(b) *Procedures for final significant guidance documents*—(1) *In general.* PBGC will submit a final significant guidance document to OMB for review under Executive Order 12866 before issuance.

(2) *Response to comments.* PBGC will provide a public response to comments on a proposed significant guidance document either in a final significant guidance document or in a companion document that addresses major concerns raised in comments.

(c) *Issuance.* All proposed and final significant guidance documents will be signed by the Director on a non-delegable basis and posted at *www.pbgc.gov/guidance.*

§ 4908.5 Public access to guidance documents.

(a) *In general.* PBGC will maintain on PBGC's public website a single, searchable, indexed database that contains, or links to PBGC's guidance documents at *www.pbgc.gov/guidance.* Any guidance document posted on the database is final unless it is a proposed significant guidance document under § 4908.4.

(b) *Nonbinding effect.* The database described in paragraph (a) of this section will state that guidance documents do not have the force and effect of law, unless expressly authorized by statute or incorporated into a contract and are not meant to bind the public in any way.

(c) *Rescinded guidance documents.* All guidance documents that are not posted on the database described in paragraph (a) of this section are considered rescinded. PBGC will not cite, use, or rely upon any guidance document that is rescinded, except to establish historical facts.

(d) *Withdrawal.* When PBGC withdraws a guidance document, PBGC will remove the hyperlink to the guidance document from the database and will clearly identify the guidance document as withdrawn. The name, title, unique identifier, and date of withdrawal will be listed on the database for at least one year after withdrawal.

§ 4908.6 Procedures for requests from the public to withdraw or modify a guidance document.

(a) *In general.* A member of the public may petition PBGC in writing for withdrawal or modification of an existing guidance document issued by PBGC.

(b) *Petition instructions.* PBGC will provide clear instructions on its website regarding how to submit petitions for withdrawal or modification of any guidance document at *www.pbgc.gov/guidance.* These instructions will include an email address, a physical mailing address for hard copy petitions, and the office responsible for coordinating responses to petitions. PBGC will clearly identify the General Counsel as the designated PBGC official to whom petitions should be directed at *GuidanceComments@pbgc.gov.*

(c) *Contents of petition.* A petition must—

(1) Specify the petitioner's name and a means for PBGC to contact the petitioner, such as an email address or a mailing address;

(2) Identify the guidance document that is the subject of the petition;

(3) Present any information and arguments in support of the request for withdrawal or modification of the guidance document, including any specific circumstances in which the guidance document is incorrect or obsolete; and

(4) Be directed to the designated PBGC official.

(d) *Response.* In response to a petition, the General Counsel, in consultation with the Chief Policy Officer and the Director, will determine whether to withdraw, modify, or retain a guidance document. PBGC will respond to a petition promptly, but no later than 90 days after receiving the petition. If PBGC withdraws a guidance document in response to a petition, PBGC will follow the procedures in § 4908.5(d) and post a response to the petition on its guidance database.

Issued in Washington, DC.

Gordon Hartogensis,

Director, Pension Benefit Guaranty Corporation.

[FR Doc. 2020–17952 Filed 8–25–20; 8:45 am]

BILLING CODE 7709–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0038; FRL–10011–32]

Inpyrfluxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of inpyrfluxam in or on multiple commodities that are identified and discussed later in this document. Valent requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 26, 2020. Objections and requests for hearings must be received on or before October 26, 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–2018–0038, 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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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 EPA's tolerance

regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0038 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 October 26, 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–2018–0038, 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.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 18, 2019 (84 FR 9735) (FRL–9989–90), 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 7F8634) by Valent U.S.A. LLC, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide inpyrfluxam, S–2399, in or on apple at 0.01 parts per million (ppm); apple, wet pomace at 0.03 ppm; beet, sugar, dried pulp at 0.05 ppm; beet, sugar, molasses at 0.03 ppm; beet, sugar, roots at 0.01 ppm; corn, field, forage at 0.02 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.02 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.02 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; peanut at 0.01 ppm; peanut, hay at 2.0 ppm; rice, grain at 0.01 ppm; rice, bran at 0.02 ppm; rice, hulls at 0.05 ppm; and soybean, seed at 0.01 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

In the **Federal Register** of May 8, 2020 (85 FR 27346) (FRL–10008–38), 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 7F8634) by Valent U.S.A. LLC, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide inpyrfluxam, S–2399, in or on corn, sweet, stover at 0.02 ppm; corn, sweet, forage at 0.02 ppm; cattle, fat at 0.01 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; eggs at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.01 ppm; milk at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts at 0.01 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received in response to the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing several tolerances at different levels than were requested. The reasons for these changes are explained in Unit IV.D.

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 inpyrfluxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with inpyrfluxam follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data 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.

The target organs of inpyrfluxam are the liver and thyroid (rats, mice, and dogs). Liver effects include increased liver weight, elevated liver enzymes, and increased incidences of diffuse hepatocellular hypertrophy. Thyroid effects include increased incidences of follicular cell hypertrophy.

Decreased motor activity was seen in the acute neurotoxicity study in female rats, but no gross or microscopic morphological changes occurred. There was no neurotoxicity observed in the subchronic neurotoxicity in rats or in any other studies. No dermal hazard was identified in the 28-day dermal toxicity study.

There was evidence of quantitative sensitivity in the developmental toxicity study in rats. In this study, decreased fetal weights were observed at a dose

lower than the presence of maternal toxicity. No quantitative susceptibility was observed in the developmental toxicity study in rabbits and the 2-generation reproduction study in rats. In the 2-generation reproduction study in rats, no reproductive effects were observed, and offspring toxicity (decreased pup weights in F1 and F2 generations) was observed in the presence (same dosage) of parental toxicity (thyroid weight changes and histopathology in P and F1 generations).

In the chronic toxicity/carcinogenicity studies in rats and mice, there was no evidence of carcinogenicity. The mutagenicity battery was negative. Inpyrfluxam is classified as ''Not likely to be carcinogenic to humans.''

Specific information on the studies received and the nature of the adverse effects caused by inpyrfluxam 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 the document titled ''Inpyrfluxam. Human Health Risk Assessment for the Section 3 Registration Action of the New Active Ingredient, Inpyrfluxam, for Foliar Application on Apple, Peanut, Rice, Soybean, and Sugar Beet; Soil Application on Corn; and Seed Treatment Uses on Canola, Cereal Grains, Legume Vegetables, and Sugar Beet'' (hereinafter ''Inpyrfluxam Human Health Risk Assessment'') on pages 42–46 in docket ID number EPA–HQ–OPP–2018–0038.

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-pesticide.*

A summary of the toxicological endpoints for inpyrfluxam used for human risk assessment can be found in the Inpyrfluxam Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to inpyrfluxam, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from inpyrfluxam 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 inpyrfluxam. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute analysis assumed tolerance-level residues or higher by combining residues of the parent and residues of the applicable metabolites of concern, adjusting for molecular weight. In addition, the assessment used 100 percent crop treated (PCT) estimates and default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, the chronic analysis assumed tolerance-level residues or higher by combining residues of the parent and residues of the applicable metabolites of concern, adjusting for molecular weight. In addition, the assessment used 100 PCT estimates and default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that inpyrfluxam 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 PCT information.* EPA did not use anticipated residue or PCT information for assessing the inpyrfluxam exposures.

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

Using the Pesticide Root Zone Model-Variable Volume Water Model (PRZM–VVWM) and Pesticide Root Zone Model-Groundwater (PRZM–GW) models, EPA calculated the estimated drinking water concentrations (EDWCs) of inpyrfluxam for acute and chronic exposures in surface and ground water. EPA used the modeled EDWCs directly in the dietary exposure model to account for the contribution of inpyrfluxam residues in drinking water as follows: 104.5 ppm was used in the acute assessment and 69.5 ppb was used in the chronic assessment.

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).

Inpyrfluxam is not being proposed to be registered for any specific use patterns that would result in residential exposure.

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to inpyrfluxam and any other substances, and inpyrfluxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that inpyrfluxam has 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 *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.* In the developmental toxicity study in rats, decreased fetal weights were observed at a dose lower than the presence of maternal toxicity. No quantitative susceptibility was observed in the developmental toxicity study in rabbits and the 2-generation reproduction study in rats. In the 2-generation reproduction study in rats, no reproductive effects were observed, and offspring toxicity (decreased pup weights in F1 and F2 generations) was observed in the presence (same dosage) of parental toxicity (thyroid weight changes and histopathology in P and F1 generations).

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 inpyrfluxam is complete.

ii. Decreased motor activity was observed in females in the acute neurotoxicity study; however, no neurotoxicity was observed in the subchronic neurotoxicity or in any other studies in the inpyrfluxam database; therefore, a developmental neurotoxicity study was not needed with the absence of neuropathology.

iii. In the 2-generation reproduction study in rats, no reproductive effects were observed, and offspring toxicity (decreased pup weights in F1 and F2 generations) was observed in the presence of parental toxicity (thyroid weight changes and histopathology in P and F1 generations). Although there were developmental effects (decreased fetal weights) in the developmental study in rats in the absence of maternal toxicity, a clear NOAEL and LOAEL were identified, and the PODs selected for risk assessment purposes are protective of the developmental effects seen in the database.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and anticipated residues to account for the metabolites of concern. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to inpyrfluxam in drinking water. These assessments will not underestimate the exposure and risks posed by inpyrfluxam.

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 inpyrfluxam will occupy 6.4% of the aPAD for all infants less than one year 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 inpyrfluxam from food and water will utilize 1.7% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for inpyrfluxam.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, inpyrfluxam is not being proposed to be registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for inpyrfluxam.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, inpyrfluxam 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 inpyrfluxam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed a multi-residue method (quick, easy, cheap, effective, rugged and safe; QuEChERS; Method No. VP–393940) for the determination of inpyrfluxam in plant commodities. For livestock commodities, adequate enforcement methodology using the high performance liquid chromatography with tandem mass detection (HPLC–MS/MS, or LC–MS/MS) is available for determination of residues of inpyrfluxam and its metabolites.

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to

which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for inpyrfluxam.

C. Response to Comments

One comment was received to the notice of filing that stated in part ''ban use of valent impyrfluxam [sic] on corn cattle meat and other sites.''

Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these inpyrfluxam tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

Some of the proposed commodity definitions for the tolerances being established are different than requested to be consistent with Agency nomenclature. EPA is not establishing a tolerance for residues in/on rice hulls as requested; it is not necessary as rice hulls are no longer considered a significant livestock feedstuff. Also, residues were less than the LOQ in the processed commodities at exaggerated rates; therefore, a tolerance for rice bran is not required. No separate tolerance is needed for apple, wet pomace since the residues on pomace will be adequately covered by the tolerance on ''apple'' due to a lack of concentration during processing. Similarly, no separate tolerances are needed for sugar beet molasses or sugar beet dried pulp since residues on those commodities will be adequately covered under ''beet, sugar, roots.'' Finally, EPA revised the tolerance value for ''peanut, hay'' from 2.0 ppm (as requested) to 2 ppm, to be consistent with OECD's rounding class practices.

V. Conclusion

Therefore, tolerances are established for residues of inpyrfluxam, including its metabolites and degradates, in or on the following plant commodities: Apple at 0.01 ppm; beet, sugar, roots at 0.01 ppm; corn, field, forage at 0.02 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 0.02 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 0.02 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, forage at 0.02 ppm; corn, sweet, stover at 0.02 ppm; peanut at 0.01 ppm; peanut, hay at 2 ppm; rice, grain at 0.01 ppm; and soybean, seed at 0.01 ppm.

Also, tolerances are established for residues of inpyrfluxam, including its metabolites and degradates, in or on the following livestock commodities: Cattle, fat at 0.01 ppm; cattle meat at 0.01 ppm; cattle, meat byproducts at 0.01 ppm; egg at 0.01 ppm; goat, fat at 0.01 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.01 ppm; hog, fat at 0.01 ppm; hog, meat at 0.01 ppm; hog, meat byproducts at 0.01 ppm; horse, fat at 0.01 ppm; horse, meat at 0.01 ppm; horse meat byproducts at 0.01 ppm; milk at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, meat at 0.01 ppm; and sheep meat byproducts at 0.01 ppm.

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), 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 on the basis of a petition under FFDCA section 408(d), 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).

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: August 11, 2020.

Edward Messina,

Acting Director, 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. Add § 180.712 to subpart C to read as follows:

§ 180.712 Inpyrfluxam; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide inpyrfluxam, including its metabolites and degradates, in or on the commodities in Table 1 to this section. Compliance with the tolerance levels specified in Table 1 to this section is to be determined by measuring only inpyrfluxam (3-(difluoromethyl)-*N*-[(3*R*)-2,3-dihydro-1,1,3-trimethyl-1*H*-inden-4-yl]-1-methyl-1*H*-pyrazole-4-carboxamide), in or on the following commodities:

TABLE 1 TO § 180.712

Commodity	Parts per million
Apple	0.01
Beet, sugar, roots	0.01
Corn, field, forage	0.02
Corn, field, grain	0.01
Corn, field, stover	0.02
Corn, pop, grain	0.01
Corn, pop, stover	0.02
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, forage	0.02
Corn, sweet, stover	0.02
Peanut	0.01
Peanut, hay	2
Rice, grain	0.01
Soybean, seed	0.01

(2) Tolerances are established for residues of inpyrfluxam, including its metabolites and degradates, in or on the commodities in Table 2 to this section. Compliance with the tolerance levels specified in Table 2 to this section is to be determined by measuring the free and conjugated forms of the sum of inpyrfluxam (3-(difluoromethyl)-*N*-[(3*R*)-2,3-dihydro-1,1,3-trimethyl-1*H*-inden-4-yl]-1-methyl-1*H*-pyrazole-4-carboxamide, and its metabolites 3-(difluoromethyl)-*N*-[1′-(hydroxymethyl)-(1′*S*,3′*R*)-1′,3′-dimethyl-2′,3′-dihydro-1′*H*-inden-4′-yl]-1-methyl-1*H*-pyrazole-4-carboxamide and 3-(difluoromethyl)-*N*-[1′-(hydroxymethyl)-(1′*R*,3′*S*)-1′,3′-dimethyl-2′,3′-dihydro-1′*H*-inden-4′-yl]-1-methyl-1*H*-pyrazole-4-carboxamid, calculated as the stoichiometric equivalent of inpyrfluxam, in or on the commodity:

TABLE 2 TO § 180.712

Commodity	Parts per million
Cattle, fat	0.01
Cattle, meat	0.01
Cattle, meat byproducts	0.01
Egg	0.01
Goat, fat	0.01
Goat, meat	0.01
Goat, meat byproducts	0.01
Hog, fat	0.01
Hog, meat	0.01
Hog, meat byproducts	0.01
Horse, fat	0.01
Horse, meat	0.01
Horse, meat byproducts	0.01
Milk	0.01
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Sheep, fat	0.01
Sheep, meat	0.01
Sheep, meat byproducts	0.01

(b)–(d) [Reserved]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket No. CDC–2020–0036; NIOSH–335]

RIN 0920–AA69

Approval Tests and Standards for Air-Purifying Particulate Respirators

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Reopening of comment period.

SUMMARY: On April 14, 2020, the Department of Health and Human Services (HHS) published an interim final rule to update regulatory requirements by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) to test and approve air-purifying particulate respirators for use in the ongoing public health emergency. Comments were to be received by August 12, 2020. This document announces a reopening of the comment period for an additional 30 days, to allow stakeholders and other interested parties additional time to respond.

DATES: The comment period for the interim final rule published April 14, 2020, at 85 FR 20598, is reopened. Written comments must be received by September 25, 2020.

ADDRESSES: You may submit written comments, identified by docket numbers CDC–2020–0036 and NIOSH–335, by either of the following two methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All information received in response to this document must include the agency name and docket number [CDC–2020–0036; NIOSH–335]. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Jeffrey Palcic, NIOSH National Personal Protective Technology Laboratory (NPPTL), Pittsburgh, PA, (412) 386–5247 (this is not a toll-free number). Information requests can also be submitted by email to *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION: On April 14, 2020, at 85 FR 20598, HHS published an interim final rule adding parallel performance standards to existing regulatory requirements in 42 CFR part 84 for powered air-purifying particulate respirators (PAPRs). These new standards allow for the approval of respirators in a new class, PAPR100, that may be better suited to the needs of workers in the healthcare and public safety sectors. The rule also consolidated the technical standards for all types of air-purifying particulate respirators into a revised subpart K; standards pertaining to obsolete respirators designed for dust, fume, and mist; pesticide; and paint spray were removed from the regulation entirely. The comment period for this rule closed on August 12, 2020.

Prior to the close of the comment period, HHS received a request to extend the comment period. Because NIOSH values input from industry partners, HHS is reopening the public comment period for an additional 30 days. Accordingly, this document announces the reopening of the docket for this activity.

Dated: August 21, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–18747 Filed 8–24–20; 4:15 pm]

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