[Federal Register Volume 85, Number 166 (Wednesday, August 26, 2020)]

[Rules and Regulations]

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[FR Doc No: 2020-18661]

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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.

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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](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

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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](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](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](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

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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](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

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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

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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:

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PART 180--[AMENDED]

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1. The authority citation for part 180 continues to read as follows:

 Authority: 21 U.S.C. 321(q), 346a and 371.

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2. Add Sec. 180.712 to subpart C to read as follows:

Sec. 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-[(3R)-

2,3-dihydro-1,1,3-trimethyl-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-

carboxamide), in or on the following commodities:

 Table 1 to Sec. 180.712

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 Parts per

 Commodity million

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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

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 (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-

[(3R)-2,3-dihydro-1,1,3-trimethyl-1H-inden-4-yl]-1-methyl-1H-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-1H-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-1H-pyrazole-4-carboxamid, calculated as the stoichiometric

equivalent of inpyrfluxam, in or on the commodity:

 Table 2 to Sec. 180.712

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 Parts per

 Commodity million

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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

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 (b)-(d) [Reserved]

[FR Doc. 2020-18661 Filed 8-25-20; 8:45 am]

BILLING CODE 6560-50-P