[Federal Register Volume 86, Number 228 (Wednesday, December 1, 2021)]

[Rules and Regulations]

[Pages 68150-68159]

From the Federal Register Online via the Government Publishing Office [[www.gpo.gov](http://www.gpo.gov/)]

[FR Doc No: 2021-25091]

=======================================================================

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

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0352 and EPA-HQ-OPP-2019-0560; FRL-8945-01-OCSPP]

Bifenthrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

[[Page 68151]]

SUMMARY: This regulation establishes tolerances for residues of

bifenthrin in or on multiple commodities which are identified and

discussed later in this document. The Interregional Project Number 4

(IR-4) and FMC Corporation requested these tolerances under the Federal

Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 1, 2021. Objections and

requests for hearings must be received on or before January 31, 2022

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 dockets for this action, identified by docket

identification (ID) number EPA-HQ-OPP-2016-0352 and EPA-HQ-OPP-2019-

0560, are 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, Acting Director,

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 numbers EPA-HQ-OPP-2016-0352 and EPA-HQ-OPP-2019-0560 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 January 31, 2022. 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 numbers EPA-HQ-OPP-2016-0352 and EPA-

HQ-OPP-2019-0560, 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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>. 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, 2016 (81 FR 71668) (FRL-

9952-19), 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

6E8482) by IR-4, Rutgers, the State University of New Jersey, 500

College Road East, Suite 201W, Princeton, NJ 08540. The petition

requested that 40 CFR 180.442 be amended by establishing tolerances for

residues of the insecticide bifenthrin, (2-methyl [1,1'-biphenyl]-3-yl)

methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2-

dimethylcyclopropanecarboxylate, in or on apple, wet pomace at 1.3

parts per million (ppm); avocado at 0.50 ppm; berry, low growing,

subgroup 13-07G at 3.0 ppm; Brassica, leafy greens, subgroup 4-16B at

15 ppm; caneberry subgroup 13-07A at 1.0 ppm; fruit, citrus, group 10-

10 at 0.05 ppm; fruit, pome, group 11-10, except mayhaw, at 0.70 ppm;

fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at

0.20 ppm; nut, tree, group 14-12 at 0.05 ppm; peach, subgroup 12-12B at

0.70 ppm; pepper/eggplant subgroup 8-10B at 0.50 ppm; pomegranate at

0.50 ppm; and tomato, subgroup 8-10A at 0.15 ppm. The October 18, 2016,

Federal Register document and the Notice of Filing in docket number

EPA-HQ-OPP-2016-0352 identified the requested tolerance for tomato

subgroup 8-10A as 0.30 ppm. However, IR-4's submitted petition

identified a tolerance of 0.15 ppm for tomato subgroup 8-10A. When

there is a discrepancy between a tolerance in the submitted Notice of

Filing and the submitted petition, EPA uses the tolerance in the

petition as the petitioned-for tolerance, which is 0.15 ppm for tomato

subgroup 8-10A.

Additionally, the petition requested, upon approval of the above

tolerances, to remove the existing tolerances in 40 CFR 180.442(a) in

or on Brassica, leafy greens, subgroup 5B at 3.5 ppm; caneberry,

subgroup 13A at 1.0 ppm; eggplant 0.05 ppm; fruit, citrus, group 10 at

0.05 ppm; grape at 0.20 ppm; groundcherry at 0.5 ppm; nut, tree, group

14 at 0.05 ppm; okra at 0.50 ppm; pear at 0.5 ppm; pepino at 0.5 ppm;

pepper, bell at 0.5 ppm; pepper, non-bell at 0.5 ppm; pistachio at 0.05

ppm; strawberry at 3.0 ppm; tomato at 0.15

[[Page 68152]]

ppm; and turnip, greens at 3.5 ppm. Finally, the petition requested

upon approval of the above tolerances, to remove the existing time-

limited tolerances in 40 CFR 180.442(b) in or on, apple at 0.5 ppm;

nectarine at 0.5 ppm; and peach at 0.5 ppm. That document referenced a

summary of the petition prepared by FMC Corporation and Makhteshim Agan

of North America, Inc. (ADAMA), the registrants, 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 February 11, 2020 (85 FR 7708) (FRL-

10005-02), 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

8F8704) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104.

The petition requested that 40 CFR 180.442 be amended by establishing

tolerances for residues of the bifenthrin, (2-methyl [1,1'-biphenyl]-3-

yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-2,2

dimethylcyclopropanecarboxylate, in or on sunflower (crop subgroup 20B)

at 0.01 ppm. That document referenced a summary of the petition

prepared by FMC Corporation, 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 petitions, EPA is

establishing some tolerances that vary from what was requested. 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 bifenthrin including exposure

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

assessment of exposures and risks associated with bifenthrin 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 predominant effects seen in most of the bifenthrin experimental

toxicology studies were behavioral changes characteristic of Type I

pyrethroids, such as muscle tremors, which are consistent with its

mode-of-action (MOA) to activate sodium channels. Additional effects

seen in one or more studies included: muscle twitching, decreased grip

strength, altered landing foot splay, depressed respiration, increased

grooming counts, loss of muscle coordination, staggered gait,

exaggerated hind limb flexion, and convulsions at high doses. Decreased

body weight and food consumption were also noted in repeat-dosing

dietary studies.

In developmental toxicity studies involving rats and rabbits,

maternal toxicity was observed (neurological effects) while no

developmental effects of biological significance were observed. In the

2-generation reproduction dietary study in the rat, tremors were noted

only in females of both generations, with one parental generation rat

observed to have clonic convulsions, and no observed effects in the

offspring. A developmental neurotoxicity study was also conducted.

Clinical signs of neurotoxicity were observed in both the adults and

offspring at the same dose levels; therefore, there is no indication of

increased qualitative or quantitative susceptibility in the young.

Bifenthrin is classified as a Group C--``possible human

carcinogen,'' based on an increased incidence of urinary bladder tumors

in mice. However, EPA has determined that quantification of risk using

a non-linear approach (i.e., reference dose (RfD)) will adequately

account for all chronic toxicity, including potential carcinogenicity,

that could result from exposure to bifenthrin for the following

reasons. First, the bladder tumors may not be uncommon in mice and are

not likely to be malignant. Second, these tumors were observed only in

male mice at the highest dose. Third, no evidence of carcinogenicity

was observed in bifenthrin carcinogenicity studies in rats. Finally,

there is a low concern for mutagenicity based on the overall results of

the available mutagenicity tests of bifenthrin.

A complete discussion of the toxicological profile for bifenthrin

and the Agency's cancer conclusion as well as specific information on

the studies received and the nature of the adverse effects caused by

bifenthrin 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 in the documents titled ``Bifenthrin: Revised

Human Health Risk Assessment for the Requested Section 3 Registration

of Bifenthrin on Pome Fruit Group 11-10 (except Mayhaw), Peach Subgroup

12-12B, Avocado, Pomegranate, Brassica Leafy Greens Subgroup 4-16B; and

Crop Group Conversions/Expansions for Tomato Subgroup 8-10A, Pepper/

Eggplant Subgroup 8-10B, Small Vine Climbing Fruit Subgroup 13-07F, Low

Growing Berry Subgroup 13-07G, Citrus Fruit Group 10 to Citrus Fruit

Group 10-10, Caneberry Subgroup 13A to Caneberry Subgroup 13-07A, and

Tree Nut Group 14 to Tree Nut Group 14-12'' (hereinafter ``Bifenthrin

Multiple Crop Human Health Risk Assessment'') and ``Bifenthrin. Human

Health Risk Assessment for the Proposed New Use on Sunflower Crop

Subgroup 20B'' in docket ID number EPA-HQ-OPP-2016-0352 in

[regulations.gov](http://regulations.gov/).

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/

[[Page 68153]]

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 bifenthrin used for

human risk assessment can be found in the Bifenthrin Multiple Crop

Human Health Risk Assessment.

C. Exposure Assessment

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

exposure to bifenthrin, EPA considered exposure under the petitioned-

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

180.442. EPA assessed dietary exposures from bifenthrin 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 bifenthrin. In estimating acute

dietary exposure, EPA used 2003-2008 food consumption data from the

United States 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, the acute assessment was refined using

distributions and point estimates derived from pesticide data program

(PDP) monitoring data, field trial data, percent crop treated (PCT)

data, and empirical processing factors.

ii. Chronic exposure. A chronic dietary endpoint has not been

selected for bifenthrin because repeated exposure does not result in a

POD lower than that resulting from acute exposure; therefore, the acute

dietary risk assessment is protective of chronic dietary risk. However,

since there are residential uses of bifenthrin, a refined chronic

dietary exposure assessment was conducted to calculate average (food

and drinking water) exposure estimates representing background dietary

exposure to support the bifenthrin aggregate risk assessment. The

assessment was refined using point estimates derived from PDP

monitoring data, field trial data, PCT data, and empirical processing

factors.

iii. Cancer. As discussed in Unit III.A., EPA has determined that

the acute reference dose (RfD) will adequately account for all repeated

exposure/chronic toxicity, including potential carcinogenicity, which

could result from exposure to bifenthrin. A separate cancer exposure

assessment was not conducted.

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

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and

information on the anticipated residue levels of pesticide residues in

food and the actual levels of pesticide residues that have been

measured in food. If EPA relies on such information, EPA must require

pursuant to FFDCA section 408(f)(1) that data be provided 5 years after

the tolerance is established, modified, or left in effect,

demonstrating that the levels in food are not above the levels

anticipated. For the present action, EPA will issue such data call-ins

as are required by FFDCA section 408(b)(2)(E) and authorized under

FFDCA section 408(f)(1). Data will be required to be submitted no later

than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data

on the actual percent of food treated for assessing chronic dietary

risk only if:

Condition a: The data used are reliable and provide a

valid basis to show what percentage of the food derived from such crop

is likely to contain the pesticide residue.

Condition b: The exposure estimate does not underestimate

exposure for any significant subpopulation group.

Condition c: Data are available on pesticide use and food

consumption in a particular area, and the exposure estimate does not

understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any

estimates used. To provide for the periodic evaluation of the estimate

of PCT as required by FFDCA section 408(b)(2)(F), EPA may require

registrants to submit data on PCT.

The acute dietary assessment used the following maximum PCT

estimates: Almonds: 40%, artichoke: 65%, green beans (fresh &

succulent): 60%, blueberries (all bushberries): 35%, broccoli: 25%,

Brussel sprouts: 5%, cabbage: 50%, caneberries: 55%, canola: 25%,

cantaloupes: 55%, carrots: 5%, cauliflower: 2.5%, celery: 45%, citrus

(all others): 2.5%, corn: 10%, cotton: 20%, cucumbers: 35%, dry beans/

peas: 5%, eggplant: 45%, grapefruit: 2.5%, grapes, juice: 10%, grapes,

table: 2.5%, grapes, wine: 5%, hazelnuts: 5%, honeydews: 90%, kumquat:

2.5%, lemons: 2.5%, lettuce; 15%, lima beans: 40%, lime: 2.5%, okra:

45%, onions: 5%, oranges, 10%, peanuts: 20%, pears: 2.5%, green peas

(fresh & succulent): 50%, pecans: 20%, peppers (all); 30%, pistachios:

55%, potatoes: 15%, pummelo: 2.5%, pumpkins: 25%, soybeans: 10%,

spinach: 15%, squash: 25%, strawberries: 70%, sweet corn: 50%,

tangerines: 2.5%, tomatoes: 45%, walnuts: 25%, and watermelons: 20%.

The acute dietary assessment also used the following maximum PCT

estimates for some of the new uses: apples: 55%, avocados: 50%,

nectarines: 65%, peaches: 35%, and pomegranates: 60%.

The following average PCT estimates for bifenthrin were used to

refine the chronic dietary risk assessment for the following crops:

Almonds: 25%, artichoke: 30%, green beans (fresh & succulent): 55%,

blueberries (all bushberries): 10%, broccoli: 15%, Brussel sprouts: 1%,

cabbage: 30%, caneberries: 45%, canola: 10%, cantaloupes: 50%, carrots:

2.5%, cauliflower: 1%, celery: 10%, citrus (all others): 1%, corn: 5%,

cotton: 15%, cucumbers: 20%, dry beans/peas: 2.5%, eggplant: 25%,

grapefruit: 1%, grapes, juice: 2.5%, grapes, table: 1%, grapes, wine:

2.5%, hazelnuts: 1%, honeydews: 25%, kumquat: 1%, lemons: 1%, lettuce;

10%, lima beans: 20%, lime: 1%, okra: 25%, onions: 2.5%, oranges, 1%,

peanuts: 10%, pears: 1%, green peas (fresh & succulent): 30%, pecans:

10%, peppers (all); 20%, pistachios: 35%, potatoes: 10%, pummelo: 1%,

pumpkins: 15%, soybeans: 5%, spinach: 2.5%, squash: 20%, strawberries:

55%, sweet corn: 40%, tangerines: 1%, tomatoes: 25%, walnuts: 15%, and

watermelons: 15%. The chronic dietary assessment also used the

following maximum PCT estimates for some of the new uses: apples: 50%,

avocados: 50%, nectarines: 65%, peaches: 35%, and pomegranates: 60%.

A default of 100% CT was used for all livestock and game

commodities, freshwater finfish, and all other registered uses where no

maximum/average PCT estimates were available. All other commodities

included for depicting food handling establishment (FHE) uses were

refined with the upper bound estimate of 4.65% for non-fumigant

treatments made in FHEs.

In most cases, EPA uses available data from United States

Department of Agriculture/National Agricultural Statistics Service

(USDA/NASS),

[[Page 68154]]

proprietary market surveys, and California Department of Pesticide

Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop

combination for the most recent 10 years. EPA uses an average PCT for

chronic dietary risk analysis and a maximum PCT for acute dietary risk

analysis. The average PCT figure for each existing use is derived by

combining available public and private market survey data for that use,

averaging across all observations, and rounding to the nearest 5%,

except for those situations in which the average PCT is less than 1% or

less than 2.5%. In those cases, the Agency would use less than 1% or

less than 2.5% as the average PCT value, respectively. The maximum PCT

figure is the highest observed maximum value reported within the most

recent 10 years of available public and private market survey data for

the existing use and rounded up to the nearest multiple of 5%, except

where the maximum PCT is less than 2.5%, in which case, the Agency uses

less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit

III.C.1.iv. have been met. With respect to Condition a, PCT estimates

are derived from Federal and private market survey data, which are

reliable and have a valid basis. The Agency is reasonably certain that

the percentage of the food treated is not likely to be an

underestimation. As to Conditions b and c, regional consumption

information and consumption information for significant subpopulations

are taken into account through EPA's computer-based model for

evaluating the exposure of significant subpopulations including several

regional groups. Use of consumption information in EPA's risk

assessment process ensures that EPA's exposure estimate does not

understate exposure for any significant subpopulation group and allows

the Agency to be reasonably certain that no regional population is

exposed to residue levels higher than those estimated by the Agency.

Other than the data available through national food consumption

surveys, EPA does not have available reliable information on the

regional consumption of food to which bifenthrin may be applied in a

particular area.

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

level water exposure models in the dietary exposure analysis and risk

assessment for bifenthrin in drinking water. These simulation models

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

characteristics of bifenthrin. 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>.

EPA used the limit of solubility as the drinking water input, i.e.,

the maximum possible residues that could occur in drinking water based

on the chemical properties of the compound. EPA used the modeled EDWCs

directly in the dietary exposure model to account for the contribution

of bifenthrin residues in drinking water as follows: 0.014 ppb was used

in the acute assessment and 0.014 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). Bifenthrin is

currently registered for the following uses that could result in

residential exposures: Lawns/turf, indoor environments, gardens/trees,

pets (dog shampoo), termiticide and indoor/outdoor surface treatment

for various residential and commercial premises.

EPA assessed residential exposure using the following assumptions.

There is the potential for residential handler and post-application

exposures from the use of bifenthrin. These exposures were assessed

using the 2012 Residential SOPs and submitted chemical-specific residue

data [bifenthrin-specific turf transferable residue (TTR; liquid and

granular) and dislodgeable foliar residue (DFR; liquid) data are

available]. EPA did not quantitatively assess the outdoor residential

handler uses in/around home foundations, outdoor impervious surfaces,

wood piles/structures and fence posts. Residential handler exposure

assessments were performed for adult homeowners applying bifenthrin

ready-to-use products (aerosol, hose-end sprayers and dog shampoos);

mixing/loading/applying liquid concentrates; loading/applying granular

formulations and applying dust formulations. The application rates for

these uses that were quantitatively assessed are equal to or higher

than those outdoor uses and thus are protective of the outdoor uses.

Dermal and inhalation risk estimates were combined in this assessment

because the toxicological effects for these exposure routes were the

same. A total aggregate risk index (ARI) was used because the levels of

concern (LOCs) for dermal exposure (100) and inhalation exposure (30)

are different. ARIs of less than 1 are risk estimates of concern. The

ARIs were calculated as follows. Aggregate Risk Index (ARI) = 1/

[(Dermal LOC / Dermal MOE) + (Inhalation LOC / Inhalation MOE)]. All

exposures are short-term in nature. There are no dermal or inhalation

risk estimates of concern for residential handlers for the registered

uses of bifenthrin.

Post-application exposure was assessed for broadcast applications

to turf, gardens/trees, indoor environments (carpets and hard floor)

and treated pets. Residential post-application exposures are expected

to be short-, intermediate- or long-term in duration. Because the

single dose and repeat dosing bifenthrin studies show that repeat

exposures do not result in lower points of departure, the residential

assessments are conducted as a series of acute exposures and the same

endpoint is used regardless of duration. Therefore, the acute/single

day residential post-application assessments are protective of expected

longer-term exposures. Dermal and incidental oral risk estimates were

combined because the toxicological effects for these exposure routes

were similar [combined Margin of Exposure (MOE) approach used since

LOCs are the same].

There were some residential post-application risk estimates of

concern identified previously in Registration Review. Specifically,

dermal post-application risks were identified for a liquid formulation

product with a maximum application rate of 2.3 lb ai/A, and risks were

identified for episodic ingestion of granules at application rates

greater than 0.34 lb ai/A. As a result, during Registration Review,

some bifenthrin labels were amended or canceled to address these risk

concerns. The product label for the liquid formulation with the high

application rate of 2.3 lb ai/A, which was canceled as of July 2021

(EPA Reg. #279-3152), was never commercialized. Because that product

was never sold or distributed, there are no exposures from that product

for consideration in the aggregate risk assessment. In addition, 25

granular products were either canceled or amended to require watering

in of the product after application when application rates were greater

than 0.34 lb ai/A. Although these label changes reduce the risks from

ingestion of granules, that use is not included in the aggregate

assessment because it is considered an episodic event and not a routine

behavior.

The following residential exposure scenarios were selected for

aggregation and represent the worst-case risk estimates: Adults

contacting treated gardens (dermal exposure); children 1 to

[[Page 68155]]

<2 years old contacting treated turf (dermal and incidental oral

exposure at the 0.23 lb ai/A rate); children 6 to <11 years old

contacting treated gardens (dermal exposure); and children 11 to 16

years old golfing on treated turf (dermal exposure).

Further information regarding EPA standard assumptions and generic

inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. Cumulative effects from substances with a common mechanism of

toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when

considering whether to establish, modify, or revoke a tolerance, the

Agency consider ``available information'' concerning the cumulative

effects of a particular pesticide's residues and ``other substances

that have a common mechanism of toxicity.''

The Agency has determined that the pyrethroids and pyrethrins share

a common mechanism of toxicity ([http://www.regulations.gov](http://www.regulations.gov/); EPA-HQ-OPP-

2008-0489-0006). As explained in that document, the members of this

group share the ability to interact with voltage-gated sodium channels

ultimately leading to neurotoxicity. In 2011, after establishing a

common mechanism grouping for the pyrethroids and pyrethrins, the

Agency conducted a cumulative risk assessment (CRA) which is available

at [http://www.regulations.gov](http://www.regulations.gov/); EPA-HQ-OPP-2011-0746. In that document,

the Agency concluded that cumulative exposures to pyrethroids (based on

pesticidal uses registered at the time the assessment was conducted)

did not present risks of concern. For information regarding EPA's

efforts to evaluate the risk of exposure to this class of chemicals,

refer to <https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids>.

Since the 2011 CRA, for each new pyrethroid and pyrethrin use, the

Agency has conducted a screen to evaluate any potential impacts on the

CRA prior to registration of that use. A new turf use for the

pyrethroid, tau-fluvalinate, was assessed after completion of the

cumulative, which did impact the worst-case non-dietary risk estimates

identified in the 2011 CRA for the turf scenario (Memo, DeLeon, H.,

D450820, 12/16/2019). However, the overall finding (i.e., that the

pyrethroid cumulative risk is below the Agency's level of concern) did

not change upon registration of this new use.

To account for the additional uses requiring tolerances in this

rule, the Agency has conducted an additional screen, taking into

account all previously approved uses and these proposed new uses. The

additional uses will not significantly impact the cumulative assessment

because dietary exposures make a minor contribution to total pyrethroid

exposure relative to residential exposures in the 2011 cumulative risk

assessment. Therefore, the results of the 2011 CRA are still valid and

there are no cumulative risks of concern for the pyrethroids/

pyrethrins.

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. Bifenthrin has been

evaluated for potential developmental effects in the rat (following

gavage and dietary administration) and in the rabbit (gavage

administration). Maternal toxicity included neurological effects

(tremors in rats and rabbits; head and forelimb twitching in rabbits).

There were no developmental effects of biological significance in

either species. The registrant submitted a Developmental Neurotoxicity

(DNT) study, which establishes a clear NOAEL for the adult and

offspring toxicity. The NOAEL in adults and offspring is similar in

magnitude, and the LOAELs are based on the clinical signs of

neurotoxicity (dams had tremors and convulsions, offspring had

increased grooming counts). Based on targeted testing in the DNT study

for common endpoints for bifenthrin, there was no increase in

sensitivity in rat pups. However, the Agency has reviewed existing

pyrethroid data and concludes that the DNT is not a particularly

sensitive study for comparing the sensitivity of young and adult

animals to pyrethroids. Some literature studies indicated

susceptibility for other pyrethroids, but in context, these studies

were conducted at relatively high doses, which may not reflect

environmental exposures. The reproductive toxicity of bifenthrin was

examined in a 2-generation reproduction dietary study in the rat.

Tremors were noted only in females of both generations, with one

parental generation rat observed to have clonic convulsions, and no

observed effects in the offspring. Overall, there is no indication of

increased juvenile sensitivity specifically to bifenthrin.

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 bifenthrin is complete.

ii. Like other pyrethroids, bifenthrin causes clinical signs of

neurotoxicity from interaction with sodium channels. These effects are

adequately assessed by the available guideline and non-guideline

studies. Bifenthrin is a Type I pyrethroid, and neurotoxic effects

characteristic of Type I pyrethroids were observed in adults in most of

the bifenthrin toxicity database. Specifically, muscle tremors and

decreased motor activity were observed in adults in guideline studies

throughout the bifenthrin toxicology database, and hind-limb flexion

was observed in adults the dermal study. For these reasons, the tremors

seen in juveniles in the 2-generation reproduction study are not

considered age-dependent effects.

iii. There was no evidence that bifenthrin resulted in increased

susceptibility in in utero rats or rabbits in the prenatal

developmental studies or in young rats in the 2-generation reproduction

study. Previously, however, EPA retained a FQPA safety factor of 3X to

account for concerns about pharmacokinetic (PK) differences between

adults and children. The Agency has re-evaluated the need for an FQPA

Safety Factor for human health risk assessments for pyrethroid

pesticides based on a review of the available guideline and literature

studies as well as data from the Council for the Advancement of

Pyrethroid Human Risk Assessment (CAPHRA) program. That recent data,

including human physiologically based pharmacokinetic (PBPK) models as

well as in vivo and in vitro data on protein binding, enzyme ontogeny,

and metabolic clearance, support the conclusion that the PK

contribution to the FQPA safety factor can be reduced to 1X for all

populations.

iv. There are no residual uncertainties identified in the exposure

databases.

[[Page 68156]]

Although the acute dietary exposure estimates are refined, the exposure

estimates will not underestimate risk for the established and proposed

uses of bifenthrin since the residue levels used are based on either

monitoring data reflecting actual residues found in the food supply, or

on high-end residues from field trials which reflect the use patterns

which would result in highest residues in foods. Furthermore,

processing factors used were either those measured in processing

studies, or default high-end factors representing the maximum

concentration of residue into a processed commodity. EPA made

conservative (protective) assumptions to assess exposure to bifenthrin

in drinking water. EPA used similarly conservative assumptions to

assess post-application exposure of children as well as incidental oral

exposure of toddlers. These assessments will not underestimate the

exposure and risks posed by bifenthrin.

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 bifenthrin will occupy 15% of the aPAD for infants (<1 year old),

the population group receiving the greatest exposure. The acute

aggregate risk assessment combines exposures to bifenthrin in food and

drinking water only and is equivalent to the acute dietary assessment.

There are no acute aggregate risks estimates of concern.

2. Chronic risk. The chronic (food and drinking water) exposure

assessment for bifenthrin was conducted solely for the purpose of

obtaining an average dietary exposure estimate for use in the aggregate

assessment. The population subgroup with the highest average dietary

exposure estimate is children 1 to 2 years old (0.000189 mg/kg/day).

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). Bifenthrin is

currently registered for uses that could result in short-term

residential exposure, and the Agency has determined that it is

appropriate to aggregate chronic exposure through food and water with

short-term residential exposures to bifenthrin.

Using the exposure assumptions described in this unit for short-

term exposures, EPA has concluded the combined short-term food, water,

and residential exposures result in an aggregate MOE of 520 for adults

(treated gardens). The short-term aggregate assessment for children 1

to less than 2 years old resulted in an MOE of 170 (treated turf at

0.23 lb ai/A). The short-term aggregate assessment for children 6 to

less than 11 years old and children 11 to 16 years old resulted in MOEs

of 1,600 (treated gardens) and 7,600 (golfing), respectively. Because

EPA's level of concern for bifenthrin is an MOE of 100 or lower, these

MOEs are not of concern.

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). While there is potential intermediate-term residential

exposure, because the single dose and repeat dosing bifenthrin studies

show that repeat exposures do not result in lower points of departure,

the residential assessments are conducted as a series of acute

exposures and the same endpoint is used regardless of duration.

Therefore, the short-term aggregate assessment is considered protective

of any intermediate-term exposures.

5. Aggregate cancer risk for U.S. population. EPA has concluded

that the acute reference dose (RfD) will adequately account for all

repeated exposures, including carcinogenicity, which could result from

exposure to bifenthrin.

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 bifenthrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with an

electron capture detector (GC/ECD) analyses for determining bifenthrin

residues in both plant and livestock commodities) 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.

The Codex has not established any MRLs for bifenthrin in or on

apple, wet pomace; avocado; fruit, pome, group 11-10; peach, or

pomegranate. The following U.S. tolerances being established are

harmonized with the Codex MRLs, which are identified in parentheses:

Caneberry subgroup 13-07A at 1 ppm (blackberry, dewberries and

raspberries); fruit, citrus, group 10-10 at 0.05 ppm (citrus fruit);

and nut, tree, group 14-12 at 0.05 ppm (tree nuts). The U.S. tolerance

for pepper/eggplant subgroup 8-10B at 0.5 ppm is harmonized with the

Codex MRL on pepper. It is not possible to harmonize with the Codex

MRLs of all commodities in the subgroup, including eggplant at 0.3 ppm

and dried chili peppers at 5 ppm.

The Codex has established an MRL for bifenthrin in or on grape at

0.3 ppm. The Agency is establishing the tolerance in or on fruit,

small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.3

ppm (rather than at 0.2 ppm, the existing U.S. tolerance on grape) to

harmonize with the Codex MRL on grape.

The Canadian MRL for bifenthrin in or on pear is 0.9 ppm and there

are no Codex MRLs for the commodities in the pome fruit crop group. EPA

is establishing the U.S. tolerance for fruit, pome, group 11-10, except

mayhaw at 0.9 ppm (rather than at the request level of 0.70 ppm based

on submitted residue data and the existing U.S. tolerance for

[[Page 68157]]

pear) to harmonize with the Canadian MRL.

EPA is establishing the tolerance for tomato subgroup 8-10A at 0.3

ppm (rather than at 0.15 ppm, the existing U.S. tolerance on tomato) to

harmonize with the Codex MRL of 0.3 ppm in/on tomato. Additionally, EPA

is establishing the tolerance for Brassica, leafy greens, subgroup 4-

16B at 4 ppm (rather than at 3.5 ppm, the existing U.S. tolerance on

Brassica, leafy greens, subgroup 5B) to harmonize with the Codex MRL of

4 ppm in/on mustard greens.

It is not possible to harmonize the U.S. tolerance for Berry, low

growing, subgroup 13-07G at 3 ppm with the Codex MRL for strawberry at

1 ppm. Reducing the U.S. tolerance would put U.S. growers at risk of

having violative residues despite legal use of the pesticide according

to the label.

C. Revisions to Petitioned-For Tolerances

EPA is establishing the tolerance at different levels than

requested for: Apple, wet pomace; avocado; berry, low growing, subgroup

13-07G; Brassica, leafy greens, subgroup 4-16B; caneberry subgroup 13-

07A; fruit, pome, group 11-10, except mayhaw; fruit, small, vine

climbing, except fuzzy kiwifruit, subgroup 13-07F; peach subgroup 12-

12B; pepper/eggplant subgroup 8-10B; pomegranate; sunflower (crop

subgroup 20B) and tomato subgroup 8-10A.

All trailing zeroes have been removed from the proposed tolerances

to be consistent with Organization for Economic Cooperation and

Development (OECD) Rounding Class Practice. In addition, the proposed

apple, wet pomace tolerance of 1.3 ppm has been established at 1.5 ppm

because the value determined is rounded following the OECD rounding

class practice.

To harmonize with the applicable international MRLs, the tolerances

for fruit, pome, group 11-10, except mayhaw; fruit, small, vine

climbing, except fuzzy kiwifruit, subgroup 13-07F; and tomato subgroup

8-10A were established at higher limits than what was proposed.

The petitioner withdrew the change to the use pattern that would

have necessitated the change to the tolerance for Brassica, leafy

greens, subgroup 4-16B from 3.5 ppm to 15 ppm. EPA is establishing the

tolerance for Brassica, leafy greens, subgroup 4-16B at 4 ppm, based on

the crop group conversion of the established tolerance on Brassica,

leafy greens, subgroup 5B and adjusting it to harmonize with the Codex

MRL for mustard greens.

The commodity definition for sunflower (crop subgroup 20B) has been

revised to sunflower subgroup 20B and the proposed tolerance at 0.01

has been established at 0.05 based on the current enforcement method

limit of quantitation (LOQ).

D. International Trade Considerations

In this rule, EPA is establishing a lower tolerance for bifenthrin

residues in or on groundcherry than the current tolerance. The current

tolerance for groundcherry is 0.5 ppm, but groundcherry is a commodity

in the proposed crop group expansion from tomato to tomato subgroup 8-

10A, for which EPA is establishing a new tolerance in this rulemaking

at 0.3 ppm. As a result, EPA intends for the allowable residues on

groundcherry to be reduced. As discussed in EPA's crop grouping

rulemaking, EPA has determined that groundcherry is similar to tomatoes

and appropriately categorized in subgroup 8-10A. See 72 FR 69150 (Dec.

7, 2007). Based on residue data supporting the 0.3 ppm tolerance for

subgroup 8-10A and the similarity of groundcherry to tomatoes, EPA

concludes that it is appropriate to reduce the tolerance on

groundcherry as well.

In accordance with the World Trade Organization's (WTO) Sanitary

and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the

WTO of the changes to these tolerances in order to satisfy its

obligations under the Agreement. In addition, the SPS Agreement

requires that Members provide a ``reasonable interval'' between the

publication of a regulation subject to the Agreement and its entry into

force to allow time for producers in exporting Member countries to

adapt to the new requirement. Accordingly, EPA is establishing an

expiration date for the existing tolerance to allow this tolerance to

remain in effect for a period of six months after the effective date of

this final rule. After the six-month period expires, this tolerance

will be reduced or revoked, as indicated in the regulatory text, and

allowable residues on groundcherry must conform to the tolerance for

subgroup 8-10A.

This reduction in tolerance level is not discriminatory; the same

food safety standard contained in the FFDCA applies equally to

domestically produced and imported foods. The new tolerance level is

supported by available residue data.

V. Conclusion

Tolerances are established for residues of bifenthrin, (2-methyl

[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3,-trifluoro-1-propenyl)-

2,2-dimethylcyclopropanecarboxylate, in or on apple, wet pomace at 1.5

ppm; avocado at 0.5 ppm; berry, low growing, subgroup 13-07G at 3 ppm;

Brassica, leafy greens, subgroup 4-16B at 4 ppm; caneberry subgroup 13-

07A at 1 ppm; fruit, citrus, group 10-10 at 0.05 ppm; fruit, pome;

group 11-10, except mayhaw at 0.9 ppm; fruit, small, vine climbing,

except fuzzy kiwifruit, subgroup 13-07F at 0.3 ppm; nut, tree, group

14-12 at 0.05 ppm; peach subgroup 12-12B at 0.7 ppm; pepper/eggplant

subgroup 8-10B at 0.5 ppm; pomegranate at 0.5 ppm; sunflower subgroup

20B at 0.05 ppm; and tomato subgroup 8-10A at 0.3 ppm.

The following tolerances are removed as unnecessary due to the

establishment of the above tolerances: Brassica, leafy greens, subgroup

5B at 3.5 ppm; caneberry subgroup 13A at 1.0 ppm; eggplant at 0.05 ppm;

fruit, citrus, group 10 at 0.05 ppm; grape at 0.2 ppm; nut, tree, group

14 at 0.05 ppm; okra at 0.50 ppm; pear at 0.5 ppm; pepino at 0.5 ppm;

pepper, bell at 0.5 ppm; pepper, nonbell at 0.5 ppm; pistachio at 0.05

ppm; strawberry at 3.0 ppm; tomato at 0.15 ppm; and turnip, greens at

3.5 ppm.

Additionally, the following Section 18 time-limited tolerances are

removed as unnecessary due to the establishment of the above permanent

tolerances: Apple at 0.5 ppm; avocado at 0.50 ppm; nectarine at 0.5

ppm; peach at 0.5 ppm; and pomegranate at 0.50 ppm.

Finally, EPA is setting a six-month expiration date for the current

groundcherry tolerance at 0.5 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in

response to petitions 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

[[Page 68158]]

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: November 10, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending

40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

IN FOOD

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. Amend Sec. 180.442 by:

0

a. In the table in paragraph (a)(1)

0

i. Adding in alphabetical order the commodities: ``Apple, wet pomace'';

``Avocado''; ``Berry, low growing, subgroup 13-07G''; ``Brassica, leafy

greens, subgroup 4-16B'';

0

ii Removing the commodities: ``Brassica, leafy greens, subgroup 5B'';

``Caneberry subgroup 13A'';

0

iii. Adding in alphabetical order the commodity ``Caneberry subgroup

13-07A'';

0

iv. Removing the commodities ``Eggplant''; ``Fruit, citrus, group 10'';

0

v. Adding in alphabetical order the commodities ``Fruit, citrus, group

10-10''; ``Fruit, pome, group 11-10, except mayhaw''; ``Fruit, small,

vine climbing, except fuzzy kiwifruit, subgroup 13-07F'';

0

vi. Removing the commodity ``Grape'';

0

vii. Revising the entry for ``Groundcherry''

0

viii. Removing the commodity ``Nut, tree, group 14'';

0

ix. Adding in alphabetical order the commodity ``Nut, tree, group 14-

12'';

0

x. Removing the commodity ``Okra'';

0

xi. Adding in alphabetical order the commodity ``Peach subgroup 12-

12B''

0

xii. Removing the commodities ``Pear''; ``Pepino''; ``Pepper, bell'';

``Pepper, nonbell'';

0

xiii. Adding in alphabetical order the commodity ``Pepper/eggplant

subgroup 8-10B'';

0

xiv. Removing the commodity ``Pistachio''

0

xv, Adding in alphabetical order the commodity ``Pomegranate'';

0

xvi. Removing the commodity ``Strawberry'';

0

xvii. Adding in alphabetical order the commodity ``Sunflower subgroup

20B'';

0

xviii. Removing the commodity ``Tomato'';

0

xix. Adding in alphabetical order the commodity ``Tomato subgroup 8-

10A''; and

0

xx. Removing the commodity ``Turnip, greens''.

0

b. Remove and reserve paragraph (b).

The additions and revisions read as follows.

Sec. 180.442 Bifenthrin; tolerances for residues.

(a)(1) \* \* \*

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

Parts per

Commodity million

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

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

Apple, wet pomace....................................... 1.5

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

Avocado................................................. 0.5

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

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

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

Brassica, leafy greens, subgroup 4-16B.................. 4

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

Caneberry subgroup 13-07A............................... 1

[[Page 68159]]

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

Fruit, citrus, group 10-10.............................. 0.05

Fruit, pome, group 11-10, except mayhaw................. 0.9

Fruit, small, vine climbing, except fuzzy kiwifruit, 0.3

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

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

Groundcherry \2\........................................ 0.5

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

Nut, tree, group 14-12.................................. 0.05

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

Peach subgroup 12-12B................................... 0.7

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

Pepper/eggplant subgroup 8-10B.......................... 0.5

Pomegranate............................................. 0.5

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

Sunflower subgroup 20B.................................. 0.05

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

Tomato subgroup 8-10A................................... 0.3

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

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

\1\There are no U.S. registrations.

\2\ This tolerance expires on June 1, 2022.

\* \* \* \* \*

[FR Doc. 2021-25091 Filed 11-30-21; 8:45 am]

BILLING CODE 6560-50-P