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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0784; FRL-10004-12]

Acetamiprid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

acetamiprid in or on multiple commodities that are identified and

discussed later in this document. Interregional Research Project Number

4 (IR-4) requested these tolerances under the Federal Food, Drug, and

Cosmetic Act (FFDCA).

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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-2018-0784, 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-2018-0784 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-2018-0784, 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 April 19, 2019 (84 FR 16430) (FRL-9991-

14), 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

8E8715) by IR-4, IR-4 Project Headquarters, Rutgers, The State

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

NJ 08540. The petition requested that 40 CFR part 180 be amended by

establishing tolerances for residues of acetamiprid, (1E)-N-[(6-chloro-

3-pyridinyl)methyl]-N'-cyano-N-methylethanimidamide, including its

metabolites and degradates in or on the following raw agricultural

commodities: Tropical and subtropical, medium to large fruit, smooth,

inedible peel, subgroup 24B at 0.50 parts per million (ppm); leafy

greens subgroup 4-16A at 3.0 ppm; leaf petiole vegetable subgroup 22B

at 3.0 ppm; celtuce at 3.0 ppm; Florence fennel at 3.0 ppm; Brassica,

leafy greens, subgroup 4-16B at 15 ppm; Vegetable, Brassica, head and

stem, group 5-16 at 1.2 ppm; kohlrabi at 1.2 ppm; fruit, stone, group

12-12 at 1.5 ppm; nut, tree, group 14-12 at 0.10 ppm; rapeseed subgroup

20A at 0.01 ppm; and cottonseed subgroup 20C at 0.70 ppm.

Additionally, the petition requested to amend 40 CFR 180.578 by

removing the established tolerances for residues of acetamiprid in or

on the following raw agricultural commodities: Vegetable, leafy, except

Brassica, group 4 at 3.00 ppm; Brassica, leafy greens, subgroup 5B at

15 ppm; turnip, greens at 15 ppm; Brassica, head and stem, subgroup 5A

at 1.20 ppm; fruit, stone, group 12, except plum, prune at 1.20 ppm;

plum, prune, fresh at 0.20 ppm; nut, tree, group 14 at 0.10 ppm;

pistachio at 0.10 ppm; canola, seed at 0.010 ppm; mustard, seed at

0.010 ppm; and cotton, undelinted seed at 0.60 ppm.

That document referenced a summary of the petition prepared by

Nippon Soda Co., Ltd. c/o Nisso America Inc, the registrant, which is

available in the docket, [http://www.regulations.gov](http://www.regulations.gov/). Comments were

received on the notice of filing. EPA's response to these comments is

discussed in Unit IV.C.

Pursuant to its authority in FFDCA section 408(d)(4)(A)(i), EPA is

establishing tolerances that vary slightly from what the petitioner

requested. The reasons for these changes are 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

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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 acetamiprid including exposure

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

assessment of exposures and risks associated with acetamiprid 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.

In all species tested, generalized nonspecific toxicity was

observed as decreases in body weight/body weight gain, food

consumption, and food efficiency. Hepatocellular hypertrophy was

observed in both mice and rats, and hepatocellular vacuolation in the

rat, but these liver effects alone are considered adaptive and not

indicative of an adverse effect. Other effects observed in the oral

studies include amyloidosis of multiple organs in the mouse

carcinogenicity study, tremors in high dose females in the mouse

subchronic study, and micro-concretions in the kidney papilla and

mammary hyperplasia in the rat chronic/carcinogenicity study.

Acetamiprid is rapidly absorbed, metabolized, and eliminated. The

metabolism study in rats indicates 96-99% absorption following an oral

administration. Peak blood concentrations in the rat occur within 1-2

hours at the low dose (1 mg/kg), 3-6 hours post-dosing at the high dose

(50 mg/kg), and the main route of excretion is through the urine, which

is nearly complete by 48 hours for all doses. Metabolites of

acetamiprid account for 79-86% of the administered radioactivity, with

6-Chloronicotinic (IC-O) acid being the most abundant metabolite. There

were no significant sex differences noted in the ADME profile in rats.

No effects were observed in the 21-day dermal study in the rabbit

and no inhalation studies were conducted. EPA has used a refined value

of 10% as a dermal absorption factor based on the rat dermal absorption

study and weight of evidence.

Evidence of qualitative susceptibility was observed in the 2-

generation reproductive study, with the offspring effects (significant

reductions in pup weights, reduction in litter size and viability,

significant delays in weaning indices and the age to attain vaginal

opening and preputial separation) considered more severe than the

decrease in parental body weights. Qualitative susceptibility was also

seen in the developmental neurotoxicity study (DNT) with offspring

effects (decreased body weight, pre-weaning survival, and startle

response) occurring in the presence of marginal parental body weight

decreases.

Evidence of neurotoxicity was observed in the rat acute

neurotoxicity study (decrease in locomotor activity, and at higher

doses: Tremors, difficulty in handling, walking on toes, dilated

pupils, chewing, coldness to the touch, abnormal gaits and/or posture,

decreased forelimb grip strength, and hind limb foot splay), subchronic

toxicity study in mice (tremors), the DNT (decreased startle response),

and comparative metabolism study (decreased alertness, reactivity,

spontaneous activity, locomotor activity, rearing, muscle tone, and

grip strength; as well as tremors, staggering, and depressed reflexes

in the rat, mouse, and/or rabbit). Subchronic immunotoxicity studies

were performed in both sexes in rats and mice, with no effects on the

immune system observed up to the highest dose tested. Acetamiprid and

its metabolites IC-0, IM-1-2, IM-1-4, IM-2-1, and IM-0 tested negative

for mutagenicity. With no treatment-related tumors seen in rats or

mice, the Agency has classified acetamiprid as not likely to be

carcinogenic to humans.

Specific information on the studies received and the nature of the

adverse effects caused by acetamiprid as well as the no-observed-

adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-

level (LOAEL) from the toxicity studies can be found at [http://www.regulations.gov](http://www.regulations.gov/) in the document titled ``Acetamiprid. Human Health

Risk Assessment for Proposed Use on Tropical and Subtropical, Medium to

Large Fruit, Smooth, Inedible Peel Subgroup 24B; Greenhouse-grown

Peppers; and Crop Group Conversions and Expansions'' on pages 38-43 in

docket ID number EPA-HQ-OPP-2018-0784.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA

identifies toxicological points of departure (POD) and levels of

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

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

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

derivation of reference values for risk assessment. PODs are developed

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

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

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

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

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

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

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

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

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

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

general principles EPA uses in risk characterization and a complete

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

A summary of the toxicological endpoints for acetamiprid used for

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

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Table 1--Summary of Toxicological Doses and Endpoints for Acetamiprid for Use in FFDCA Human Health Risk

Assessment

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

Point of departure

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

safety factors risk assessment

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Acute dietary (All Populations). NOAEL = 10 mg/kg/day Acute RfD = 0.1 mg/ Co-critical studies.

UFA = 10X kg/day Developmental Neurotoxicity in

UFH = 10X aPAD = 0.1 mg/kg/day rat.

FQPA SF = 1X LOAEL = 45 mg/kg/day based on

decreased early pup survival on

PND 0-1, and decreased startle

response on PND 20/60 in males.

Acute Neurotoxicity Study in rat.

LOAEL = 30 mg/kg/day based on

decreased locomotor activity.

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

Chronic dietary (All NOAEL= 7.1 mg/kg/day Chronic RfD = 0.071 Chronic Toxicity/Carcinogenicity

populations). UFA = 10X mg/kg/day Study in rats.

UFH = 10X cPAD = 0.071 mg/kg/ LOAEL = 17.5 mg/kg/day based on

FQPA SF = 1X day decreased body weight and body

weight gains in females and

hepatocellular vacuolation in

males.

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

Incidental oral short-term (1 to NOAEL= 10 mg/kg/day LOC for MOE = 100 Developmental Neurotoxicity in

30 days). UFA = 10X rat.

UFH = 10X LOAEL = 45 mg/kg/day based on

FQPA SF = 1X decreased body weight and body

weight gains in offspring,

decreased early pup survival on

PND 0-1, and decreased startle

response on PND 20/60 in males.

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

Incidental oral long-term NOAEL= 7.1 mg/kg/day LOC for MOE = 100 Chronic Toxicity/Carcinogenicity

(greater than 6 months). UFA= 10X Study in rats.

UFH= 10X LOAEL = 17.5 mg/kg/day based on

FQPA SF = 1X decreased body weight and body

weight gains in females and

hepatocellular vacuolation in

males.

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

Dermal short- and intermediate- Oral study NOAEL = LOC for MOE = 100 Developmental Neurotoxicity in

term (1 to 30 days; 1 to 6 10 mg/kg/day rat.

months). UFA = 10X LOAEL = 45 mg/kg/day based on

UFH = 10X decreased body weight and body

DAF = 10% weight gains in offspring,

FQPA SF = 1X decreased early pup survival on

PND 0-1, and decreased startle

response on PND 20/60 in males.

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

Dermal long-term (greater than 6 Dermal (or oral) LOC for MOE = 100 Chronic Toxicity/Carcinogenicity

months). study NOAEL = 7.1 Study in rats.

mg/kg/day LOAEL = 17.5 mg/kg/day based on

UFA = 10X decreased body weight and body

UFH = 10X weight gains in females and

DAF = 10% hepatocellular vacuolation in

FQPA SF = 1X males.

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

Inhalation short-term (1 to 30 Oral study NOAEL = LOC for MOE = 100 Developmental Neurotoxicity in

days). 10 mg/kg/day rat.

Inhalation toxicity LOAEL = 45 mg/kg/day based on

assumed to be decreased body weight and body

equivalent to oral weight gains in offspring,

toxicity decreased early pup survival on

UFA = 10X PND 0-1, and decreased startle

UFH = 10X response on PND 20/60 in males.

FQPA SF = 1X

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

Cancer (Oral, dermal, Classification: ``Not likely to be carcinogenic to humans''.

inhalation).

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

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). DAF = Dermal Absorption Factor.

C. Exposure Assessment

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

exposure to acetamiprid, EPA considered exposure under the petitioned-

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

180.578. EPA assessed dietary exposures from acetamiprid 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 acetamiprid. In estimating acute

dietary exposure, EPA used food consumption information from the United

States Department of Agriculture (USDA) 2003-2008 National Health and

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Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

As to residue levels in food, the acute dietary exposure assessment was

unrefined and used tolerance-level residues and 100 percent crop

treated (PCT).

ii. Chronic exposure. In conducting the chronic dietary exposure

assessment, EPA used the food consumption data from the USDA 2003-2008

NHANES/WWEIA. As to residue levels in food, the chronic dietary

exposure assessment was slightly refined using PCT information for some

commodities. Aside from these commodities, the analyses were based on

tolerance-level residues and the assumption of 100 PCT. In addition,

conservative default processing factors were used for many processed

commodities, while empirical processing factors were used for a limited

number of processed commodities.

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

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

Therefore, a dietary exposure assessment for the purpose of assessing

cancer risk is unnecessary.

iv. Anticipated residue and PCT information. 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 Agency estimated the PCT for existing uses as follows:

In the acute assessment, 100 PCT was assumed for all commodities.

In the chronic assessment, the PCT estimates used were as follows:

1% of almonds, 30% of apples, 10% of apricots, 5% of asparagus, 10% of

blueberries, 5% of broccoli, 10% of cabbage, 5% of caneberries, 15% of

cantaloupes, 10% of cauliflower, 40% of celery, 5% of cherries, 5% of

cotton, 2.5% of cucumbers, 2.5% of grapefruit, 2.5% of grapes, 2.5% of

lemons, 15% of lettuce, 1% of nectarines, 2.5% of onions, 2.5% of

oranges, 5% of peaches, 35% of pears, 1% of pecans, 5% of peppers, 5%

of pistachios, 2.5% plums/prunes, 2.5% of potatoes, 5% of pumpkins, 10%

of spinach, 5% of squash, 30% of strawberries, 1% of sweet corn, 5% of

tomatoes, 15% of walnuts, and 5% of watermelons.

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 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

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 acetamiprid 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 acetamiprid in drinking water. These simulation models

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

characteristics of acetamiprid. 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 Pesticide in Water Calculator (PWC) and Provisional

Cranberry Model, the estimated drinking water concentrations (EDWCs) of

acetamiprid for acute exposures are estimated to be 88.1 parts per

billion (ppb) in surface water and 211 ppb in ground water, and for

chronic exposures are estimated to be 12.7 ppb in surface water and 175

ppb in ground water.

Modeled estimates of drinking water concentrations were directly

entered into the dietary exposure model. For the acute dietary risk

assessment, the water concentration value of 211 ppb was used to assess

the contribution from drinking water. For the chronic dietary risk

assessment, the water concentration of value 175 ppb was used to assess

the contribution from 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).

Acetamiprid is currently registered for the following uses that

could result in residential exposures: Gardens and trees, spot-on pet

treatment, fly control, indoor crack/crevice, mattresses for bed bug

control, and animal barns. EPA assessed residential exposure using the

following assumptions: Residential handler dermal and inhalation

exposure are expected to occur from the use of the registered

acetamiprid formulations on ornamentals, vegetables, and fruit trees.

All residential handler exposures are expected to be short-term in

duration. Residential handler dermal exposure is expected to occur from

the registered acetamiprid spot-on product when applied to dogs.

Inhalation exposure from spot-on products is considered to be

negligible. Residential handler

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dermal and inhalation exposures from applications to indoor

environments was not assessed based on current Agency policy because

the labels for the products that are used in indoor environments

require personal protective equipment (PPE). Residential handler

exposure from the fly bait use was not assessed, as exposures are

expected to be insignificant due to incorporation of acetamiprid in the

glue.

There is the potential for post-application exposure for

individuals exposed as a result of being in an environment that has

been treated with acetamiprid. The quantitative risk assessment for

residential post-application exposures is based on the following

scenarios: Short-term dermal exposure to gardens (gardens, trees,

indoor plants); short-, intermediate-, and long-term dermal and

incidental oral exposure to the dog spot-on treatment; short-term

dermal, inhalation, and incidental oral exposure from the indoor crack

and crevice and bed bug mattress uses; and short-term dermal and

incidental oral exposure from the fly bait granule use. Post-

application dermal exposures from foundation, perimeter, and spot

treatments outdoors, along with post-application inhalation exposure,

are considered negligible and were not assessed. Acetamiprid is also

registered for use as a termiticide. A quantitative assessment for

potential post-application inhalation and dermal exposure resulting

from a commercial termiticide application in a residential setting is

not needed, as all applications are made to the soil/foundation around/

underneath a structure. In this case, exposure to acetamiprid vapors is

not expected. Additionally, EPA believes that inhalation and dermal

exposure to acetamiprid from bed bug treatments (applied directly to

the space where people are living vs. application to the foundation/

structure) would be protective of the termiticide uses of acetamiprid.

The lifestages selected for each post-application scenario are

based on the Agency's 2012 Residential SOPs. While not the only

lifestage potentially exposed for these post-application scenarios, the

lifestage that is included in the quantitative assessment, (i.e.,

Children (1 < 2 years), children (3 < 6 years), children (6 < 12

years), adult), is health protective for the exposures and risk

estimates for any other potentially exposed lifestage.

Based on the proposed uses, short- and intermediate-term exposures

are expected for the proposed use profile. Since the same endpoint and

POD were selected for short- and intermediate-term durations, short-

term exposure and risk estimates are considered protective of potential

intermediate-term exposure and risk.

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.''

EPA has not found acetamiprid to share a common mechanism of

toxicity with any other substances, and acetamiprid does not appear to

produce a toxic metabolite produced by other substances. For the

purposes of this tolerance action, therefore, EPA has assumed that

acetamiprid does not have a common mechanism of toxicity with other

substances. For information regarding EPA's efforts to determine which

chemicals have a common mechanism of toxicity and to evaluate the

cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

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

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

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

and postnatal toxicity and the completeness of the database on toxicity

and exposure unless EPA determines based on reliable data that a

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

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

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

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

reliable data available to EPA support the choice of a different

factor.

2. Prenatal and postnatal sensitivity. Evidence of qualitative

susceptibility was observed in the 2-generation reproductive study,

with the offspring effects (significant reductions in pup weights,

reduction in litter size and viability, significant delays in weaning

indices and the age to attain vaginal opening and preputial separation)

considered more severe than the decrease in parental body weights.

Qualitative susceptibility was also seen in the DNT with offspring

effects (decreased body weight, pre-weaning survival, and startle

response) occurring in the presence of marginal parental body weight

decreases.

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 acetamiprid is complete.

ii. Acetamiprid produced signs of neurotoxicity in the high dose

groups in the acute and developmental neurotoxicity studies in rats and

the subchronic toxicity study in mice. However, no neurotoxic findings

were reported in the subchronic neurotoxicity study in rats.

Additionally, there are clear NOAELs identified for the effects

observed in the toxicity studies. The doses and endpoints selected for

risk assessment are protective and account for all toxicological

effects observed in the database.

iii. No quantitative or qualitative evidence of increased

susceptibility of fetuses to in utero exposure to acetamiprid was

observed in the developmental toxicity study in either rats or rabbits.

Although increased qualitative susceptibility was seen in the

reproduction toxicity and the DNT study, the degree of concern for the

effects is low. There are clear NOAELs for the offspring effects and

regulatory doses were selected to be protective of these effects. No

other residual uncertainties were identified with respect to

susceptibility. The endpoints and doses selected for acetamiprid are

protective of adverse effects in both offspring and adults.

iv. There are no residual uncertainties identified in the exposure

databases. The acute dietary food exposure assessment was performed

based on 100 PCT and tolerance-level residues, and the chronic dietary

exposure assessment was slightly refined using PCT information for some

commodities. EPA made conservative (protective) assumptions in the

ground and surface water modeling used to assess exposure to

acetamiprid 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 acetamiprid.

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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 acetamiprid will occupy 89% of the aPAD for children 1 to 2 years

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

acetamiprid from food and water will utilize 48% of the cPAD for

children 1 to 2 years old, the population group receiving the greatest

exposure.

Long-term aggregate risk assessments were conducted to assess risks

for adults and children and include exposure through oral (children

only) and dermal routes. The oral and dermal endpoints for long-term

exposure durations are the same (decreased body weight and body weight

gains), and therefore exposures from these pathways are aggregated. In

accordance with the FQPA, the combined exposure from these pathways is

added to the background dietary exposure from the chronic dietary

exposure assessment.

The Agency selected only the most conservative, or worst case,

scenarios for each lifestage. For both adults and children, worst-case

long-term scenarios reflect post-application exposure to pets treated

with spot-on products. As the LOCs are identical for all routes of

exposure, and since the POD for all routes of exposure is derived from

an oral study, the long-term aggregate MOEs were calculated by adding

the exposures and dividing the POD (7.1 mg/kg) by the sum of the

exposures.

EPA has concluded the combined long-term food, water, and

residential exposures result in aggregate MOEs of 110 for children 1 to

less than 2 years old and 360 for adults. Because EPA's level of

concern for acetamiprid is a MOE of 100 or below, these MOEs are not of

concern.

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).

Acetamiprid 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 acetamiprid.

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,

460 for children 6 to less than 12 years old, 340 for children 3 to

less than 6 years old, and 130 for children 1 to less than 2 years old.

Because EPA's level of concern for acetamiprid is a 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, and

intermediate-term exposure is expected; however, since the same

endpoint and POD were selected for short- and intermediate-term

durations, short-term exposure and risk estimates are considered

protective of potential intermediate-term exposure and risk.

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

evidence of carcinogenicity in two adequate rodent carcinogenicity

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

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

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

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

exposure to acetamiprid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Approved tolerance enforcement methods for acetamiprid residues in

crops are available, including methods using gas chromatography with

electron capture detection (GC/ECD) analysis for vegetables and non-

citrus fruits, high-performance liquid chromatography with ultraviolet

detection (HPLC/UV) analysis for citrus fruits only, and HPLC with

tandem mass spectrometric detection (LC/MS/MS) analysis for vegetables

and non-citrus fruits. An approved HPLC/UV tolerance enforcement method

for livestock matrices is available.

The methods 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 following table summarizes the tolerances being established by

this document and the corresponding Codex tolerances. The U.S.

tolerance in Cottonseed subgroup 20C is harmonized with the Codex MRL

in cotton seed. The U.S. tolerance in Fruit, stone, group 12-12 is

harmonized with the Codex MRL in cherry, which has the highest MRL of

the individual group 12-12 commodities with Codex MRLs. EPA is not able

to harmonize the other tolerances with Codex MRLs because the U.S.

tolerances are higher. Establishing a U.S. tolerance at a lower level

to harmonize with Codex would put U.S. growers at risk of having

violative residues despite legal use of the pesticide according to the

label.

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U.S. tolerances established in this rulemaking (40 CFR Sec. Codex

180.578) -------------------------------------------------

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Tolerance Commodity MRL (mg/kg)

Commodity (ppm)

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Brassica, leafy greens, subgroup 4-16B........ 15 Chinese broccoli................ 0.4

Celtuce....................................... 3 ................................ ..............

Cottonseed subgroup 20C....................... 0.7 Cotton seed..................... 0.7

Florence, fennel, fresh leaves and stalk...... 3 ................................ ..............

Fruit, stone, group 12-12..................... 1.5 Cherry.......................... 1.5

Nectarine, peach................ 0.7

Dried prune..................... 0.6

Plum............................ 0.2

Kohlrabi...................................... 1.2 ................................ ..............

Leaf petiole vegetable subgroup 22B........... 3 Celery.......................... 1.5

Leafy greens subgroup 4-16A................... 3 ................................ ..............

Nut, tree, group 14-12........................ 0.1 Tree nuts....................... 0.06

Rapeseed subgroup 20A......................... 0.01 ................................ ..............

Tropical and subtropical, medium to large 0.5 ................................ ..............

fruit, smooth, inedible peel, subgroup 24B.

Vegetable, brassica, head and stem, group 5-16 1.2 Broccoli, cauliflower........... 0.4

Cabbage......................... 0.7

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C. Response to Comments

One commenter stated that ``EPA has not fully evaluated the

sufficiency of the submitted data at this time or whether the data

support granting of the pesticide petitions.'' The commenter does not

indicate what additional data might be necessary, why the commenter

questions the sufficiency of the available data, or what about the

Agency's findings is unsupported. Contrary to the commenter's position,

the Agency has in fact fully evaluated all the data submitted on

acetamiprid and determined that the toxicological and exposure

databases on acetamiprid are complete, i.e., they do not contain any

data gaps at this time, and dietary and residential exposure and risk

have not been underestimated. Taking all that information into

consideration, EPA has concluded that the tolerances for acetamiprid

are safe.

The other comments submitted raised more general concerns about the

use of pesticides and questioned a separate tolerance exemption.

Neither raise issues relevant to this tolerance rulemaking.

D. Revisions to Petitioned-For Tolerances

EPA is establishing some of the tolerances at different levels than

petitioned for in order to be consistent with the Agency's rounding

class practice, which is based on the rounding procedures of the

Organisation for Economic Co-operation and Development. EPA corrected

the commodity definition for Fennel, Florence, fresh leaves and stalk.

Finally, EPA is removing the existing tolerance in Plum, prune, dried,

because it is no longer needed with the establishment of the tolerance

in Fruit, stone, group 12-12; although not requested in the original

petition, the need to remove this tolerance was confirmed in subsequent

correspondence with the petitioner.

V. Conclusion

Therefore, tolerances are established for residues of acetamiprid

in or on Brassica, leafy greens, subgroup 4-16B at 15 ppm; Celtuce at 3

ppm; Cottonseed subgroup 20C at 0.7 ppm; Fennel, Florence, fresh leaves

and stalk at 3 ppm; Fruit, stone, group 12-12 at 1.5 ppm; Kohlrabi at

1.2 ppm; Leaf petiole vegetable subgroup 22B at 3 ppm; Leafy greens

subgroup 4-16A at 3 ppm; Nut, tree, group 14-12 at 0.1 ppm; Rapeseed

subgroup 20A at 0.01 ppm; Tropical and subtropical, medium to large

fruit, smooth, inedible peel, subgroup 24B at 0.5 ppm; and Vegetable,

brassica, head and stem, group 5-16 at 1.2 ppm.

Additionally, the following existing tolerances are removed as

unnecessary due to the establishment of the above tolerances: Brassica,

head and stem, subgroup 5A; Brassica, leafy greens, subgroup 5B;

Canola, seed; Cotton, undelinted seed; Fruit, stone, group 12, except

plum, prune; Mustard, seed; Nut, tree, group 14; Pistachio; Plum,

prune, dried; Plum, prune, fresh; Turnip greens; and Vegetable, leafy,

except brassica, group 4.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances under FFDCA section

408(d) in response to a petition submitted to the Agency. The Office of

Management and Budget (OMB) has exempted these types of actions from

review under Executive Order 12866, entitled ``Regulatory Planning and

Review'' (58 FR 51735, October 4, 1993). Because this action has been

exempted from review under Executive Order 12866, this action is not

subject to Executive Order 13211, entitled ``Actions Concerning

Regulations That Significantly Affect Energy Supply, Distribution, or

Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled

``Protection of Children from Environmental Health Risks and Safety

Risks'' (62 FR 19885, April 23, 1997), nor is it considered a

regulatory action under Executive Order 13771, entitled ``Reducing

Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3,

2017). This action does not contain any information collections subject

to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501

et seq.), nor does it require any special considerations under

Executive Order 12898, entitled ``Federal Actions to Address

Environmental Justice in Minority Populations and Low-Income

Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis

of a petition under FFDCA section 408(d), such as the tolerances in

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

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

seq.), do not apply.

This action directly regulates growers, food processors, food

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

action alter the relationships or distribution of power and

responsibilities established by Congress in the preemption provisions

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

this action will not

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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: January 24, 2020.

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. 180.578, amend the table in paragraph (a)(1) as follows:

0

a. Remove the entries for ``Brassica, head and stem, subgroup 5A'' and

``Brassica, leafy greens, subgroup 5B'';

0

b. Add alphabetically the entry ``Brassica, leafy greens, subgroup 4-

16B'';

0

c. Remove the entry for ``Canola, seed'';

0

d. Add alphabetically the entries ``Celtuce'' and ``Cottonseed subgroup

20C'';

0

e. Remove the entry for ``Cotton, undelinted seed'';

0

f. Add alphabetically the entries ``Fennel, florence, fresh leaves and

stalk'' and ``Fruit, stone, group 12-12'';

0

g. Remove the entry for ``Fruit, stone, group 12, except plum, prune'';

0

h. Add alphabetically the entries ``Kohlrabi''; ``Leaf petiole

vegetable subgroup 22B''; and ``Leafy greens subgroup 4-16A'';

0

i. Remove the entries for ``Mustard, seed'' and ``Nut, tree, group

14'';

0

j. Add alphabetically the entry ``Nut, tree, group 14-12'';

0

k. Remove the entries for ``Pistachio''; ``Plum, prune, dried''; and

``Plum, prune, fresh'';

0

l. Add alphabetically the entries ``Rapeseed subgroup 20A'' and

``Tropical and subtropical, medium to large fruit, smooth, inedible

peel, subgroup 24B'';

0

m. Remove the entry for ``Turnip greens'';

0

n. Add alphabetically the entry ``Vegetable, brassica, head and stem,

group 5-16''; and

0

o. Remove the entry for ``Vegetable, leafy, except brassica, group 4''.

The revisions and additions read as follows:

Sec. 180.578 Acetamiprid; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

Brassica, leafy greens, subgroup 4-16B...................... 15

\* \* \* \* \*

Celtuce..................................................... 3

\* \* \* \* \*

Cottonseed subgroup 20C..................................... 0.7

Fennel, florence, fresh leaves and stalk.................... 3

\* \* \* \* \*

Fruit, stone, group 12-12................................... 1.5

\* \* \* \* \*

Kohlrabi.................................................... 1.2

Leaf petiole vegetable subgroup 22B......................... 3

Leafy greens subgroup 4-16A................................. 3

Nut, tree, group 14-12...................................... 0.1

\* \* \* \* \*

Rapeseed subgroup 20A....................................... 0.01

\* \* \* \* \*

Tropical and subtropical, medium to large fruit, smooth, 0.5

inedible peel, subgroup 24B................................

Vegetable, brassica, head and stem, group 5-16.............. 1.2

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\* \* \* \* \*

[FR Doc. 2020-02038 Filed 2-13-20; 8:45 am]

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