Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

While some Native Alaskan tribes and villages could be impacted by this amendment, the EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The amendments will not have a significant effect on emissions and will likely remove barriers to the installation of new, lower emission engines in remote communities.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.

Dated: June 27, 2019.

Andrew R. Wheeler,

Administrator.

For the reasons set forth in the preamble, 40 CFR part 60 is amended as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart IIII—Standards of Performance for Stationary Compression Ignition Internal Combustion Engines

■ 2. Section 60.4216 is amended by revising paragraph (c) to read as follows:

§ 60.4216 What requirements must I meet for engines used in Alaska?

* * * * *

(c) Manufacturers, owners, and operators of stationary CI ICE that are located in remote areas of Alaska may choose to meet the applicable emission standards for emergency engines in §§ 60.4202 and 60.4205, and not those for non-emergency engines in §§ 60.4201 and 60.4204, except that for 2014 model year and later non-emergency CI ICE, the owner or operator of any such engine must have that engine certified as meeting at least Tier 3 p.m. standards.

* * * * *

[FR Doc. 2019–14372 Filed 7–3–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0186; FRL–9994–37]

Indoxacarb; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of indoxacarb in or on grass forage and grass hay. 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 on mixed stands of alfalfa and grasses. Tolerances are already established for residues of indoxacarb in/on alfalfa forage and alfalfa hay and this regulation establishes maximum permissible levels for residues of indoxacarb in or on grass forage and grass hay. The time-limited tolerances expire on December 31, 2022.

DATES: This regulation is effective July 5, 2019. Objections and requests for hearings must be received on or before September 3, 2019 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–2019–0186, is available at *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 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 *https://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 40 CFR part 180 through the Government Printing Office's e-CFR site at *https://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 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–2019–0186 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 3, 2019. 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–2019–0186, by one of the following methods:

- *Federal eRulemaking Portal: 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/where-send-comments-EPA-dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://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 indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4] [oxadiazine-4a(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-e][1,3,4] [oxadiazine-4a(3H)-carboxylate, in/on grass, forage at 10 parts per million (ppm) and in/on grass, hay at 50 ppm. These time-limited tolerances expire on December 31, 2022.

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 Indoxacarb in Mixed Stands of Alfalfa and Grasses and FFDCA Tolerances

The California Department of Pesticide Regulations (CDPR) notified EPA that an emergency condition exists with respect to control of alfalfa weevils in mixed stands of alfalfa and grasses in the Intermountain Region of California. According to CDPR, an urgent and nonroutine situation arose due to the weevils' developing resistance to the commonly relied-upon pyrethroids, and without a suitable pesticide control, significant losses were expected due to yield and quality decreases. Indoxacarb is registered for use in alfalfa but not for grasses and thus there was a need for an emergency exemption for use in mixed stands of alfalfa and grasses. 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. EPA has authorized a specific exemption under FIFRA section 18 for the use of indoxacarb on mixed stands of alfalfa and grasses for control of alfalfa weevils in California.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of indoxacarb in or on grass, forage and grass, hay. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2) and decided that the necessary tolerance 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 to address an urgent and 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, 2022, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on grass, forage and grass, hay 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 the levels that were 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 indoxacarb meets FIFRA's registration requirements for use on grasses or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as bases for registration of indoxacarb by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as authority for persons in any State other than California 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 indoxacarb, 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 use and the time-limited tolerances for combined residues of indoxacarb on grass, forage and grass, hay at 10 ppm and 50 ppm, respectively. There are existing tolerances for residues of indoxacarb in/on meat and milk commodities, and EPA has determined that the existing tolerances for meat and milk commodities will not be exceeded by additional residues in grass forage and hay. EPA's assessment of exposures and risks associated with establishing the 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 (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 or level at which no adverse effects are observed (the NOAEL) and the lowest level 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/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for indoxacarb used for human risk assessment is discussed in Unit III of the final rule published in the **Federal Register** of December 8, 2017 (82 FR 57860) (FRL–9970–39).

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to indoxacarb, EPA considered exposure under the time-limited tolerances established by this action as well as all existing indoxacarb tolerances in 40 CFR 180.564. EPA assessed dietary exposures from indoxacarb 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. Acute effects were identified for indoxacarb. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used full distributions of residue levels from the results of field trials reflecting maximum use patterns in all commodities and used maximum Percent Crop Treated (PCT) estimates.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the EPA used food consumption information from the USDA's 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA used average residue levels based on the results of field trials reflecting maximum use patterns in all commodities and used average PCT estimates.

iii. *Cancer.* Based on the data referenced in Unit IV.A., EPA has concluded that indoxacarb does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the maximum and average PCT for the acute and chronic dietary assessments for existing uses as follows:

- *For acute dietary assessment:* Apples: 10%; apricots: 15%; blueberries: 5%; broccoli: 70%; cabbage: 35%; cantaloupe: 10%; cauliflower: 60%; celery: 5%; cherries: 2.5%; cotton: 2.5%; cucumbers: 10%; grapes: 5%; lettuce: 15%; nectarines: 15%; peaches: 10%; peanuts: 10%; pears: 2.5%; peppers: 30%; plums/prunes: 5%; potatoes: 2.5%; soybeans: 2.5%; spinach: 5%; squash: 5%; sweet corn: 10%; and tomatoes: 40%.
- *For chronic dietary assessment:* Apples: 5%; apricots: 5%; blueberries: 5%; broccoli: 45%; cabbage: 20%; cantaloupe: 5%; cauliflower: 35%; celery: 5%; cherries: 2.5%; cotton: 2.5%; cucumbers: 2.5%; grapes: 2.5%; lettuce: 5%; nectarines: 15%; peaches: 2.5%; peanuts: 5%; pears: 1%; peppers: 15%; plums/prunes: 5%; potatoes: 2.5%; soybeans: 1%; spinach: 2.5%; squash: 2.5%; sweet corn: 2.5%; and tomatoes: 20%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most

recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 2.5%. In those cases, estimates of average PCT between 1% and 2.5% are rounded to 2.5% and estimates of average PCT less than 1% are rounded to 1%. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except for those situations in which the maximum PCT is less than 2.5%. In those cases, EPA uses a maximum PCT value of 2.5%.

The Agency believes that the three conditions discussed in Unit IV.B.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which indoxacarb may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for indoxacarb in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of indoxacarb. 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 Surface Water Concentration Calculator (SWCC) model and the Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of indoxacarb for acute exposures are estimated to be 39 parts per billion (ppb) for surface water and 131 ppb for ground water; for chronic exposures the EDWCs are 11 ppb for surface water and 123 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, a time series distribution of ground water modeled residues was used to assess the contribution to drinking water. For chronic dietary risk assessment, a single point water concentration value of 123 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).

Indoxacarb is currently registered for the following uses that could result in residential exposures: Pet spot-on uses, spot and crack and crevice applications indoors, outdoor broadcast (*i.e.,* turf), perimeter and foundations, spot outdoors (*i.e.,* direct mound applications for fire ants), and crack and crevice outdoors. Based on these use scenarios, EPA assessed residential exposure using the following assumptions:

• Spot and crack and crevice exposures were not quantified due to formulation types that minimize the potential for handler and postapplication exposures (*i.e.,* gels or bait stations). Risks from spot and crack and crevice were not quantified because exposures from these formulation types are expected to be negligible.

• *Residential handler exposure:* There is a potential for dermal and inhalation exposure. Residential handler inhalation exposure is considered negligible for applying ready-to-use pet spot-ons. Residential handler dermal exposures are expected for ready-to-use pet spot-ons, however dermal exposures were not quantified due to the lack of a dermal endpoint. Residential handler inhalation and dermal exposures are considered negligible for applying ready-to-use materials (*i.e.,* baits or stations).

• *Residential post-application dermal and incidental oral exposure:* Postapplication assessments were not conducted for ant mound uses, because these are considered perimeter/spot uses; residential exposure is expected to be negligible. Spot and crack and crevice exposures were not quantified for gels or bait stations; exposure is considered negligible. A golfer assessment was not conducted, due to the lack of a dermal endpoint. Postapplication inhalation exposure is generally not assessed following application to pets and turf. The combination of low vapor pressure (1.9×10^{-10} mm Hg at 25 °C for indoxacarb) of active ingredients typically used in pet and turf pesticide products, and the small amounts of pesticide applied to pets is expected to result in only negligible inhalation exposure. Ingestion of granules is considered an episodic event and not a routine behavior. Because the Agency does not expect this to occur on a regular basis, concern for human health is related to acute poisoning rather than short-term residue exposure. For these reasons, the episodic ingestion scenario is not included in the aggregate assessment. The only route of residential exposure for inclusion in the adult aggregate assessment is inhalation. However, for adults it would be inappropriate to aggregate inhalation exposures with background dietary exposures because the toxicity endpoints for the inhalation and short-term oral routes are different. Therefore, the only residential exposures that were combined are for children 1 to <2 years old in the short-term aggregate assessment that reflects hand-to-mouth exposures from post-application exposure to spot treatment on carpets, and children 1 to <2 years old in the intermediate- and long-term aggregate assessment that reflects exposures from treated pets.

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 indoxacarb to share a common mechanism of toxicity with any other substances, and

indoxacarb does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that indoxacarb 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.* There was no evidence of reproductive effects in rats. There was no evidence of increased susceptibility in developing fetuses or in the offspring following prenatal and/or postnatal exposure to indoxacarb in rats or rabbits. There was no evidence of increased susceptibility in the young in the developmental neurotoxicity study in rats.

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 indoxacarb is complete.

ii. The acute neurotoxicity, subchronic toxicity, and developmental neurotoxicity studies for indoxacarb are available and all endpoints used in the risk assessment are protective of neurotoxic effects.

iii. There is no evidence that indoxacarb results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases.

The Agency estimated maximum and average PCT values for the acute and chronic dietary assessments, as shown in unit IV.B.1.iv. Food residues were taken from the results of supervised field trial studies reflecting maximum use patterns. Drinking water residues were included in the dietary assessments as follows: A point estimate of 123 ppb was used for the chronic assessment and the time series distribution of ground water modeled residues was used in the acute assessment as a residue distribution file in the Monte Carlo analysis. For food commodities, Residue Distribution Files (RDFs) were constructed for the probabilistic acute dietary assessment as appropriate, and average residues were used for blended commodities. For the chronic dietary assessment, either average residue levels from field trial studies were used or for crops where no residues were found, a value of ½ the limit of quantitation was assumed. 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 indoxacarb.

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 adequate MOEs exist.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to indoxacarb will occupy 56% of the aPAD for children ages 1–2, 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 indoxacarb from food and water will utilize 35% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure. EPA has concluded the combined long-term food, water, and residential exposures result in an aggregate MOE of 260 (food, water, and residential) for children aged 1–2. Because EPA's level of concern for indoxacarb is an MOE of 100 or below, this MOE is not of concern. For adults, residential inhalation exposures cannot be aggregated because they are based on different effects than for oral exposures. Therefore, long-term aggregate risk for adults is equivalent to the chronic dietary risk noted in this unit.

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). Indoxacarb 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 to children aged 1–2 years through food and water with short-term residential exposures to indoxacarb. For adults, residential inhalation exposures cannot be aggregated with chronic dietary because they are based on different effects than for oral exposures. Because chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk) and inhalation risk has been assessed for adults, no further assessment of short-term risk is necessary for adults, and EPA relies on the findings from the chronic dietary risk assessment and inhalation assessment, as noted in unit IV.D.2 and IV.D.3, for evaluating short-term risk to adults for indoxacarb.

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 120 (food, water, and residential) for children aged 1–2. Because EPA's level of concern for indoxacarb is an MOE of 100 or below, this MOE is 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). Indoxacarb is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure to children ages 1–2 years through food and water with intermediate-term residential exposures to indoxacarb. For adults, residential inhalation exposures cannot be aggregated with chronic dietary because they are based on different effects than for oral exposures. Because 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 for adults, and EPA relies on the findings from the chronic dietary risk assessment, as noted in unit IV.D.2, for evaluating intermediate-term risk to adults for indoxacarb.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures for children aged 1–2 years result in an aggregate MOE of 260. Because EPA's level of concern for indoxacarb is an MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, indoxacarb 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 indoxacarb residues.

V. Other Considerations

A. Analytical Enforcement Methodology

For the enforcement of tolerances established on crops, two High Performance Liquid Chromatograph/Ultraviolet Detection (HPLC/UV) methods, DuPont protocols AMR 2712–93 and DuPont–11978, are available for use. The limits of quantitation (LOQs) for these methods range from 0.01 to 0.05 ppm for a variety of plant commodities. A third procedure, Gas Chromatograph/Mass-Selective Detection (GC/MSD), DuPont method AMR 3493–95 Supplement No. 4, is also available for the confirmation of residues in plants.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

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 MRLs for indoxacarb in/on grass forage or grass hay.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4] [oxadiazine-4a(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-e][1,3,4] [oxadiazine-4a(3H)-carboxylate, in or on grass, forage at 10 ppm and grass, hay at 50 ppm. These tolerances expire on 12/31/2022.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA 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 FFDCA 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 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).

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: June 28, 2019.

Donna Davis,

Acting 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 § 180.564, add paragraph (b) to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the indoxacarb, including its metabolites and degradates, in or on the specified agricultural commodities in the table below, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the table below is to be determined by measuring only indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-e][1,3,4] [oxadiazine-4a(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-e][1,3,4] [oxadiazine-4a(3H)-carboxylate.

The tolerances expire on the dates specified in the table.

Commodity	Parts per million	Expiration date
Grass, forage	10	12/31/2022
Grass, hay	50	12/31/2022

* * * * *

[FR Doc. 2019–14325 Filed 7–3–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 435

[EPA–HQ–OW–2016–0598; FRL–9995–74–OW]

Decision on Supplemental Information on the Effluent Limitations Guidelines and Standards for the Oil and Gas Extraction Point Source Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of decision.

SUMMARY: The Environmental Protection Agency (EPA) is providing notice of its decision to not revise the final rule establishing pretreatment standards for discharges of pollutants into publicly owned treatment works (POTWs) from onshore unconventional oil and gas (UOG) extraction facilities. In 2016, the EPA promulgated the final rule, Effluent Limitations Guidelines and Standards for the Oil and Gas Extraction Point Source Category (the unconventional oil and gas or UOG rule), based on record information indicating that all facilities subject to the rule were meeting the zero discharge of pollutants requirement in the rule. After promulgation, the EPA received information indicating that certain facilities subject to the final rule were not meeting the rule's zero discharge of pollutants requirement. This notice provides new data and information, the EPA's analyses of that data and announces the Agency's decision to not revise the final UOG rule in response to the remand in *Pennsylvania Grade Crude Oil Coalition* v. *EPA,* No. 16–4064 (3rd Cir., August 31, 2017), requiring the EPA to consider further information and take any appropriate action with regard to the final rule.

DATES: This decision shall be considered issued for purposes of judicial review at 1 p.m. Eastern Standard Time on July 19, 2019. Section 509(b)(1) of the CWA, judicial review of this decision can be had only by filing a petition for review in the U.S. Court of Appeals within 120 days after the decision is considered issued for purposes of judicial review.

FOR FURTHER INFORMATION CONTACT: For more information, see the EPA's website: *https://www.epa.gov/eg/unconventional-oil-and-gas-extraction-effluent-guidelines.* For technical information, contact Karen Feret, Engineering and Analysis Division (4303T), Office of Water, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone: 202–566–1915; email: *feret.karen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

Entities potentially affected by this action include:

Category	Example of regulated entity	North American Industry Classification System (NAICS) code
Industry	Crude Petroleum and Natural Gas Extraction	211111
Industry	Natural Gas Liquid Extraction	211112

B. Obtaining Copies of This Document and Related Information

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2016–0598. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

II. Why is EPA issuing this decision?

The EPA promulgated the UOG rule on June 28, 2016. 81 FR 41845. The UOG rule regulates wastewater pollutants from unconventional oil and gas extraction activities under Subpart C (Onshore Subcategory) of the oil and gas extraction effluent guidelines. The UOG rule is a national rule that prohibits onshore unconventional oil and gas extraction operations from discharging pollutants in wastewater to publicly owned treatment works (POTWs), in other words, a ''zero discharge'' requirement. The UOG rule defines the term ''unconventional oil and gas operations'' to include operations involving ''crude oil and natural gas produced by a well drilled into a shale and/or tight formation (including, but not limited to, shale gas, shale oil, tight gas, and tight oil).'' See 40 CFR 435.33(a)(2)(i). In promulgating the rule, the EPA explained that UOG wastewaters are not typical of POTW influent wastewater, and as a result some UOG extraction wastewater pollutants: Can be discharged untreated from a POTW to the receiving stream (*i.e.,* the POTW is not designed to treat the pollutant); can cause the disruption of the POTW treatment operations (*e.g.,* biological treatment is inhibited); can accumulate in biosolids, limiting their