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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0561; FRL-9999-70]

Indaziflam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indaziflam in or on the tropical and subtropical fruit (edible peel) group 23 and tropical and subtropical fruit (inedible peel) group 24. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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-2018-0561, is available at *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*.

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-2018-0561 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2018-0561, by one of the following methods:

• *Federal eRulemaking Portal*: *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 December 21, 2018 (83 FR 65660) (FRL-9985-67), 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 8E8686) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of indaziflam, N-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1H-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates, in or on the raw agricultural commodities Fruit, tropical and subtropical, edible peel, group 23 at 0.01 ppm and Fruit, tropical and subtropical, inedible peel, group 24 at 0.01 ppm. The petition also requested to amend 40 CFR 180.653 by removing the established tolerance for residues of indaziflam in or on the raw agricultural commodity Fruit, tropical and subtropical, small fruit, edible peel, subgroup 23A at 0.01 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Although not requested, EPA is removing the tolerance for "banana" since it is covered by the new group 24 tolerance. Also, the tolerance expression is being modified as well. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all

anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for indaziflam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with indaziflam 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.

Metabolism studies with rats indicate that indaziflam is rapidly and completely (>90%) absorbed by the oral route, although absorption may become saturated at higher doses. Following absorption, indaziflam is distributed to multiple tissues, with the highest levels found in the liver, skin, and thyroid. Metabolism of indaziflam was extensive and occurred primarily via oxidation to form carboxylic acid and hydroxylated metabolites. Based on *in vivo* dermal absorption data from rats and comparative *in vitro* absorption data from rat and human skin, dermal absorption

for humans is estimated to be 7.3%.

The nervous system is the major target for toxicity in rats and dogs. Evidence of neurotoxicity (e.g., decreased motor activity, clinical signs, and/or neuropathology) was observed in both species throughout the database, which included the dog subchronic and chronic toxicity studies; the rat acute, subchronic, and developmental neurotoxicity (DNT) studies; the rat two-generation reproduction study; the rat chronic toxicity study; and the rat combined carcinogenicity/chronic toxicity study. In repeated-dose studies, the dog was the more sensitive species, showing the lowest no observed adverse effects levels (NOAELs) and lowest observed adverse effects levels (LOAELs) among all available studies, based on neuropathology (degenerative nerve fibers in the brain, spinal cord, and sciatic nerve). At higher doses, three dogs in the subchronic study were prematurely terminated due to excessive clinical signs including ataxia, tremors, decreased pupil response, seizures, and other findings.

In the rat, a marginal decrease in motor/locomotor activity was observed in females in the acute neurotoxicity study. Decreases in motor/locomotor activity were also seen in the subchronic neurotoxicity study in females and in the DNT study in male offspring at post-natal day (PND) 21. Clinical signs of neurotoxicity were observed in the acute, subchronic, and developmental neurotoxicity studies and consisted primarily of tremors, changes in activity and reactivity, repetitive chewing, dilated pupils, and oral, perianal, and nasal staining. Similar clinical signs of neurotoxicity were observed in the 2-generation reproduction study, the rat chronic toxicity study, and the combined rat carcinogenicity/chronic toxicity study. Neuropathology findings were also observed in the rat manifested as focal/multifocal vacuolation of the median eminence of the brain and the pituitary *pars nervosa* and degenerative nerve fibers in the Gasserian ganglion, sciatic nerve, and tibial nerve. Evidence of neurotoxicity

was not seen in the mouse following subchronic or chronic exposure.

Other organs affected by indaziflam in mice and rats included the kidney, liver, thyroid, stomach, seminal vesicles, and ovaries. Effects on the kidney were observed following chronic exposure in rats and mice while effects on the liver were observed following chronic exposure in the rat. Effects on the thyroid were only observed in multiple dose rat studies and usually in the male only. Increased thyroid stimulating hormone (TSH) measured at 3 and 14 weeks in the 90-day and 1-year studies showed an increase in males at week 3. Histopathological alterations (thyroid follicular cell hypertrophy at 90 days and 1 year, as well as colloid alterations at chronic exposure times) were observed, but no increases in thyroid weight were noted. Thyroid histopathology was observed at a lower dose in the two-year study, compared to the 90-day and 1-year studies. Chronic exposures also led to atrophied or small seminal vesicles in male rats and glandular erosion/necrosis in the stomach and blood-filled ovarian cysts/follicles in female mice. In rats, effects observed on the liver, thyroid, kidney, and seminal vesicles occurred at doses that were similar to or higher than those that produced neurotoxicity. However, these effects in the rat occurred at higher doses than those at which neurotoxicity was observed in the dog. Decreased body weight was also observed in most subchronic and chronic studies following oral exposure to indaziflam. There was no evidence of immunotoxicity in the available studies, which included a guideline immunotoxicity study in the rat. No systemic effects were observed in the rat following a 28-day dermal exposure period.

Since the previous assessment, the maternal findings in the rat developmental toxicity study have been revised because the decreases in maternal weight gain and food consumption did not result in reduced mean maternal body weight at any dose tested and no other maternal findings were reported. Decreased mean fetal weight was observed at the highest dose tested,

indicating increased quantitative susceptibility. However, no evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rabbits, a developmental neurotoxicity study in rats, or in a 2-generation reproduction study in rats. No developmental effects were observed in rabbits up to maternally toxic dose levels. Decreased pup weight and delays in sexual maturation (preputial separation in males and vaginal patency in females) were observed in the rat two-generation reproductive toxicity study, along with clinical signs of toxicity, at a dose causing parental toxicity that included coarse tremors, renal toxicity, and decreased weight gain. In the developmental neurotoxicity study, transiently decreased motor activity (PND 21 only) in male offspring was observed and was considered a potential neurotoxic effect. It was observed at a dose that also caused clinical signs of neurotoxicity along with decreased body weight in maternal animals.

Indaziflam showed no evidence of carcinogenicity in the two-year dietary rat and mouse bioassays. All genotoxicity studies that were conducted on indaziflam were negative.

Specific information on the studies received and the nature of the adverse effects caused by indaziflam as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document titled "Indaziflam – Aggregate Human Health Risk Assessment of the Proposed New Use on Lowbush Blueberry, and Crop Group Expansions to Tropical and Subtropical Fruit, Edible Peel, Group 23 and Tropical and Subtropical Fruit, Inedible Peel, Group 24" on pages 29-39 in docket ID number EPA-HQ-OPP-2018-0561.

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-pesticide*.

A summary of the toxicological endpoints for indaziflam used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Indaziflam for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children and females 13 to 49 years old)	NOAEL = 7.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.075 mg/kg/day aPAD = 0.075 mg/kg/day	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day, based on axonal degenerative microscopic findings in the brain, spinal cord, and sciatic nerve.
Chronic dietary (All populations)	NOAEL= 2 mg/kg/day UF_A = 10x	Chronic RfD = 0.02 mg/kg/day cPAD = 0.02	Chronic Dietary Toxicity Study in Dogs LOAEL = 6/7 mg/kg/day

	UF_H = 10x FQPA SF = 1x	mg/kg/day	M/F, based on nerve fiber degenerative lesions in the brain, spinal cord, and sciatic nerve.
Incidental oral short-term (1 to 30 days)	NOAEL= 7.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day, based on axonal degenerative microscopic findings in the brain, spinal cord, and sciatic nerve.
Dermal short-term (1 to 30 days)	Oral study NOAEL = 7.5 mg/kg/day (dermal absorption rate = 7.3%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day, based on axonal degenerative microscopic findings in the brain, spinal cord, and sciatic nerve.
Inhalation short-term (1 to 30 days)	Oral study NOAEL= 7.5 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic Gavage Toxicity Study in Dogs LOAEL = 15 mg/kg/day, based on axonal degenerative microscopic findings in the brain, spinal cord, and sciatic nerve.
Cancer (Oral, dermal, inhalation)	No Evidence of Carcinogenicity. Classified as "Not Likely to be Carcinogenic to Humans."		

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. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to indaziflam, EPA considered exposure under the petitioned-for tolerances as well as all existing indaziflam tolerances in 40 CFR 180.653. EPA assessed dietary exposures from indaziflam 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 indaziflam. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute assessment was based on tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure*. In estimating chronic dietary exposure, EPA used 2003-2008 food consumption information from the USDA's NHANES/WWEIA. As to residue levels in food, the chronic assessment was based on tolerance-level residues and 100 PCT.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that indaziflam 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*. EPA did not use anticipated residue estimates or PCT information in the dietary assessment for indaziflam. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for indaziflam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of indaziflam. Further information regarding EPA drinking water models used in pesticide exposure assessments can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Residues of concern in drinking water are indaziflam, triazine indanone, indaziflam-

carboxylic acid, indaziflam-olefin, indaziflam-hydroxyethyl, and fluoroethyl diaminotriazine (FDAT). With the exception of FDAT, all of the metabolites are assumed to have comparable toxicity to the parent due to structural similarity (i.e., both rings intact). However, FDAT, a single-ring metabolite, is not expected to be more toxic than the parent indaziflam based on FDAT's non-neurotoxic mode of action. The Agency calculated total indaziflam estimated drinking water concentrations (EDWCs) for residues of concern that are structurally similar to indaziflam (i.e., indaziflam, triazine-indanone, indaziflam-carboxylic acid, indaziflam-hydroxyethyl, and indaziflam-olefin), and separate EDWCs for total FDAT, including its fluoroethyl-triazinanedione (ROI1) degradate. The Agency combined the total indaziflam and total FDAT EDWCs for use in the dietary assessments.

Based on the Pesticide in Water Calculator (PWC), the EDWCs of combined residues of indaziflam for acute exposures are estimated to be 84 parts per billion (ppb) for surface water and 3.7 ppb for ground water, and for chronic exposures are estimated to be 26 ppb for surface water and 3.7 ppb for 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 84 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration value of 26 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Indaziflam is currently registered for the following uses that could result in residential exposures: turf, gardens, and trees. EPA assessed residential exposure using the following

assumptions: short-term dermal and inhalation handler exposure is expected for adults as a result of applying products containing indaziflam to lawns/turf and gardens/trees using a variety of application equipment. Short-term post-application dermal exposure is expected for adults, children 11 to less than 16 years old, and children 6 to less than 11 years old as a result of playing, mowing, and/or golfing on treated turf. Short-term dermal and incidental oral exposure (hand to mouth, object to mouth, incidental soil ingestion) is expected for children 1 to less than 2 years old as a result from playing on treated turf/lawns. Lastly, short-term post-application dermal exposure is expected for adults and children 6 to less than 11 years old as result of application to gardens and trees.

The Agency selected only the most conservative, or worst case, residential adult and child scenarios to be included in the aggregate estimates, based on the lowest overall MOE (i.e., highest risk estimates). The worst-case residential exposure scenario for both adults and children resulted from short-term dermal and incidental oral (for children only) post-application exposure to treated turf. 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 indaziflam to share a common mechanism of toxicity with any other substances, and indaziflam does not appear to produce a toxic metabolite produced by other

substances. For the purposes of this tolerance action, therefore, EPA has assumed that indaziflam 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*. Since the previous assessment, the maternal findings in the rat developmental toxicity study have been revised because the decreases in maternal weight gain and food consumption did not result in reduced mean maternal body weight at any dose tested and no other maternal findings were reported. Decreased mean fetal weight was observed at the highest dose tested, indicating increased quantitative susceptibility. However, no evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rabbits, a developmental neurotoxicity study in rats, or in a 2-generation reproduction study in rats. No developmental effects were observed in rabbits up to

maternally toxic dose levels. Decreased pup weight and delays in sexual maturation (preputial separation in males and vaginal patency in females) were observed in the rat two-generation reproductive toxicity study, along with clinical signs of toxicity, at a dose causing parental toxicity that included coarse tremors, renal toxicity and decreased weight gain. In the developmental neurotoxicity study, transiently decreased motor activity (PND 21 only) in male offspring was observed and was considered a potential neurotoxic effect. It was observed at a dose that also caused clinical signs of neurotoxicity along with decreased body weight in maternal animals.

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 indaziflam is complete.

ii. Evidence of neurotoxicity was observed in dogs and rats throughout the database, which included the dog subchronic toxicity study; the rat subchronic toxicity; the rat acute, subchronic, and developmental neurotoxicity screening batteries; the rat two-generation reproduction study; the rat chronic toxicity study; and the rat combined carcinogenicity/chronic toxicity study. Evidence of neurotoxicity was manifested as neuropathology in dogs and as decreased motor activity and clinical signs (e.g., tremors) in rats. Evidence of neurotoxicity was the most consistent effect (seen in dogs and rats), the most sensitive toxicological finding (based on neuropathology in dogs) and is being used as the basis for the risk assessment.

iii. No developmental effects were observed in rabbits up to maternally toxic dose levels. Offspring effects in the DNT study in rats and multi-generation toxicity studies only occurred in the presence of maternal toxicity and were not considered more severe than the parental effects.

However, decreased fetal weight was observed in the rat developmental toxicity study in the absence of adverse maternal effects. Therefore, the Agency concluded that there is evidence of increased quantitative susceptibility to rat fetuses exposed *in utero* to indaziflam. In all studies, clear NOAELs/LOAELs were identified for maternal/parental and fetal/offspring effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to indaziflam 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 indaziflam.

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 indaziflam will occupy 19% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to indaziflam from food and water will utilize 7.8% of the cPAD for all infants less than 1 year old, the population group receiving the

greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of indaziflam 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). Indaziflam 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 indaziflam. 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 1,400 for adults and 580 for children 1 to less than 2 years old. Because EPA's level of concern for indaziflam is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, indaziflam is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for indaziflam.

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

carcinogenicity in two adequate rodent carcinogenicity studies, indaziflam 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 indaziflam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectrometry detection (LC/MS/MS) method (DH-003-P07-02) for fruit and nut tree matrices for indaziflam and FDAT) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex

level.

The Codex has not established any MRLs for indaziflam.

C. Revisions to Petitioned-For Tolerances

Although not requested, EPA is also removing the existing tolerance for "banana" because it is superseded by the new crop group 24 tolerance. Also, EPA is amending the tolerance expression for indaziflam to correct the residues that should be measured in determining compliance with the established tolerance levels. The Agency has determined that residues of the FDAT metabolite should be aggregated with residues of indaziflam when evaluating compliance with established tolerance levels. This revision does not require any changes in tolerance levels because those tolerance levels were established based on aggregated residues of FDAT and indaziflam. In accordance with its policy to improve the consistency and clarity of its tolerance expressions, EPA is revising the tolerance expression in this rulemaking.

V. Conclusion

Therefore, tolerances are established for residues of indaziflam in or on Fruit, tropical and subtropical, edible peel, group 23 at 0.01 ppm and Fruit, tropical and subtropical, inedible peel, group 24 at 0.01 ppm.

Additionally, the existing tolerances for both the tropical and subtropical, small fruit, edible peel, subgroup 23A and banana are removed as unnecessary due to the establishment of the above tolerances.

Lastly, the tolerance expression in paragraph (a) is modified to read as follows: *"General.* Tolerances are established for residues of the herbicide indaziflam, *N*-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the

tolerance levels specified in the table below is to be determined by measuring only indaziflam and FDAT, 6-[(1*R*)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine, calculated as the stoichiometric equivalent of indaziflam, in or on the commodity."

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 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: September 18, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. Section 180.653(a) is amended as follows:

a. Revise the introductory text; and

b. In the table:

i. Add a heading for the table;

ii. Remove the entry for "Banana";

iii. Add alphabetically the entries "Fruit, tropical and subtropical, edible peel, group 23" and "Fruit, tropical and subtropical, inedible peel, group 24";

iv. Remove the entry for "Fruit, tropical and subtropical, small fruit, edible peel, subgroup 23A"; and

v. Remove footnote 2 to the table.

The revision and additions read as follows:

§ 180.653 Indaziflam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide indaziflam, *N*-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only indaziflam and FDAT, 6-[(1*R*)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine, calculated as the stoichiometric equivalent of indaziflam, in or on the commodity.

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Fruit, tropical and subtropical, edible peel, group 23	0.01
Fruit, tropical and subtropical, inedible peel, group 24	0.01
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