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. 1501 et seq.).

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 any technical standards to the 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.


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:


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.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
<th>Expiration date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caneberry sub-group 13-07A</td>
<td>4.0</td>
<td>12/31/2019</td>
</tr>
<tr>
<td>Bushberry sub-group 13-07B</td>
<td>5.0</td>
<td>12/31/2019</td>
</tr>
</tbody>
</table>

| * * * * |

[FR Doc. 2016–24932 Filed 10–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Pyriddane; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide pyriddane 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) 305–7099; 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/textidx?&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
document 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 180.494 in or
on apple at 0.05 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
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)(ii) 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
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 0.05 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
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 health. 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.,
piloerection, hypoactivity, tremors, and partially
closed eyes). In the repeat dose
developmental 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
body weight 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
body weight) 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,
apparental 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 oral
neurotoxicity study in rats, male
animals had increased incidences of

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 583863) 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

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

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 estimating 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 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.

   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 IIIA., 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 FFDCA 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 FFDCA section 408(b)(2)(E) and authorized under FFDCA 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 FFDCA 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 FFDCA 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%; tangelo 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 underestimate. 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/standard-operating-procedures-residential-pesticide.

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, termiteicides, 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 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 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 are not available to 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.

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: residuumethods@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-buty1-5-(4-tet-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; pachino 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.


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:


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

[Amended]
§ 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 is to be determined by measuring the insecticide pyridaben [2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-one] and [2-tert-butyl-5-(1,1-dimethyl-2-carboxy-1-methylethyl) benzylthio]-4-chloropyridazin-3(2H)-one] on the animal commodity.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cranberry</td>
<td>0.5</td>
</tr>
</tbody>
</table>

* * * * *

[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.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almond, hulls</td>
<td>4.0</td>
</tr>
<tr>
<td>Apple, wet pomace</td>
<td>0.75</td>
</tr>
<tr>
<td>Berry, low growing, subgroup 13–07G, except cranberry</td>
<td>2.5</td>
</tr>
<tr>
<td>Canistel</td>
<td>0.10</td>
</tr>
<tr>
<td>Cattle, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Cattle, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Cattle, meat byproducts</td>
<td>0.05</td>
</tr>
<tr>
<td>Citrus, dried pulp</td>
<td>1.5</td>
</tr>
<tr>
<td>Citrus, oil</td>
<td>10.0</td>
</tr>
<tr>
<td>Cucumber</td>
<td>0.50</td>
</tr>
<tr>
<td>Fruit, citrus group 10–10</td>
<td>0.9</td>
</tr>
<tr>
<td>Fruit, pome group 11–10</td>
<td>0.75</td>
</tr>
<tr>
<td>Fruit, small vine, climbing, except fuzzy kiwifruit, subgroup 13–07F</td>
<td>2.0</td>
</tr>
<tr>
<td>Fruit, stone group 12–12</td>
<td>3.0</td>
</tr>
<tr>
<td>Goat, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Goat, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Goat, meat byproducts</td>
<td>0.05</td>
</tr>
<tr>
<td>Hog, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Hog, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Hog, meat byproducts</td>
<td>0.05</td>
</tr>
<tr>
<td>Hop, dried cones</td>
<td>1.0</td>
</tr>
<tr>
<td>Horse, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Horse, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Horse, meat byproducts</td>
<td>0.05</td>
</tr>
<tr>
<td>Mango</td>
<td>0.10</td>
</tr>
<tr>
<td>Milk</td>
<td>0.01</td>
</tr>
<tr>
<td>Nut, tree group 14–12</td>
<td>0.05</td>
</tr>
<tr>
<td>Papaya</td>
<td>0.10</td>
</tr>
<tr>
<td>Sapodilla</td>
<td>0.10</td>
</tr>
<tr>
<td>Sapote, black</td>
<td>0.10</td>
</tr>
<tr>
<td>Sapote, maney</td>
<td>0.10</td>
</tr>
<tr>
<td>Sheep, fat</td>
<td>0.05</td>
</tr>
<tr>
<td>Sheep, meat</td>
<td>0.05</td>
</tr>
<tr>
<td>Sheep, meat byproducts</td>
<td>0.05</td>
</tr>
<tr>
<td>Star apple</td>
<td>0.10</td>
</tr>
<tr>
<td>Tomato</td>
<td>0.15</td>
</tr>
</tbody>
</table>

* * * * *

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

[9 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