016-0091; Amdt. No. 190-18]

RIN 2137-AF26

**Pipeline Safety: Enhanced Emergency Order Procedures**

**AGENCY:** Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

**ACTION:** Interim final rule.

**SUMMARY:** This interim final rule (IFR) establishes regulations implementing the emergency order authority conferred on the Secretary of Transportation (Secretary) by the “Protecting our Infrastructure of Pipelines and Enhancing Safety Act of 2016” (PIPES Act). These regulations are mandated by the PIPES Act and, in accordance with the Act, PHMSA is establishing procedures for the issuance of emergency orders that will be used to address an unsafe condition or practice, or combination of unsafe conditions or practices, that pose an imminent hazard to public health and safety or the environment. By implementing this statutory mandate, PHMSA will enhance its existing enforcement authority to respond immediately to conditions or practices that exist in a subset of, or across, the pipeline industry. This IFR solely affects agency enforcement procedures to implement the emergency order provisions of the law and; therefore, this rulemaking results in no additional burden or compliance costs to industry. PHMSA is issuing this IFR because the PIPES Act directs PHMSA to first issue temporary regulations. However, the agency invites comments and will, if appropriate, make changes to the IFR prior to the issuance of a final rule, which the agency must