[Federal Register Volume 87, Number 138 (Wednesday, July 20, 2022)]

[Rules and Regulations]

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[FR Doc No: 2022-15410]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0356; FRL-9839-01-OCSPP]

Spiropidion; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of the

insecticide spiropidion and its metabolites and degradates in or on

multiple commodities which are identified and discussed later in this

document. Syngenta Crop Protection, LLC requested these tolerances

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

DATES: This regulation is effective July 20, 2022. Objections and

requests for hearings must be received on or before September 19, 2022

and must be filed in accordance with the instructions provided in 40

CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket

identification (ID) number EPA-HQ-OPP-2021-0356, is available at

[https://www.regulations.gov](https://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 and the OPP Docket is (202) 566-1744. Please review the

visitor instructions and additional information about the EPA Docket

Center and Reading Room that are available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director,

Registration Division (7505T), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Avenue NW,

Washington, DC 20460; main telephone number: (202) 566-1030; email

address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

 You may be potentially affected by this action if you are an

agricultural producer, food manufacturer, or pesticide manufacturer.

The following list of North American Industrial Classification System

(NAICS) codes is not intended to be exhaustive, but rather provides a

guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

 Crop production (NAICS code 111).

 Animal production (NAICS code 112).

 Food manufacturing (NAICS code 311).

 Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

 You may access a frequently updated electronic version of EPA's

tolerance regulations at 40 CFR part 180 through the Office of the

Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

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-2021-0356 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

September 19, 2022. Addresses for mail and hand delivery of objections

and hearing requests are provided in 40 CFR 178.25(b).

 In addition to filing an objection or hearing request with the

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

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

inclusion in the public docket. Information not marked confidential

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

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

request, identified by docket ID number EPA-HQ-OPP-

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2021-0356, by one of the following methods:

 Federal eRulemaking Portal: [https://www.regulations.gov](https://www.regulations.gov/).

Follow the online instructions for submitting comments. Do not submit

electronically any information you consider to be CBI or other

information whose disclosure is restricted by statute.

 Mail: OPP Docket, Environmental Protection Agency Docket

Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC

20460-0001.

 Hand Delivery: To make special arrangements for hand

delivery or delivery of boxed information, please follow the

instructions at <https://www.epa.gov/dockets/contacts.html>. Additional

instructions on commenting or visiting the docket, along with more

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

II. Summary of Petitioned-For Tolerance

 In the Federal Register of June 28, 2021 (86 FR 33924) (FRL-10025-

08), 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

0E8880) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro,

NC 27419-8300. The petition requested that 40 CFR part 180 be amended

by establishing tolerances for residues of the insecticide spiropidion,

[3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-2-oxo-1,8-

diazaspiro[4.5]dec-3-en-4-yl ethyl carbonate] and its metabolite

SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-

diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-

1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one], in or

on the following raw agricultural/processed and livestock commodities:

cucurbit vegetables (crop group 9) at 0.8 parts per million (ppm);

fruiting vegetables (crop group 8) at 1.5 ppm; soybeans at 3 ppm;

potato (crop subgroup 1C) at 1.5 ppm; poultry meat at 0.01 ppm; meat

byproducts of poultry at 0.01 ppm; fat of poultry at 0.01 ppm; eggs at

0.01 ppm; milk and milk byproducts at 0.01 ppm; meat byproducts of

cattle, goat, hogs, horses and sheep at 0.3 ppm; fat of cattle, goat,

hogs, horses and sheep at 0.04 ppm; wet tomato peel at 3 ppm; dried

tomato pomace at 40 ppm; tomato paste at 3 ppm; tomato puree at 2 ppm;

dried tomatoes at 15 ppm; soy meal at 5 ppm; soy flour at 5 ppm;

pollard at 4 ppm; soy aspirated grain fractions at 6 ppm; raw peeled

potatoes at 3 ppm; baked potatoes with skin at 3 ppm; potato chips/

fries at 2 ppm; potato granules/flakes at 5 ppm; potato process waste

at 3 ppm; dried potato pulp at 3 ppm; and potato protein at 5 ppm. That

document referenced a summary of the petition prepared by Syngenta Crop

Protection, LLC, the registrant, which is available in the docket,

[https://www.regulations.gov](https://www.regulations.gov/). There were no comments received in

response to the notice of filing.

 Based on review of the data supporting the petition and EPA policy,

EPA has revised some of the commodity definitions and tolerance levels

from the petition. The reason for these changes are explained in Unit

IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

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

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

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

reasonable certainty that no harm will result from aggregate exposure

to the pesticide chemical residue, including all anticipated dietary

exposures and all other exposures for which there is reliable

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

residential settings but does not include occupational exposure.

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

consideration to exposure of infants and children to the pesticide

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

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

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

.''

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

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

scientific data and other relevant information in support of this

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

determination on aggregate exposure for spiropidion including exposure

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

assessment of exposures and risks associated with spiropidion follows.

A. Toxicological Profile

 EPA has evaluated the available toxicity data and considered its

validity, completeness, and reliability as well as the relationship of

the results of the studies to human risk. EPA has also considered

available information concerning the variability of the sensitivities

of major identifiable subgroups of consumers, including infants and

children. The toxicological database for spiropidion is complete and

indicates that decreased body weight and mortality were the most common

adverse effects observed. The dog was the most sensitive species with

effects including severe clinical signs (salivation, unsteadiness on

feet, ataxia, being subdued, twitching, abnormal breathing,

hypersensitivity, and tremors) leading to humane euthanasia after

acute, subchronic and chronic exposure at doses >=30 mg/kg/day. No

additional treatment related effects in dogs were observed at doses

that did not cause severe clinical signs. These effects occurred at

doses ~4x lower and ~7x lower than the doses at which effects were

observed in rats and mice, respectively. In rats, decreased body weight

was observed at the highest dose tested following a 28-day exposure.

Additionally, in rats, minimal to mild thyroid follicular cell

hypertrophy was consistently observed across subchronic durations. In

mice, premature death was observed in both sexes at the highest dose

tested (448.6/465.4 mg/kg/day male/female) following subchronic

exposure. At lower dose levels in mice, increased urea and blood urea

nitrogen concentrations, increased alkaline phosphatase levels

(females), decreased albumin levels and albumin/globulin ratio

(females), and increased liver weights (males) were observed. However,

these findings were not considered adverse, as there were no

corroborating macroscopic or microscopic pathology findings noted in

mice. Following chronic exposure in the rat and mouse, no adverse

effects were observed up to the highest dose tested. Decreased body

weight in males and severe convulsions in females were observed at a

relatively high dose (500 mg/kg) in the acute neurotoxicity study in

rats. No adverse effects were observed in rats following exposures via

the dermal route up to the limit dose.

 There was no evidence of increased pre- or post-natal sensitivity

or susceptibility observed in the database. No adverse parental,

offspring, or reproductive effects were observed in the two-generation

reproductive toxicity study up to the highest dose tested. No adverse

parental or developmental effects were observed in the rat and rabbit

developmental toxicity studies up to the highest dose tested.

 Spiropidion is classified as ``Not Likely to Be Carcinogenic to

Humans'' based on a lack of treatment related neoplastic lesions in two

species and no mutagenic concerns.

 Specific information on the studies received and the nature of the

adverse effects caused by spiropidion as well as the no observed

adverse effect level

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(NOAEL) and the lowest observed adverse effect level (LOAEL) from the

toxicity studies can be found at [https://www.regulations.gov](https://www.regulations.gov/) in the

document entitled ``Spiropidion: First Food Use; Human Health Risk

Assessment for the Establishment of Permanent Tolerances without U.S.

Registration for Residues in or on Soybean, Tomato, Bell and Nonbell

Peppers, Muskmelon, Watermelon, Cucumber, Pumpkin, and Potato'' in

docket ID number EPA-HQ-OPP-2021-0356.

B. Toxicological Points of Departure/Levels of Concern

 Once a pesticide's toxicological profile is determined, EPA

identifies points of departure (PODs) and levels of concern (LOCs) 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 <https://www.epa.gov/risk>.

 A summary of the toxicological endpoints for spiropidion used for

human risk assessment can be found in the Spiropidion Human Health Risk

Assessment.

C. Exposure Assessment

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

exposure to spiropidion, EPA considered exposure under the petitioned-

for tolerances. EPA assessed dietary exposures from spiropidion 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 spiropidion. Acute dietary (food only) exposure and risk

assessments were conducted using the Dietary Exposure Evaluation Model

software with the Food Commodity Intake Database (DEEM-FCID) Version

4.02. This software uses 2005-2010 food consumption data from the U.S.

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

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

assessment includes bell and nonbell pepper, cucumber, muskmelon,

potato, pumpkin, soybean, tomato, watermelon, and fat and meat

byproducts of cattle, goats, horses, and sheep.

 EPA conducted an unrefined acute dietary (food only) exposure

assessment for the proposed uses of spiropidion. EPA's default

processing factors for potato dry commodities, dried tomato, tomato

paste, tomato puree, and soybean flour were set to 1 as processing data

for these commodities are available and no appreciable concentration of

residues that would require an additional tolerance was identified. In

addition, EPA's default processing factors were also used for dried

bell and dried nonbell pepper. It was assumed that 100% of the crops

were treated. As the request is for tolerances without U.S.

registration, residues in drinking water are not expected.

 Results of the acute dietary assessment indicate that the general

U.S. population and all other population subgroups have exposure and

risk estimates below EPA's level of concern (LOC). The acute dietary

exposure estimate is 3.2% of the aPAD for the general U.S. population,

and 7.3% of the aPAD for the highest exposed population subgroup,

children 1-2 years old.

 ii. Chronic exposure. In conducting the chronic dietary (food only)

exposure assessment, EPA used DEEM-FCID Version 4.02 with 2005-2010

food consumption data from the USDA's NHANES/WWEIA. EPA's default

processing factors for potato dry commodities, dried tomato, tomato

paste, tomato puree, and soybean flour were set to 1 as processing data

for these commodities are available and no concentration of residues

that would require an additional tolerance was required. In addition,

EPA's default processing factors were also used for dried bell and

dried nonbell pepper. It was assumed that 100% of the crops were

treated. As the request is for tolerances without U.S. registration,

residues in drinking water are not expected.

 EPA conducted an unrefined chronic dietary (food only) exposure

assessment for the proposed uses of spiropidion. Results of the chronic

dietary assessment indicate that the general U.S. population and all

other population subgroups have exposure and risk estimates below EPA's

LOC. The chronic dietary exposure estimate is 2.3% of the cPAD for the

general U.S. population, and 6.7% of the cPAD for the highest exposed

population subgroup, children 1-2 years old.

 iii. Cancer. EPA determines whether quantitative cancer exposure

and risk assessments are appropriate for a food-use pesticide based on

the weight of the evidence from cancer studies and other relevant data.

Cancer risk is quantified using a linear or nonlinear approach. If

sufficient information on the carcinogenic mode of action is available,

a threshold or nonlinear approach is used and a cancer RfD is

calculated based on an earlier noncancer key event. If carcinogenic

mode of action data are not available, or if the mode of action data

determines a mutagenic mode of action, a default linear cancer slope

factor approach is utilized. Based on the data summarized in Unit

III.A., EPA has concluded that spiropidion does not pose a cancer risk

to humans. Therefore, a dietary exposure assessment for the purpose of

assessing cancer risk was unnecessary.

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

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

dietary assessment for spiropidion. Tolerance level residues and/or 100

PCT were assumed for all food commodities.

 2. Dietary exposure from drinking water. Spiropidion is not

registered for use in the United States; therefore, EPA assumes that

there is no exposure through groundwater or surface water sources of

drinking water. Because residues are not expected in drinking water,

dietary risk estimates include exposures from food only.

 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 fleas and tick control on pets). Spiropidion is not

registered for any specific use patterns that would result in

residential exposure.

 4. Cumulative effects from substances with a common mechanism of

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

considering whether to establish, modify, or revoke a

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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 spiropidion to share a common mechanism of

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

produce a toxic metabolite produced by other substances. For the

purposes of this tolerance action, EPA has assumed that spiropidion

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 <https://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

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

shall apply an additional ten-fold (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 Food Quality

Protection Act (FQPA) Safety Factor (SF). In accordance with Section

408(b)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA

either retains the default value of 10x margin of safety 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 toxicology database is

complete and is adequate for the purpose of assessing prenatal and

postnatal susceptibility based on the following considerations: (1) the

toxicity database is complete and includes adequate studies to assess

potential susceptibility in the young; (2) no effects were identified

in the prenatal developmental studies or in the two-generation

reproduction toxicity study up to the highest dose tested; and (3) the

endpoints chosen for risk assessment are protective of any potential

susceptibility that may occur at higher doses.

 3. Conclusion. EPA has determined that reliable data show the

safety of infants and children would be adequately protected if the

FQPA SF of 10x were reduced to 1x. That decision is based on the

following findings:

 i. The toxicology database is considered complete and is adequate

for the purpose of assessing prenatal and postnatal susceptibility.

Acceptable guideline studies for developmental, reproductive toxicity,

and neurotoxicity are available for FQPA SF assessment.

 ii. There is evidence of potential neurotoxicity in the acute

neurotoxicity study (ACN) (severe convulsions in females) and in the

subchronic and chronic dog studies (clinical signs indicative of

potential neurotoxicity); however, concern is low because (1) the

effects observed in the ACN were observed at a relatively high dose

(500 mg/kg); (2) clear NOAELs were identified for the neurotoxic

effects; and (3) the points of departure chosen for risk assessment are

protective of any potential neurotoxicity observed in the database.

 iii. There was no evidence of increased quantitative or qualitative

pre-natal susceptibility in the rabbit or rat developmental toxicity

studies or postnatal susceptibility in the two-generation reproduction

toxicity study up to the highest doses tested. Even though these

studies did not test up to the limit dose, there is little concern

about the potential for toxicity and/or susceptibility at higher doses

than those tested since (1) the current POD (15 mg/kg/day) is

protective of any potential developmental and/or reproductive effects

that may occur above the highest tested doses used in these studies

(>30.6/24.1 mg/kg/day [M/F]) and (2) the dog is the more sensitive

species and additional developmental and reproductive studies in the

rat and rabbit are not expected to have a lower POD than currently

used.

 iv. There are no residual uncertainties identified in the exposure

databases. An unrefined dietary exposure assessment was completed, and

tolerance level residues and 100 PCT were assumed; therefore, dietary

exposures will not underestimate the exposure and risks posed by

spiropidion.

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. Imported commodities will be the only source of

exposure for spiropidion in the U.S.; therefore, the aggregate

assessment was limited to food exposure (acute and chronic). As a

result, the aggregate assessments are equivalent to the dietary

assessments and are not of concern. Based on the explanation in Unit

III.C.3., acute residential exposure to residues of spiropidion is not

expected.

 2. Chronic risk. Imported commodities will be the only source of

exposure for spiropidion in the U.S.; therefore, the aggregate

assessment was limited to food exposure (acute and chronic). As a

result, the aggregate assessments are equivalent to the dietary

assessments and are not of concern. Based on the explanation in Unit

III.C.3., chronic residential exposure to residues of spiropidion is

not expected.

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

account short-term residential exposure plus chronic exposure to food

and water (considered to be a background exposure level). Because no

short-term exposure scenario has been identified for spiropidion, no

short-term aggregate exposure is expected.

 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). Because no intermediate-term exposure scenario has been

identified for spiropidion, no intermediate-term aggregate exposure is

expected.

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

evidence of carcinogenicity in two adequate rodent carcinogenicity

studies, spiropidion 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 U.S. population, or to infants and children from

aggregate exposure to spiropidion residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

 Syngenta has submitted an acceptable method description and method

validation data and an independent laboratory validation (ILV) for a

``Quick, Easy, Cheap, Effective, Rugged, and Safe'' method (QuEChERS)

liquid chromatography done with tandem mass spectroscopy (LC/MS/MS),

Method No. BPL19-0035, for the determination of residues of spiropidion

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and metabolite SYN547305 in crop commodities for purposes of regulatory

enforcement. In addition, Syngenta has submitted an acceptable method

description and method validation data and an ILV for LC/MS/MS Method

No. PG26LL for the determination of residues of metabolites SYN547305

(free and conjugated) in livestock commodities for purposes of

regulatory enforcement.

 These methods may be requested from: Analytical Chemistry Branch,

Environmental Science Center, 701 Mapes Road, Suite 5350, Ft. Meade, MD

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

residuemethods@epa.gov.

B. International Residue Limits

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

tolerances with international standards whenever possible, consistent

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

considers the international maximum residue limits (MRLs) established

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

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

Food and Agriculture Organization/World Health Organization food

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

standards-setting organization in trade agreements to 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 Joint Meeting on Pesticide Residues (JMPR) proposed Codex MRLs

for residues of spiropidion in or on soybean; melon, watermelon,

cucumber, tomato, potato, pumpkin, bell and nonbell pepper; meat

byproduct of cattle, goat, hogs, horses, and sheep; fat of cattle,

goat, hogs, horses, and sheep. The JMPR recommendations will be

considered by the Codex Committee on Pesticide Residues (CCPR) and

potentially adopted by the Codex Alimentarius Commission this year. The

tolerance level for residues in pumpkin and tomato have been harmonized

to the proposed Codex MRLs. The tolerance level for residues in bell

and nonbell pepper have not been harmonized with the proposed Codex

MRLs because the MRL is lower than the tolerance for pepper and

harmonizing could result in a situation where compliance with label

directions results in residues in excess of the tolerance.

C. Revisions to Petitioned-For Tolerances

 EPA is establishing tolerances for most of the commodities

requested by the petitioner; however, a number of the tolerances being

established as part of this action differ from what was initially

requested in the tolerance petition. All of the revisions and/or

changes to the petitioned-for tolerances and the reasoning behind those

changes were presented to the petitioner and subsequently accepted. The

reasoning for those revisions are explained in full detail below.

 EPA revised the commodity definitions for the requested tolerances

for soybeans; cucurbit vegetables (crop group 9); fruiting vegetables

(crop group 8); potato (crop subgroup 1C); fat of cattle, goat, horse

and sheep; and meat byproduct of cattle, goat, horse and sheep to be

consistent with EPA's commodity vocabulary. Several of the requested

tolerances are being established at levels that differ from what was

requested based on available residue data and the use of the

Organization for Economic Co-operation and Development (OECD) MRL

calculator and/or for harmonization purposes. EPA has also determined

that tolerances for residues in the processed commodities of potato and

tomato are not required because the tolerances for the raw commodities

are sufficient to cover the processed commodities. In addition, based

upon estimated dietary burden and the results of the metabolism study,

hog and poultry tolerances are not needed. Further, a tolerance for

milk is not being established based upon results in the ruminant

feeding study in that milk does not contain residues of spiropidion.

 EPA has determined that tolerances for residues in the processed

commodities of soybean and pollard are not required. Soybean and

pollard are considered to be minor livestock feed items, and EPA does

not set tolerances for, nor does it require residue data on minor

livestock feed items. The tolerance for soybean, seed is sufficient to

cover these processed commodities; therefore, a tolerance for soybean

and pollard are not needed. Based upon a soybean processing study, EPA

has also determined that a tolerance for soybean aspirated grain

fractions is not required because it is covered by the tolerance set on

soybean, seed.

 Although the petitioner originally requested tolerances for crop

group 8, crop group 9 and crop subgroup 1C, EPA is establishing

tolerances only for the representative commodities for which residue

data were submitted.

V. Conclusion

 Therefore, tolerances are established for residues of the

insecticide spiropidion and its metabolites and degradates in or on

cucumber at 0.8 ppm; muskmelon at 0.9 ppm; pepper, bell at 1.5 ppm;

pepper, nonbell at 1.5 ppm; potato at 1.5 ppm; pumpkin at 0.9 ppm;

soybean, seed at 3 ppm; tomato at 0.8 ppm; watermelon at 0.9 ppm;

cattle, fat at 0.03 ppm; cattle, meat byproducts at 0.3 ppm; goat, fat

at 0.03 ppm; goat, meat byproducts at 0.3 ppm; horse, fat at 0.03ppm;

horse, meat byproducts at 0.3 ppm; sheep, fat at 0.03 ppm; sheep, meat

byproducts at 0.3 ppm. Compliance with tolerances for the plant

commodities will be determined by measuring only the sum of spiropidion

[3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-2-oxo-1,8-

diazaspiro[4.5]dec-3-en-4-yl ethyl carbonate] and its metabolite

SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-

diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-

1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one],

calculated as the stoichiometric equivalent of spiropidion, in or on

the plant commodities. Compliance with the tolerances for the livestock

commodities will be determined by measuring only SYN547305 [3-(4-

chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-

diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-

1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one],

calculated as the stoichiometric equivalent of spiropidion, in or on

the livestock commodities.

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). This action does not

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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.

 Dated: July 13, 2022.

Edward Messina,

Director, Office of Pesticide Programs.

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

40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

IN FOOD

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

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

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2. Add Sec. 180.723 to subpart C to read as follows:

Sec. 180.723 Spiropidion; tolerances for residues.

 (a) General. (1) Tolerances are established for residues of the

insecticide spiropidion, including its metabolites and degradates, in

or on the commodities in Table 1 to this paragraph (a)(1). Compliance

with the tolerance levels specified in Table 1 to this paragraph (a)(1)

is to be determined by measuring only the sum of spiropidion [3-(4-

chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-2-oxo-1,8-

diazaspiro[4.5]dec-3-en-4-yl ethyl carbonate] and its metabolite

SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-

diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-

1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one],

calculated as the stoichiometric equivalent of spiropidion, in or on

the following plant commodities:

 Table 1 to Paragraph (a)(1)

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

 Parts per

 Commodity million

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

Cucumber \1\................................................ 0.8

Muskmelon \1\............................................... 0.9

Pepper, bell \1\............................................ 1.5

Pepper, nonbell \1\......................................... 1.5

Potato \1\.................................................. 1.5

Pumpkin \1\................................................. 0.9

Soybean, seed \1\........................................... 3

Tomato \1\.................................................. 0.8

Watermelon \1\.............................................. 0.9

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\1\ There are no U.S. registrations for this commodity as of July 20,

 2022.

 (2) Tolerances are established for residues of the insecticide

spiropidion, including its metabolites and degradates, in or on the

commodities in Table 2 to this paragraph (a)(2). Compliance with the

tolerance levels specified in Table 2 to this paragraph (a)(2) is to be

determined by measuring only SYN547305 [3-(4-chloro-2,6-dimethyl-

phenyl)-8-methoxy-1-methyl-1,8-diazaspiro[4.5]decane-2,4-dione; and 2-

(4-chloro-2,6-dimethyl-phenyl)-1-hydroxy-8-methoxy-4-methyl-4,8-

diazaspiro[4.5]dec-1-en-3-one], calculated as the stoichiometric

equivalent of spiropidion, in or on the following livestock

commodities:

 Table 2 to Paragraph (a)(2)

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 Parts per

 Commodity million

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Cattle, fat \1\............................................. 0.03

Cattle, meat byproducts \1\................................. 0.3

Goat, fat \1\............................................... 0.03

Goat, meat byproducts \1\................................... 0.3

Horse, fat \1\.............................................. 0.03

Horse, meat byproducts \1\.................................. 0.3

Sheep, fat \1\.............................................. 0.03

Sheep, meat byproducts \1\.................................. 0.3

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\1\ There are no U.S. registrations for this commodity as of July 20,

 2022.

 (b)-(d) [Reserved]

[FR Doc. 2022-15410 Filed 7-19-22; 8:45 am]

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