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[Pages 8447-8454]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0718 and EPA-HQ-OPP-2019-0076; FRL-10002-06]

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

difenoconazole in or on vegetable, root, subgroup 1A, except ginseng;

vegetable, leaves of root and tuber, group 2; and tea, dried. In

addition, this regulation amends the tolerances for residues of

difenoconazole in or ginseng; cattle, liver; goat, liver; horse, liver;

and sheep, liver. Syngenta Crop Protection, LLC requested these

tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 14, 2020. Objections and

requests for hearings must be received on or before April 14, 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-2018-0718 and EPA-HQ-OPP-2019-

0076, 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-2018-0718 and EPA-HQ-OPP-2019-0076 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 April 14, 2020. Addresses for mail and hand

delivery of objections and hearing requests are provided in 40 CFR

178.25(b).

In addition to filing an objection or hearing request with the

Hearing Clerk as described in 40 CFR part 178, please submit a copy of

the filing (excluding any Confidential Business Information (CBI)) for

inclusion in the public docket. Information not marked confidential

pursuant to 40 CFR part 2 may be disclosed publicly by EPA without

prior notice. Submit the non-CBI copy of your objection or hearing

request, identified by docket ID number EPA-HQ-OPP-2018-0718 and EPA-

HQ-OPP-2019-0076, 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 June 7, 2019 (84 FR 26630) (FRL-9993-93)

and in the Federal Register of May 9, 2019 (84 FR 20320) (FRL-9992-36),

EPA issued documents pursuant to FFDCA section 408(d)(3), 21 U.S.C.

346a(d)(3), announcing the filing of pesticide petitions (PP 8F8695 and

8E8728, respectively) by Syngenta Crop Protection, LLC, P.O. Box 18300,

Greensboro, NC 27419. Pesticide

[[Page 8448]]

petition 8F8695 requested that 40 CFR 180.475 be amended by

establishing tolerances for residues of the fungicide difenoconazole in

or on root vegetable crop subgroup 1A at 0.60 parts per million (ppm)

and leaves of root and tuber vegetables crop group 2 at 8.0 ppm; PP

8E8728 requested the establishment of a tolerance for residues of

difenoconazole in or on tea at 30 ppm. Those documents referenced

summaries of the petitions prepared by Syngenta Crop Protection, LLC,

the registrant, which are available in their respective dockets, [http://www.regulations.gov](http://www.regulations.gov/). One comment was received on EPA's May 9, 2019

notice of filing in docket number EPA-HQ-OPP-2019-0076. EPA's response

to this comment is discussed in Unit IV.C.

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

establishing tolerances that vary from what the petitioner requested as

permitted by FFDCA section 408(d)(4)(A)(i). These differences are

explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

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

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

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

reasonable certainty that no harm will result from aggregate exposure

to the pesticide chemical residue, including all anticipated dietary

exposures and all other exposures for which there is reliable

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

residential settings, but does not include occupational exposure.

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

consideration to exposure of infants and children to the pesticide

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

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

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

.''

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

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

scientific data and other relevant information in support of this

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

determination on aggregate exposure for difenoconazole including

exposure resulting from the tolerances established by this action.

EPA's assessment of exposures and risks associated with difenoconazole

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.

Subchronic and chronic toxicity studies with difenoconazole in mice

and rats showed decreased body weights and effects on the liver (e.g.,

hepatocellular hypertrophy, liver necrosis, fatty changes in the

liver). No systemic toxicity was observed at the limit dose in a rat

dermal toxicity study. Difenoconazole exhibits low acute toxicity by

the oral, dermal and inhalation routes of exposure. It is not an eye or

skin irritant and is not a sensitizer.

Acute and subchronic neurotoxicity studies showed evidence of mild

neurotoxic effects. However, the selected endpoints of toxicity for

risk assessment are protective of any potential neurotoxicity.

The available toxicity studies indicated no increased

susceptibility of rats or rabbits from in utero or postnatal exposure

to difenoconazole. In prenatal developmental toxicity studies in rats

and rabbits and in the 2-generation reproduction study in rats, fetal

and offspring toxicity, when observed, occurred at equivalent or higher

doses than in the maternal and parental animals. In a rat developmental

toxicity study, developmental effects were observed at doses higher

than those which caused maternal toxicity. Developmental effects in the

rat included increased incidence of ossification of the thoracic

vertebrae and thyroid, decreased number of sternal centers of

ossification, increased number of ribs and thoracic vertebrae, and

decreased number of lumbar vertebrae. In the rabbit study,

developmental effects (increases in post-implantation loss and

resorptions and decreases in fetal body weight) were also seen at

maternally toxic (decreased body weight gain and food consumption)

doses. Since the developmental effects are more severe than the

maternal effects, qualitative susceptibility is indicated in the rabbit

developmental study; however, the selected POD is protective of this

effect. In the 2-generation reproduction study in rats, toxicity to the

fetuses and offspring, when observed, occurred at equivalent or higher

doses than in the maternal and parental animals.

Although there is some evidence that difenoconazole affects

antibody levels at doses that cause systemic toxicity, there are no

indications in the available studies that organs associated with immune

function, such as the thymus and spleen, are affected by

difenoconazole. Difenoconazole is not mutagenic or genotoxic, and no

evidence of carcinogenicity was seen in rats. Evidence for

carcinogenicity was seen in mice as induction of liver tumors at doses

which were considered to be excessively high for carcinogenicity

testing. Difenoconazole has been classified as ``Suggestive Evidence of

Carcinogenic Potential'' based on liver tumors observed in mice. EPA

has concluded that the chronic point of departure (POD) for assessing

chronic risk will be protective of any cancer effects for the following

reasons: (1) Tumors were seen in only one species; (2) carcinoma tumors

were observed only at the two highest doses in the mouse

carcinogenicity study; (3) benign tumors and necrosis were observed at

the mid-dose; (4) the absence of tumors at the study's lower doses; (5)

the absence of genotoxic or mutagenic effects. The cRfD is well below

the no-observed- adverse-effect-level (NOAEL) of the mouse

carcinogenicity study, at which no effects on the biological endpoints

relevant to tumor development (i.e., hepatocellular hypertrophy, liver

necrosis, fatty changes in the liver and bile stasis) were seen. As a

result, EPA has concluded that a nonlinear RfD approach is appropriate

for assessing cancer risk to difenoconazole and a separate quantitative

cancer exposure assessment is unnecessary.

Specific information on the studies received and the nature of the

adverse effects caused by difenoconazole 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 ``Difenoconazole. Human Health Risk

Assessment for Proposed New Foliar Uses on All Members of Vegetable,

Root, Subgroup 1A and Vegetable, Leaves of Root and Tuber, Group 2 and

Establishment of a Tolerance with No U.S. Registration in/on Imported

Tea'' in docket ID number EPA-HQ-OPP-2018-0718.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA

identifies toxicological POD and levels of concern to use in evaluating

the risk posed by human exposure to the pesticide. For

[[Page 8449]]

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

NOAEL and 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 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 difenoconazole used

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

Table 1--Summary of Toxicological Doses and Endpoints for Difenoconazole 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 (All populations).. NOAEL = 25 mg/kg/day Acute RfD = 0.25 mg/ Acute Neurotoxicity Study in Rats.

UFA = 10x........... kg/day. LOAEL = 200 mg/kg/day in males

UFH = 10x........... aPAD = 0.25 mg/kg/ based on reduced fore-limb grip

FQPA SF = 1x........ day. strength in males on Day 1 and

increased motor activity on Day

1.

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

Chronic dietary (All populations) NOAEL= 0.96 mg/kg/ Chronic RfD = 0.01 Combined Chronic Toxicity/

day mg/kg/day. Carcinogenicity (rat, dietary).

UFA = 10x........... cPAD = 0.01 mg/kg/ LOAEL = 24.1/32.8 mg/kg/day (male/

UFH = 10x........... day. female) based on cumulative

FQPA SF = 1x........ decreases in body-weight gains.

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

Oral short-term (1 to 30 days)... NOAEL= 1.25 mg/kg/ Residential LOC for Reproduction and Fertility Study

day MOE = <100. (rat dietary).

UFA = 10x........... Parental/Offspring LOAEL = 12.5 mg/

UFH = 10x........... kg/day based on decreased pup

FQPA SF = 1x........ weight in in males on Day 21 and

reduction in body weight gain of

F0 females prior to mating,

gestation and lactation.

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

Dermal short-term (1 to 30 days) NOAEL = 1.25 mg/kg/ LOC for MOE = <100. Reproduction and Fertility Study

and intermediate-term (1 to 6 day (dermal (rat, dietary).

months). absorption factor = Parental/Offspring LOAEL = 12.5 mg/

6%) kg/day based on decreased pup

UFA = 10x........... weight in males on Day 21 and

UFH = 10x........... reduction in body weight gain of

FQPA SF = 1x........ F0 females prior to mating,

gestation and lactation.

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

Inhalation short-term (1 to 30 NOAEL= 1.25 mg/kg/ LOC for MOE = <100. Reproduction and Fertility Study

days) and intermediate-term (1 day (rat, dietary).

to 6 months). UFA = 10x........... Parental/Offspring LOAEL = 12.5 mg/

\* Inhalation and oral absorption UFH = 10x........... kg/day based on decreased pup

assumed equivalent. FQPA SF = 1x........ weight in males on Day 21 and

reduction in body weight gain of

F0 females prior to mating,

gestation and lactation.

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

Cancer (Oral, dermal, inhalation) Difenoconazole is classified ``Suggestive Evidence of Carcinogenic

Potential''. Quantification of cancer risk is not required. The RfD would

address the concern for chronic toxicity, including carcinogenicity, likely

to result from exposure to difenoconazole.

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

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 difenoconazole, EPA considered exposure under the

petitioned-for tolerances as well as all existing difenoconazole

tolerances in 40 CFR 180.475. EPA assessed dietary exposures from

difenoconazole 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 difenoconazole. In estimating acute dietary exposure, EPA used food

consumption information from the United States Department of

Agriculture (USDA) National Health and Nutrition Examination Survey,

What We Eat in America, (NHANES/WWEIA) 2003 to 2008. As to residue

levels in food, EPA assumed tolerance-level residues, 100 percent crop

treated (PCT), and available empirical or default processing factors.

ii. Chronic exposure. In conducting the chronic dietary exposure

assessment EPA used the food consumption data from the USDA NHANES/

WWEIA 2003 to 2008. As to residue levels in food, EPA used tolerance-

level residues for some commodities, average field trial residues and

USDA Pesticide Data Program monitoring samples for the remaining

commodities, available

[[Page 8450]]

empirical or default processing factors, and average PCT assumptions

for some commodities.

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

concluded that a nonlinear RfD approach is appropriate for assessing

cancer risk due to difenoconazole. Cancer risk was assessed using the

same exposure estimates as discussed in Unit III.C.1.ii., chronic

exposure.

iv. Anticipated residue and PCT information. Section 408(b)(2)(E)

of FFDCA authorizes EPA to use available data and information on the

anticipated residue levels of pesticide residues in food and the actual

levels of pesticide residues that have been measured in food. If EPA

relies on such information, EPA must require pursuant to FFDCA section

408(f)(1) that data be provided 5 years after the tolerance is

established, modified, or left in effect, demonstrating that the levels

in food are not above the levels anticipated. For the present action,

EPA will issue such data call-ins as are required by FFDCA section

408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be

required to be submitted no later than 5 years from the date of

issuance of these tolerances.

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

on the actual percent of food treated for assessing chronic dietary

risk only if:

Condition a: The data used are reliable and provide a

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

is likely to contain the pesticide residue.

Condition b: The exposure estimate does not underestimate

exposure for any significant subpopulation group.

Condition c: Data are available on pesticide use and food

consumption in a particular area, the exposure estimate does not

understate exposure for the population in such area.

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

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

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

registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows: Almond

15%, apples 25%, apricot 10%, artichoke 15%, blueberry 10%, broccoli

2.5%, cabbage 10%, cantaloupe 2.5%, carrot 2.5%, cauliflower 2.5%,

cherry 2.5%, cucumbers 5%, garlic 10%, grapefruit 10%, grape (raisin)

10%, grape (table) 25%, grape (wine) 15%, hazelnut 2.5%, lemon 5%,

onions 10%, orange 5%, peach 10%, pear 10%, pecan 5%, peppers 15%,

pistachio 10%, plum/prune 10%, potato 20%, pumpkin 5%, soybean 2.5%,

squash 10%, strawberry 2.5%, sugar beets 20%, sweet corn 5%, tangerine

5%, tomato 35%, walnut 5%, watermelon 15%, and wheat 15%.

In most cases, EPA uses available data from United States

Department of Agriculture/National Agricultural Statistics Service

(USDA/NASS), 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. The average PCT figures

for each existing use is derived by combining available public and

private market survey data for that use, averaging across all

observations, and rounding up 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

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

the exposure of significant subpopulations including several regional

groups. Use of this consumption information in EPA's risk assessment

process ensures that EPA's exposure estimate does not understate

exposure for any significant subpopulation group and allows the Agency

to be reasonably certain that no regional population is exposed to

residue levels higher than those estimated by the Agency. Other than

the data available through national food consumption surveys, EPA does

not have available reliable information on the regional consumption of

food to which difenoconazole may be applied in a particular area.

2. Dietary exposure from drinking water. The drinking water

assessment was performed using a total toxic residue method, which

considers both parent difenoconazole and its major metabolite, CGA

205375, or total toxic residues (TTR) from difenoconazole uses, in

surface and groundwater. The Agency used screening level water exposure

models in the dietary exposure analysis and risk assessment for

difenoconazole in drinking water. These simulation models take into

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

characteristics of difenoconazole plus CGA 205375. 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 Tier II Pesticide in Water Calculator (PWC v1.52)

model and Tier 1 Rice Model, the estimated drinking water

concentrations (EDWCs) of TTR of difenoconazole for acute exposures are

estimated to be 33.4 parts per billion (ppb) for surface water and 2.0

ppb for ground water. Chronic exposure EDWCs for non-cancer assessments

are estimated to be 27.4 ppb for surface water and 0.60 ppb for ground

water.

Modeled estimates of drinking water concentrations were directly

entered into the dietary exposure model. For acute dietary risk

assessment, the water concentration value of 33.4 ppb was used to

assess the contribution to drinking water. For chronic dietary risk

assessment, the water concentration of value 27.4 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 flea and tick control on pets). Difenoconazole is

currently registered for the following uses that could result in

residential exposures: Treatment of ornamental plants in commercial and

residential landscapes and interior plantscapes as well as turf

applications to golf courses. EPA assessed residential exposure using

the following assumptions: For residential handlers, adult short-term

dermal and inhalation exposure is expected from mixing, loading, and

applying difenoconazole on ornamentals (gardens and trees). For

residential post-application exposures, short-term dermal exposure is

expected for both adults and children (6 < 11 years old and 11 < 16

years old) from post-application activities in treated residential

landscapes and on golf courses. There are no residential uses

[[Page 8451]]

for difenoconazole that would result in incidental oral exposure to

children.

The scenarios used in the aggregate assessment were those that

resulted in the highest exposures. The highest exposures consist of the

short-term dermal exposure to adults from post-application activities

in treated gardens and short-term dermal exposure to children 6 to 11

years old from post-application activities in treated gardens. 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.''

Unlike other pesticides for which EPA has followed a cumulative

risk approach based on a common mechanism of toxicity, EPA has not made

a common mechanism of toxicity finding as to difenoconazole and any

other substances, although EPA has previously concluded that there are

no conclusive data that difenoconazole shares a common mechanism of

toxicity with other conazole pesticides. Although the conazole

fungicides (triazoles) produce 1,2,4 triazole and its acid-conjugated

metabolites (triazolylalanine and triazolylacetic acid), 1,2,4 triazole

and its acid-conjugated metabolites do not contribute to the toxicity

of the parent conazole fungicides (triazoles). A separate aggregate

risk assessment was conducted for triazole and the conjugated triazole

metabolites (Common Triazole Metabolites: Updated Aggregate Human

Health Risk Assessment to Address New Section 3 Registrations For Use

of Difenoconazole and Mefentrifluconazole; DP451447, dated May 15,

2019) and it can be found at [https://www.regulations.gov](https://www.regulations.gov/) at docket ID

number EPA-HQ-OPP-2018-0002. These new uses of difenoconazole

considered with existing uses of triazole compounds do not result in a

risk of concern for 1,2,4-trizaole and its metabolites. Difenoconazole

does not appear to produce any other toxic metabolite produced by other

substances. For the purposes of this action, therefore, EPA has not

assumed that difenoconazole 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

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

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

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

and postnatal toxicity and the completeness of the database on toxicity

and exposure unless EPA determines based on reliable data that a

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

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

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

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

reliable data available to EPA support the choice of a different

factor.

2. Prenatal and postnatal sensitivity. The available toxicity

studies indicated no increased quantitative susceptibility of rats or

rabbits from in utero or postnatal exposure to difenoconazole. In

prenatal developmental toxicity studies in rats and rabbits and in the

2-generation reproduction study in rats, fetal/offspring toxicity, when

observed, occurred at equivalent or higher doses than in the maternal/

parental animals. In rabbits there was qualitative susceptibility since

the developmental effects were more severe than the maternal effects

seen at the same dose; however, the selected POD is protective of this

effect. In a rat developmental toxicity study, developmental effects

were observed at doses higher than those which caused maternal

toxicity. Developmental effects in the rat included increased incidence

of ossification of the thoracic vertebrae and hyoid, decreased number

of sternal centers of ossification, increased number of ribs and

thoracic vertebrae, and decreased number of lumbar vertebrae. In the

rabbit study, developmental effects (increases in post-implantation

loss and resorptions and decreases in fetal body weight) were also seen

at maternally toxic (decreased body weight gain and food consumption)

doses. In the two-generation reproduction study in rats, toxicity to

the fetuses/offspring (reduction in the body weight of F1 male pups),

when observed, occurred at equivalent or higher doses than in the

maternal/parental animals (reductions in body weight gain).

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 difenoconazole is sufficient for a

full hazard evaluation and is considered adequate to evaluate risks to

infants and children.

ii. There are no clear signs indication that difenoconazole is a

neurotoxic chemical following acute, subchronic, or chronic dosing in

multiple species in the difenoconazole database. The effects observed

in acute and subchronic neurotoxicity studies are considered non-

adverse as they were transient in nature and were only observed in one

sex (males as reduced fore-limb grip strength with no histologic

findings) and the selected endpoints of toxicity for risk assessment

are protective of any potential neurotoxicity. There is no need for a

developmental neurotoxicity study or additional UFs to account for

neurotoxicity.

iii. There is no evidence that difenoconazole results in increased

quantitative susceptibility in in utero rats or rabbits in the prenatal

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

study. However, in the developmental toxicity study in rabbits,

developmental effects (increases in post-implantation loss and

resorptions and decreases in fetal body weight) were also seen at

maternally toxic doses (decreased body weight gain and food

consumption). Because these effects are more severe, qualitative

susceptibility is evident in the rabbit. The PODs selected to assess

dietary exposures are protective of these effects.

iv. There are no residual uncertainties identified in the exposure

databases. The dietary food exposure assessments were performed based

on tolerance-level residues and 100% CT for the acute assessment while

the chronic assessment used USDA Pesticide Data Program (PDP)

monitoring data, average field trial residues for some commodities,

tolerance level residues for remaining commodities, and average percent

crop treated for some commodities. These assumptions will not

underestimate dietary exposure to difenoconazole. EPA made conservative

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

to assess exposure to difenoconazole in drinking water. EPA used

similarly conservative assumptions to assess post-application exposure

of children. These

[[Page 8452]]

assessments will not underestimate the exposure and risks posed by

difenoconazole.

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

aPAD and 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 difenoconazole will occupy 52% of the aPAD for all infants <1 year

old, the population group receiving the greatest exposure.

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

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

difenoconazole from food and water will utilize 53% of the cPAD for all

infants <1 year old, the population group receiving the greatest

exposure. Based on the explanation in Unit III.C.3., regarding

residential use patterns, chronic residential exposure to residues of

difenoconazole is not expected.

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

account short-term residential exposure plus average exposure levels to

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

Difenoconazole 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 difenoconazole.

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 aggregate MOEs of 180 for adults

and 240 for children 6 to <11 years old. Because EPA's level of concern

for difenoconazole is an MOE of 100 or below, 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). An intermediate-term adverse effect was identified; however,

difenoconazole 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

difenoconazole.

5. Aggregate cancer risk for U.S. population. As discussed in Unit

III.A., EPA has determined that use of the chronic reference dose will

be protective of the potential for cancer risk. Because the chronic

exposure does not exceed the Agency's level of concern, EPA concludes

that exposure to difenoconazole would not pose an unacceptable cancer

risk.

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 difenoconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate tolerance enforcement method, gas chromatography with

nitrogen-phosphorus detection (GC/NPD) method AG-575B, is available for

the determination of residues of difenoconazole in/on plant

commodities. An adequate enforcement method, gas chromatography with

mass spectrometry detection (GC/MSD) method AG-676A, is also available

for the determination of residues of difenoconazole per se in/on canola

and barley commodities. A confirmatory method, GC/MSD method AG-676, is

also available.

An adequate tolerance enforcement method, Method REM 147.07b, is

available for livestock commodities. The method determines residues of

difenoconazole and CGA-205375 in livestock commodities by liquid

chromatography with tandem mass spectrometry detection (LC-MS/MS).

Adequate confirmatory methods, Method AG-544A and Method REM 147.06,

are available for the determination of residues of difenoconazole and

CGA-205375, respectively, in livestock commodities.

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 has established MRLs for difenoconazole in or on carrot at

0.2 ppm; edible offal at 1.5 ppm; sugar beet at 0.2 ppm; ginseng at

0.08 ppm; ginseng, dried at 0.8 ppm; and ginseng, extracts at 0.6 ppm.

Several of these MRLs are different than the tolerances established for

difenoconazole in the United States. The U.S. tolerance in/on crop

subgroup 1A, except ginseng (0.6 ppm), being established in this

rulemaking, is based on radish root data and cannot be harmonized with

the Codex MRL for carrot, which is lower than the subgroup tolerance;

doing so could result in exceedances of the tolerances even when

growers followed label directions. The U.S. tolerance for ginseng has

been harmonized with the Codex MRL for ginseng, dried and is inclusive

of the lower tolerances for ginseng and ginseng, extracts. The

tolerances for cattle, liver; goat, liver; horse, liver; and sheep,

liver cannot be harmonized with Codex MRLs due to different dietary

burdens.

C. Response to Comments

EPA received one comment opposing pesticide residues in food,

although no substantive information was provided for EPA to take into

consideration in its safety assessment. Although the commenter

generally expressed concern about the potential for exposure to

difenoconazole to be carcinogenic, EPA has evaluated the available data

on

[[Page 8453]]

carcinogenicity and exposure and determined that aggregate exposure to

difenoconazole will not cause a cancer risk. The FFDCA authorizes EPA

to establish tolerances that permit certain levels of pesticide

residues in or on food when the Agency can determine that such residues

are safe. EPA has made that determination for the tolerances subject to

this action; the commenter provided no information relevant to that

conclusion.

D. Revisions to Petitioned-For Tolerances

The terms ``tea;'' ``root vegetable crop subgroup 1A;'' ``leaves of

root and tuber vegetables crop group 2'' requested in the petition are

being replaced with ``tea, dried;'' ``vegetable, root, subgroup 1A,

except ginseng;'' and ``vegetable, leaves of root and tuber, group 2'',

respectively, to reflect the correct commodity definitions. The EPA has

modified the tolerance on tea, dried from the requested 30 ppm to 15

ppm to harmonize with Japan's draft MRL. The ginseng tolerance has been

removed from the vegetable, root, subgroup 1A and set at 0.8 to

harmonize with the highest Codex MRL. Tolerances for cattle, liver;

goat, liver; horse, liver; and sheep, liver have been increased from

0.40 to 0.7 ppm based on the re-calculated dairy cattle dietary burden

and the available feeding study data for residues of difenoconazole and

its metabolite CGA-205375. Trailing zeroes have been removed from

tolerances in accordance with current Agency practices.

E. International Trade Considerations

In this final rule, EPA is reducing the existing tolerance for

ginseng from 1.0 ppm to 0.8 ppm in order to harmonize with the Codex

MRL. Available residue data demonstrates that the new tolerance is

sufficient to cover residues on ginseng.

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

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

WTO of this revision in order to satisfy its obligation. 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. At this

time, EPA is establishing an expiration date for the existing ginseng

tolerance to allow that tolerance to remain in effect for a period of

six months after the effective date of this final rule, in order to

address this requirement. After the six month period expires, residues

of difenoconazole on ginseng cannot exceed the new tolerance of 0.8

ppm.

This reduction in tolerance levels is not discriminatory; the same

food safety standard contained in the FFDCA applies equally to

domestically produced and imported foods. The new tolerance levels are

supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of

difenoconazole, difenoconazole, in or on vegetable, root, subgroup 1A,

except ginseng at 0.6ppm; vegetable, leaves of root and tuber, group 2

at 8 ppm; and tea, dried at 15 ppm. Tolerances are amended for ginseng

from 1.0 to 0.8 ppm; and cattle, liver; goat, liver; horse, liver; and

sheep, liver from 0.40 ppm to 0.7 ppm. In addition, the Agency is

removing the existing tolerances for beet, sugar; and carrot as they

are unnecessary upon the establishment of the tolerance for vegetable,

root, subgroup 1A, except ginseng. Finally, the Agency is amending the

existing tolerance for ginseng by adding an expiration date.

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 tolerance in this

final rule, do not require the issuance of a proposed rule, the

requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et

seq.), do not apply.

This action directly regulates growers, food processors, food

handlers, and food retailers, not States or tribes, nor does this

action alter the relationships or distribution of power and

responsibilities established by Congress in the preemption provisions

of FFDCA section 408(n)(4). As such, the Agency has determined that

this action will not have a substantial direct effect on States or

tribal governments, on the relationship between the National Government

and the States or tribal governments, or on the distribution of power

and responsibilities among the various levels of government or between

the Federal Government and Indian tribes. Thus, the Agency has

determined that Executive Order 13132, entitled ``Federalism'' (64 FR

43255, August 10, 1999) and Executive Order 13175, entitled

``Consultation and Coordination with Indian Tribal Governments'' (65 FR

67249, November 9, 2000) do not apply to this action. In addition, this

action does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act

(UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would

require Agency consideration of voluntary consensus standards pursuant

to section 12(d) of the National Technology Transfer and Advancement

Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.),

EPA will submit a report containing this rule and other required

information to the U.S. Senate, the U.S. House of Representatives, and

the Comptroller General of the United States prior to publication of

the rule in the Federal Register. This action is not a ``major rule''

as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,

Agricultural commodities, Pesticides and pests, Reporting and

recordkeeping requirements.

[[Page 8454]]

Dated: December 19, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

0

2. In Sec. 180.475:

0

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

0

i. Remove the entries ``Beet, sugar'' and ``Carrot''.

0

ii. Revise the entry for ``Ginseng''.

0

iii. Add a second entry for ``Ginseng'' after the existing entry for

``Ginseng'' and add alphabetically the entries ``Tea, dried'';

``Vegetable, leaves of root and tuber, group 2''; and ``Vegetable,

root, subgroup 1A, except ginseng''.

0

iv. Add footnotes 1 and 2 to the end of the table.

0

b. Revise the entries ``Cattle, liver''; ``Goat, liver''; ``Horse,

liver''; and ``Sheep, liver'' in the table in paragraph (a)(2).

The additions and revisions read as follows:

Sec. 180.475 Difenoconazole; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

Ginseng \2\................................................. 1.0

Ginseng..................................................... 0.8

\* \* \* \* \*

Tea, dried \1\.............................................. 15

\* \* \* \* \*

Vegetable, leaves of root and tuber, group 2................ 8

Vegetable, root, subgroup 1A, except ginseng................ 0.6

\* \* \* \* \*

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\1\ There are no U.S. registrations for these commodities.

\2\ This tolerance expires on August 14, 2020.

(2) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

Cattle, liver............................................... 0.7

\* \* \* \* \*

Goat, liver................................................. 0.7

\* \* \* \* \*

Horse, liver................................................ 0.7

\* \* \* \* \*

Sheep, liver................................................ 0.7

\* \* \* \* \*

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\* \* \* \* \*

[FR Doc. 2020-02241 Filed 2-13-20; 8:45 am]

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