

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0551; FRL-9973-10]

Indaziflam; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of indaziflam in or on rangeland, pastures, and areas subject to the Conservation Reserve Program (CRP). This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide in or on grass, forage, fodder, and hay, group 17, forage and grass, forage, fodder, and hay, group 17, hay, grown in rangeland, pastures, and areas subject to the CRP. This regulation establishes a maximum permissible level for residues of indaziflam in or on these commodities. The time-limited tolerances expire on December 31, 2020.

DATES: This regulation is effective February 23, 2018. Objections and requests for hearings must be received on or before April 24, 2018, 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-2017-0551, 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 L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfrNotices@epa.gov.

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 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp> and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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-2017-0551 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 24, 2018. 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-2017-0551, 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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of the herbicide 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 grass, forage, fodder, and hay, group 17, forage at 30 parts per million (ppm) and grass, forage, fodder, and hay, group 17, hay at 100 ppm from use on rangeland, pastures, and areas subject to the CRP. These time-limited tolerances expire on December 31, 2020.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.*, without having received any petition from an outside party.

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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Indaziflam on Rangeland, Pastures, and Areas Subject to the CRP

The Wyoming Department of Agriculture (WDA) requested a specific emergency exemption for the use of indaziflam in rangeland, pastures, and areas subject to the conservation reserve program (CRP) to control medusahead (*Taeniatherum caput-medusae*) and ventenata (*Ventenata dubia*) in the Wyoming counties of Sheridan, Johnson, Cambell, Crook, and Weston. Medusahead and ventenata have recently become established in Wyoming. These pests are potentially two of the greatest risks to Wyoming cattle production because they degrade rangeland forage and hay production. Medusahead has reduced forage production by 80%. Visual assessments of areas invaded by ventenata suggest it offers very little forage. In addition to reducing the forage production, ventenata and medusahead also increase forage silica content by 1.5 and 4 times respectively. This produces poorer quality forage that is less palatable and harder for cattle to digest. If these pests are not controlled, potential statewide invasion can happen in less than 25 years. After having reviewed the submission, EPA determined that an emergency condition exists for this

State, and that the criteria for approval of an emergency exemption are met.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of indaziflam in or on rangeland, pastures, and areas subject to the CRP. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent, non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2020, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on grass, forage, fodder, and hay, group 17, forage and grass, forage, fodder, and hay, group 17, hay on rangeland, pastures, and areas subject to the CRP after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether indaziflam meets FIFRA’s registration requirements for use on rangeland, pastures, and areas subject to the CRP or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of indaziflam by a State for special local needs under FIFRA section 24(c), nor does this tolerance by itself serve as the authority for persons in any State other than Wyoming to use this pesticide on the applicable crops under FIFRA section 18, absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for indaziflam, contact the Agency’s Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Consistent with 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 expected as a result of this emergency exemption request and the time-limited tolerances for residues of indaziflam on grass, forage, fodder, and hay, group 17, forage at 30 ppm and grass, forage, fodder, and hay, group 17, hay at 100 ppm from use on rangeland, pastures, and areas subject to the CRP. EPA’s assessment of exposures and risks associated with establishing time-limited tolerances follows.

A. 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>.

A summary of the toxicological endpoints for indaziflam used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of January 29, 2014 (79 FR 4624) (FRL-9903-88).

B. Exposure Assessment

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

exposure to indaziflam, EPA considered exposure under the time-limited tolerances established by this action as well as all existing indaziflam tolerances in 40 CFR 180.653. EPA assessed dietary exposures from indaziflam in food as follows:

i. *Acute and chronic exposures.* Acute effects were identified for indaziflam. In estimating acute and chronic dietary exposures, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA notes that previous indaziflam assessments used screening-level assessments which assumed tolerance-level residues and 100% crop treated for all included commodities. There are no uses on human foods associated with this section 18 emergency use and there is no expectation of quantifiable residues in livestock commodities. This emergency exemption does not result in any changes to the previous dietary exposure and risk estimates.

ii. *Cancer.* Based on the data summarized in Unit IV.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.

iii. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for indaziflam. Tolerance level residues and 100% CT 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 assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Pesticide in Water Calculator (PWC) and the Tier 1 Rice model, the estimated drinking water concentrations (EDWCs) of indaziflam for acute exposures are estimated to be 84 parts per billion (ppb) for surface water and 3.7 ppb for ground water. For chronic exposures for non-cancer assessments 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 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 16, and children 6 to 11 years old as a result of playing, mowing and/or golfing on treated turf. Short-term dermal and incidental oral exposures (hand to mouth, object to mouth, incidental soil ingestion) are expected for children 1 to 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 11 years old as result of application to gardens and trees. The Agency selected only the most conservative residential adult and child scenarios to be included in the aggregate estimates, based on the lowest overall MOE (i.e., highest risk estimates). The most conservative 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: <https://www.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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

C. 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 SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rats and rabbits, a developmental toxicity study in rats, or in a reproduction study in rats. In the rat developmental toxicity study, decreased fetal weight was observed in the presence of maternal effects that included decreased body weight gain and food consumption. 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 2-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 on post-natal day (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 that 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 2-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 was therefore used as the adverse effect of concern in the risk assessment. The endpoints selected for risk assessment are based on and protective of the neurotoxic effects seen in the guideline studies.

iii. No developmental effects were observed in rabbits up to maternally toxic dose levels. Offspring effects in the developmental neurotoxicity study in rats and multi-generation toxicity studies only occurred at exposure levels that also produced maternal toxicity and these offspring effects were not considered more severe than the parental effects. In addition, clear NOAELs/LOAELs were identified for these studies. Therefore, EPA concluded that there is no evidence of increased quantitative or qualitative susceptibility to rat or rabbit fetuses exposed *in utero* and/or postnatally to indaziflam.

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.

D. 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 document for acute exposure, the acute dietary exposure from food and water to indaziflam will occupy 19% of the aPAD for all infants, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this document for chronic exposure, EPA has concluded that chronic exposure to indaziflam from food and water will utilize 8% of the cPAD for all infants, the population group receiving the greatest exposure. Based on the explanation in the unit 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 document 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. Because EPA's level of concern for indaziflam 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; 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.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (liquid chromatography with tandem mass spectrometry detection (LC/MS/MS) method (DH-003-P07-02) 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 FFDC 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, FFDC section 408(b)(4) requires that

EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for indaziflam.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of the herbicide 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 grass, forage, fodder, and hay, group 17, forage at 30 parts per million (ppm) and grass, forage, fodder, and hay, group 17, hay at 100 ppm from use on rangeland, pastures, and areas subject to the CRP. These tolerances expire on December 31, 2020.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDC sections 408(e) and 408(l)(6). 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 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 in accordance with FFDC sections 408(e) and 408(l)(6), 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 FFDC 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).

VIII. 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: February 6, 2018.

Michael L. 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. In § 180.653, revise paragraph (b) to read as follows:

§ 180.653 Indaziflam; tolerances for residues.

* * * * *

(b) Section 18 emergency exemptions. Time-limited tolerances specified in the following table are established for residues of the herbicide 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 specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the table in this paragraph (b) is to be determined by measuring only indaziflam and FDAT, 6-[(1R)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine (converted to parent equivalents), in or on the commodity. The tolerances expire on the date specified in the table.

Table with 3 columns: Commodity, Parts per million, Expiration date. Rows include Grass, forage, fodder, and hay, Group 17, forage (30 ppm, 12/31/2020) and Grass, forage, fodder, and hay, Group 17, hay (100 ppm, 12/31/2020).

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