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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0560; FRL-10002-21]

Fenhexamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

fenhexamid in or on multiple commodities identified and discussed later

in this document. Interregional Research Project No. 4 (IR-4) requested

these tolerances under the Federal Food, Drug, and Cosmetic Act

(FFDCA).

DATES: This regulation is effective January 16, 2020. Objections and

requests for hearings must be received on or before March 16, 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-2018-0560, 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. Please review the visitor instructions and

additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division

(7505P), Office of Pesticide Programs, Environmental Protection Agency,

1200 Pennsylvania Ave, NW, Washington, DC 20460-0001; main telephone

number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto: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-2018-0560 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

March 16, 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-

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2018-0560, 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>. Additional

instructions on commenting or visiting the docket, along with more

information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the Federal Register of October 18, 2018 (83 FR 52787) (FRL-

9984-21), 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

8E8689) by Interregional Research Project Number 4 (IR-4) Rutgers, The

State University of New Jersey, 500 College Road East, Suite 201W,

Princeton, NJ 08540. The petition requested that 40 CFR 180.553 be

amended by establishing tolerances for residues of the fungicide

fenhexamid, (N-2,3-dichloro-4-hydroxyphenyl)-1-

methylcyclohexanecarboxamide), in or on arugula at 30.0 parts per

million (ppm); berry, low growing, subgroup 13-07G at 3.0 ppm;

bushberry subgroup 13-07B at 5.0 ppm; caneberry subgroup 13-07A at 20.0

ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-

07F at 4.0 ppm; fruit, stone, group 12-12, except plum, prune, fresh,

postharvest at 10.0 ppm; garden cress at 30.0 ppm; kiwifruit, fuzzy at

30.0 ppm; leafy greens, subgroup 4-16A, except spinach at 30.0 ppm;

onion, bulb, crop subgroup 3-07A at 2.0 ppm; onion, green, subgroup 3-

07B at 30.0 ppm; upland cress at 30.0 ppm; vegetable, fruiting, group

8-10, except non-bell pepper at 2.0 ppm. Also, the petition requested

to remove existing tolerances in 40 CFR 180.553 for residues of the

fungicide fenhexamid in or on the raw agricultural commodities:

Bushberry subgroup 13B at 5.0 ppm; caneberry subgroup 13A at 20.0 ppm;

cilantro, leaves at 30.0 ppm; fruit, stone, group 12, except plum,

prune, fresh, postharvest at 10.0 ppm; grape at 4.0 ppm; juneberry at

5.0 ppm; kiwifruit, postharvest at 15.0 ppm; leafy greens subgroup 4A,

except spinach at 30.0 ppm; lingonberry at 5.0 ppm; salal at 5.0 ppm;

strawberry at 3.0 ppm; and vegetable, fruiting, group 8, except nonbell

pepper at 2.0 ppm. That document referenced a summary of the petition

prepared by Arysta LifeSciences, 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.

Based upon review of the data supporting the petition, EPA is

establishing tolerances at levels that vary from what the petitioner

requested, in accordance with its authority under section

408(d)(4)(A)(i) of the FFDCA. The reasons for these changes are

explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a

tolerance (the legal limit for a pesticide chemical residue in or on a

food) only if EPA determines that the tolerance is ``safe.'' Section

408(b)(2)(A)(ii) of FFDCA defines ``safe'' to mean that ``there is a

reasonable certainty that no harm will result from aggregate exposure

to the pesticide chemical residue, including all anticipated dietary

exposures and all other exposures for which there is reliable

information.'' This includes exposure through drinking water and in

residential settings, but does not include occupational exposure.

Section 408(b)(2)(C) of FFDCA requires EPA to give special

consideration to exposure of infants and children to the pesticide

chemical residue in establishing a tolerance and to ``ensure that there

is a reasonable certainty that no harm will result to infants and

children from aggregate exposure to the pesticide chemical residue. . .

.''

Consistent with FFDCA section 408(b)(2)(D), and the factors

specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available

scientific data and other relevant information in support of this

action. EPA has sufficient data to assess the hazards of and to make a

determination on aggregate exposure for fenhexamid including exposure

resulting from the tolerances established by this action. EPA's

assessment of exposures and risks associated with fenhexamid 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.

Following repeated oral dosing, the most toxicologically relevant

effects were hematological changes (decreased red blood cell (RBC)

counts, hemoglobin, and hematocrit and increased Heinz bodies) in dogs,

and decreased body weights, increased food consumption, and decreased

liver and/or kidney weights in rats and mice. There is no evidence of

immunotoxicity or neurotoxicity in the fenhexamid database. There is no

evidence of qualitative or quantitative susceptibility in the

developmental studies in rats and rabbits. In the reproductive study,

decreased body weights in F1 and F2 pups were observed in the presence

of maternal toxicity. However, there is no concern for increased

susceptibility of offspring because a clear no-observed-adverse-effect-

level (NOAEL) and a well-characterized dose response for offspring

effects was observed in the presence of maternal toxicity. There were

no adverse effects observed in a dermal toxicity study up to the

highest dose tested (1,000 mg/kg/day). Although no subchronic

inhalation study is available for fenhexamid, a 5-day range finding

inhalation study reported lung-specific effects (macroscopic grey

coloration of the lungs and marginal increases in lung weights) at the

highest dose tested. However, concern for these effects is low because

they occurred at a dose more than 7X higher than the selected

inhalation points of departure (POD). In an acute neurotoxicity study

in rats, the only effect observed was a marginally decreased mean body

temperature in male rats following a single high dose of 2,000 mg/kg.

This effect is not considered to be biologically significant.

Based on the lack of evidence of carcinogenicity in rats and mice

and on the lack of genotoxicity in an acceptable battery of

mutagenicity studies, EPA has classified fenhexamid as ``not likely''

to be a human carcinogen. Specific information on the studies received

and the nature of the adverse effects caused by fenhexamid 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 titled Fenhexamid: ``Human

Health Risk Assessment for Section 3 Registration for New Uses in/on

Onion Bulb Subgroup 3-07A; Onion Green Subgroup 3-07B; Fuzzy Kiwifruit;

Crop Group Conversions/Expansions for Fruit

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Small Vine Climbing, except Fuzzy Kiwifruit Subgroup 13-07F; Berry Low

Growing Subgroup 13-07G; Caneberry Subgroup 13-07A; Bushberry Subgroup

13-07B; Fruit Stone Group 12-12, except Plum, Prune Fresh; Leafy Greens

Subgroup 4-16A except Spinach; Vegetable Fruiting Group 8-10 except Non

bell Pepper; and to Establish Individual Tolerances on Arugula; Garden

cress; Upland Cress'' at page 27 in docket ID number EPA-HQ-OPP-2018-

0560.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA

identifies toxicological points of departure (POD) and levels of

concern to use in evaluating the risk posed by human exposure to the

pesticide. For hazards that have a threshold below which there is no

appreciable risk, the toxicological POD is used as the basis for

derivation of reference values for risk assessment. PODs are developed

based on a careful analysis of the doses in each toxicological study to

determine the dose at which no adverse effects are observed (the NOAEL)

and the lowest dose at which adverse effects of concern are identified

(the LOAEL). Uncertainty/safety factors are used in conjunction with

the POD to calculate a safe exposure level--generally referred to as a

population-adjusted dose (PAD) or a reference dose (RfD)--and a safe

margin of exposure (MOE). For non-threshold risks, the Agency assumes

that any amount of exposure will lead to some degree of risk. Thus, the

Agency estimates risk in terms of the probability of an occurrence of

the adverse effect expected in a lifetime. For more information on the

general principles EPA uses in risk characterization and a complete

description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for fenhexamid used for

human risk assessment is shown in Table 1 of this unit.

Table 1--Summary of Toxicological Doses and Endpoints for Fenhexamid for Use in Human Health Risk Assessment

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Point of departure

Exposure/scenario and uncertainty/ RfD, PAD, LOC for Study and toxicological effects

safety factors risk assessment

----------------------------------------------------------------------------------------------------------------

Acute dietary (General population Not selected. No appropriate toxicological endpoint attributable to a single

including infants and children). exposure was identified in the available toxicology studies.

------------------------------------------------------------------------------

Chronic dietary (All populations) NOAEL = 17 mg/kg/day Chronic RfD = 0.17 1-year feeding study (dog).

UFA = 10x........... mg/kg/day. LOAEL = 124 mg/kg/day based on

UFH = 10x........... cPAD = 0.17 mg/kg/ decreased RBC counts, hemoglobin,

FQPA SF = 1x........ day. and hematocrit and increased

Heinz bodies in males and

females; increased adrenal

weights and intracytoplasmic

vacuoles in adrenal cortex in

females.

------------------------------------------------------------------------------

Cancer (Oral).................... Classification: ``Not likely to be Carcinogenic to Humans'' based on the

absence of significant tumor increases in two adequate rodent

carcinogenicity studies.

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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.

UFA = extrapolation from animal to human (interspecies). UFH = potential variation in sensitivity among

members of the human population (intraspecies).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary

exposure to fenhexamid, EPA considered exposure under the petitioned-

for tolerances as well as all existing fenhexamid tolerances in 40 CFR

180.553. EPA assessed dietary exposures from fenhexamid 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. No such effects were

identified in the toxicological studies for fenhexamid; therefore, a

quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic exposure. In conducting the chronic dietary exposure

assessment, EPA used the Dietary Exposure Evaluation Model software

with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This

software uses 2003-2008 food consumption data from the U.S. Department

of Agriculture's (USDA's) National Health and Nutrition Examination

Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in

food, EPA conducted an unrefined chronic dietary exposure assessment

using tolerance-level residues, 100 percent crop treated (100 PCT), and

HED's 2018 default processing factors.

iii. Cancer. Based on the data summarized in Unit III.A., EPA has

concluded that fenhexamid does not pose a cancer risk to humans.

Therefore, a dietary exposure assessment for the purpose of assessing

cancer risk is unnecessary.

iv. Anticipated residue and percent crop treated (PCT) information.

EPA did not use anticipated residue and/or PCT information in the

dietary assessment for fenhexamid. Tolerance-level residues and/or 100%

CT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening-

level water exposure models in the dietary exposure analysis and risk

assessment for fenhexamid in drinking water. These simulation models

take into account data on the physical, chemical, and fate/transport

characteristics of fenhexamid. 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>.

Based on the Pesticides in Water Calculator (PWC version 1.52; Feb.

2016) model, the estimated drinking water concentrations (EDWCs) of

fenhexamid for chronic exposures for non-cancer assessments, EDWCs of

fenhexamid are estimated to be 144 ppb for surface water and 1986 ppb

for ground water.

Modeled estimates of drinking water concentrations were directly

entered into the dietary exposure model. For chronic dietary risk

assessment, the water concentration of value 1986 ppb was used to

assess the contribution to drinking water.

3. From non-dietary exposure. The term ``residential exposure'' is

used in this document to refer to non-occupational, non-dietary

exposure (e.g., for lawn and garden pest control, indoor pest control,

termiticides, and

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flea and tick control on pets). Fenhexamid is not 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 method of toxicity, EPA has not made a

common mechanism of toxicity finding as to fenhexamid and any other

substances and fenhexamid 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 fenhexamid 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/standard-operating-procedures-residential-pesticide>.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA

shall apply an additional tenfold (10X) margin of safety for infants

and children in the case of threshold effects to account for prenatal

and postnatal toxicity and the completeness of the database on toxicity

and exposure unless EPA determines based on reliable data that a

different margin of safety will be safe for infants and children. This

additional margin of safety is commonly referred to as the FQPA Safety

Factor (SF). In applying this provision, EPA either retains the default

value of 10X, or uses a different additional safety factor when

reliable data available to EPA support the choice of a different

factor.

2. Prenatal and postnatal sensitivity. There is no evidence of

qualitative or quantitative susceptibility in the developmental studies

in rats and rabbits. In the reproductive study, decreased body weights

in F1 and F2 pups were observed in the presence of maternal toxicity.

However, there is no concern for increased susceptibility of offspring

because a clear no-observed-adverse-effect-level (NOAEL) and a well-

characterized dose response for offspring effects was observed in the

presence of maternal toxicity.

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 fenhexamid is complete.

ii. There is no indication that fenhexamid is a neurotoxic chemical

and there is no need for a developmental neurotoxicity study or

additional UFs to account for neurotoxicity.

iii. There is no evidence that fenhexamid results in increased

susceptibility in in utero rats or rabbits in the prenatal

developmental studies and no concern for any increased susceptibility

in the young from the 2-generation reproduction study due to the clear

dose-response and NOAEL of that study.

iv. There are no residual uncertainties identified in the exposure

databases. The dietary food exposure assessments were performed based

on 100 PCT and tolerance-level residues. EPA made conservative

(protective) assumptions in the ground and surface water modeling used

to assess exposure to fenhexamid in drinking water. These assessments

will not underestimate the exposure and risks posed by fenhexamid.

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. An acute aggregate risk assessment takes into

account acute exposure estimates from dietary consumption of food and

drinking water. No adverse effect resulting from a single oral exposure

was identified and no acute dietary endpoint was selected. Therefore,

fenhexamid is not expected to pose an acute risk.

2. Chronic risk. Using the exposure assumptions described in this

unit for chronic exposure, EPA has concluded that chronic exposure to

fenhexamid from food and water will utilize 79% of the cPAD for all

infants (<1 year old), the population subgroup receiving the greatest

exposure. There are no residential uses for fenhexamid. Based on the

explanation in Unit III.C.3., regarding residential use patterns,

chronic residential exposure to residues of fenhexamid is not expected.

3. Short-term risk. Short-term aggregate exposure takes into

account short-term residential exposure plus chronic exposure to food

and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, fenhexamid is

not registered for any use patterns that would result in short-term

residential exposure. Short-term risk is assessed based on short-term

residential exposure plus chronic dietary exposure. Because there is no

short-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-term risk is necessary, and EPA relies on

the chronic dietary risk assessment for evaluating short-term risk for

fenhexamid.

4. Intermediate-term risk. Intermediate-term aggregate exposure

takes into account intermediate-term residential exposure plus chronic

exposure to food and water (considered to be a background exposure

level).

An intermediate-term adverse effect was identified; however,

fenhexamid is not registered for any use patterns that would result in

intermediate-term residential exposure. Intermediate-term risk is

assessed based on intermediate-term residential exposure plus chronic

dietary exposure. Because there is no 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 intermediate-term risk), no further assessment

of intermediate-term risk is necessary, and EPA relies on the chronic

dietary risk assessment for evaluating intermediate-term risk for

fenhexamid.

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

evidence of carcinogenicity in two adequate rodent carcinogenicity

studies, fenhexamid is not expected to pose a cancer risk to humans.

6. Determination of safety. Based on these risk assessments, EPA

concludes that there is a reasonable certainty that no harm will result

to the general population, or to infants and children from aggregate

exposure to fenhexamid residues.

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IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology Bayer AG Method 00362, a high-

performance liquid chromatography (HPLC) method with electrochemical

detection (ECD) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry

Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD

20755-5350; telephone number: (410) 305-2905; email

address:[residuemethods@epa.gov](mailto:residuemethods@epa.gov).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S.

tolerances with international standards whenever possible, consistent

with U.S. food safety standards and agricultural practices. EPA

considers the international maximum residue limits (MRLs) established

by the Codex Alimentarius Commission (Codex), as required by FFDCA

section 408(b)(4). The Codex Alimentarius is a joint United Nations

Food and Agriculture Organization/World Health Organization food

standards program, and it is recognized as an international food safety

standards-setting organization in trade agreements to which the United

States is a party. EPA may establish a tolerance that is different from

a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain

the reasons for departing from the Codex level.

Codex MRLs for head and leaf lettuce; eggplant, tomato, and bell

pepper; and apricot, nectarine, and peach are harmonized with the U.S.

tolerances for fenhexamid on leafy greens subgroup 4-16A, except

spinach; vegetable, fruiting, group 8-10, except non bell pepper; and

fruit, stone, group 12-12, except plum, prune, dried, respectively. The

Codex MRLs for other stone fruits in crop group 12-12 are lower than

the crop group tolerance; harmonizing with them could result in over-

tolerance residues in the U.S. despite legal use of the pesticide

according to the label.

The established U.S. tolerances for fenhexamid in or on caneberry

subgroup 13-07A and kiwifruit, fuzzy are 20 ppm and 30 ppm

respectively. These values are higher than the Codex MRL values of 15

ppm for individual commodities in caneberry subgroup 13-07A and

kiwifruit, fuzzy. The U.S. tolerance values for fenhexamid on caneberry

subgroup 13-07A and kiwifruit, fuzzy were determined based on expected

residues resulting from U.S. use pattern; harmonizing with Codex MRL

values may result in over tolerance residues. The established U.S.

tolerances for residues of fenhexamid in grape and strawberry are

currently harmonized with Canada but are lower than the established

Codex MRLs. These U.S. tolerances were established as part of a joint

review with the Health Canada Pest Management Regulatory Agency (PMRA);

therefore, EPA is not raising these tolerances to harmonize with Codex.

C. Revisions to Petitioned-For Tolerances

EPA has revised the proposed tolerances for residues of fenhexamid

on onion bulb subgroup 3-07A; onion green subgroup 3-07B; fuzzy

kiwifruit; fruit small vine climbing, except fuzzy kiwifruit subgroup

13-07F; berry low growing subgroup 13-07G; caneberry subgroup 13-07A;

bushberry subgroup 13-07B; fruit stone group 12-12, except plum prune

fresh; leafy greens subgroup 4-16A except spinach; vegetable fruiting

group 8-10 except nonbell pepper; arugula; garden cress and upland

cress based on current OECD rounding classes. In addition, EPA

corrected the commodity definition for fruit, stone, group 12-12,

except plum, prune, fresh and plum, prune, dried.

V. Conclusion

Therefore, tolerances are established for residues of fenhexamid,

in or on arugula at 30 ppm; berry, low growing, subgroup 13-07G at 3

ppm; bushberry subgroup 13-07B at 5 ppm; caneberry subgroup 13-07A at

20 ppm; cress, garden at 30 ppm; cress, upland at 30 ppm; fruit, small,

vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 4 ppm; fruit,

stone, group 12-12, except plum, prune at 10 ppm; kiwifruit, fuzzy at

30 ppm; leafy greens, subgroup 4-16A, except spinach at 30 ppm; onion,

bulb, subgroup 3-07A at 2 ppm; onion, green, subgroup 3-07B at 30 ppm;

and vegetable, fruiting, group 8-10, except nonbell pepper at 2 ppm.

Additionally, the existing tolerances on the following commodities

are removed as unnecessary due to the establishment of the above

tolerances: bushberry subgroup 13B; caneberry subgroup 13A; cilantro,

leaves; fruit, stone, group 12, except plum, prune, fresh, postharvest;

grape; juneberry; kiwifruit, postharvest; leafy greens subgroup 4A,

except spinach; lingonberry; salal; strawberry; and vegetable,

fruiting, group 8, except nonbell pepper. Finally, EPA is revising the

tolerance expression to be consistent with Agency policy.

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

[[Page 2659]]

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: December 6, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

0

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

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

0

2. In Sec. 180.553, amend paragraph (a) as follows:

0

a. Revise the introductory text;

0

b. Add alphabetically the entries for ``Arugula'' and ``Berry, low

growing, subgroup 13-07G'';

0

c. Remove the entry for ``Bushberry subgroup 13B'';

0

d. Add alphabetically the entry for ``Bushberry subgroup 13-07B'';

0

e. Remove the entry for ``Caneberry subgroup 13A'';

0

f. Add alphabetically the entry for ``Caneberry subgroup 13-07A'';

0

g. Remove the entry for ``Cilantro, leaves'';

0

h. Add alphabetically the entries for ``Cress, garden''; ``Cress,

upland''; ``Fruit, small, vine climbing, except fuzzy kiwifruit,

subgroup 13-07F''; and ``Fruit, stone, group 12-12, except plum,

prune'';

0

i. Remove the entries for ``Fruit, stone, group 12, except plum, prune,

fresh, postharvest''; ``Grape''; and ``Juneberry'';

0

j. Add alphabetically the entry for ``Kiwifruit, fuzzy'';

0

k. Remove the entries for ``Kiwifruit, postharvest'' and ``Leafy

greens subgroup 4A, except spinach'';

0

l. Add alphabetically the entry for ``Leafy greens, subgroup 4-16A,

except spinach'';

0

m. Remove the entry for ``Lingonberry'';

0

n. Add alphabetically the entries for ``Onion, bulb, subgroup 3-07A''

and ``Onion, green, subgroup 3-07B'';

0

o. Remove the entries for ``Salal''; ``Strawberry''; and ``Vegetable,

fruiting, group 8, except nonbell pepper''; and

0

p. Add alphabetically the entry for ``Vegetable, fruiting, group 8-10,

except non bell pepper''.

The revisions and additions read as follows:

Sec. 180.553 Fenhexamid; tolerances for residues.

(a) General. Tolerances are established for residues of fenhexamid,

including its metabolites and degradate, in or on the commodities in

the table in this paragraph (a). Compliance with the tolerance levels

specified in this paragraph (a) is to be determined by measuring only

fenhexamid (N-2,3-dichloro-4-hydroxyphenyl)-1-

methylcyclohexanecarboxamide).

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Parts per

Commodity million

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\* \* \* \* \* \* \*

Arugula................................................. 30

\* \* \* \* \* \* \*

Berry, low growing, subgroup 13-07G..................... 3

Bushberry subgroup 13-07B............................... 5

Caneberry subgroup 13-07A............................... 20

Cress, garden........................................... 30

Cress, upland........................................... 30

\* \* \* \* \* \* \*

Fruit, small, vine climbing, except fuzzy kiwifruit, 4

subgroup 13-07F........................................

Fruit, stone, group 12-12, except plum, prune........... 10

\* \* \* \* \* \* \*

Kiwifruit, fuzzy........................................ 30

Leafy greens, subgroup 4-16A, except spinach............ 30

Onion, bulb, subgroup 3-07A............................. 2

Onion, green, subgroup 3-07B............................ 30

\* \* \* \* \* \* \*

Vegetable, fruiting, group 8-10, except nonbell pepper.. 2

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\* \* \* \* \*

[FR Doc. 2020-00080 Filed 1-15-20; 8:45 am]

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