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: November 9, 2017.

Daniel J. Rosenblatt,

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 § 180.116, revise paragraph (a) to read as follows:

§ 180.116 Ziram; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide ziram (zinc dimethyldithiocarbamate), including its metabolites and degradates, in or on the commodities in the table below as a result of the application of ziram. Compliance with the tolerance levels specified below is to be determined by measuring total dithiocarbamates, determined as CS2, evolved during acid digestion and expressed as zinc ethylenebisdithiocarbamate.

Commodity	Parts per million
Almond	[1] 0.10
Apple	[1] 7.0
Apricot	[1] 7.0
Blueberry	[1] 7.0
Cherry, sweet	[1] 7.0
Cherry, tart	[1] 7.0
Grape	7.0
Hazelnut	0.10
Huckleberry	7.0
Peach	7.0
Pear	[1] 7.0
Pecan	0.10
Quince	[1] 7.0
Strawberry	7.0
Tomato	[1] 7.0

[1] Some of these tolerances were established on the basis of data acquired at the public hearings held in 1950 (formerly § 180.101) and the remainder were established on the basis of pesticide petitions presented under the procedure specified in the amendment to the Federal Food, Drug, and Cosmetic Act by Public Law 518, 83d Congress (68 Stat. 511).

* * * * *

[FR Doc. 2017–25713 Filed 12–7–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0095; FRL–9970–39]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indoxacarb in or on corn, field, forage; corn, field, stover; corn, field, grain. E. I. du Pont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 8, 2017. Objections and requests for hearings must be received on or before February 6, 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–2017–0095, 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, 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 Printing 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–2017–0095 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 February 6, 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–2017–0095, 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 June 8, 2017 (82 FR 26641) (FRL–9961–14), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F8536) by E. I. du Pont de Nemours and Company, 974 Centre Road, Wilmington, Delaware 19805. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide indoxacarb, [(S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)-phenyl] amino]carbonyl]indeno[1,2e] [1,3,4]oxadiazine-4a(3H)-carboxylate], and [(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 corn, field, forage at 10 parts per million (ppm); corn, field, stover at 15 ppm; corn, field, aspirated grain fractions at 45 ppm; corn, field flour at 0.07 ppm; corn, field, meal at 0.03 ppm; corn, field, oil at 0.05 ppm; corn, field, grain at 0.02 ppm. That document referenced a summary of the petition prepared by E. I. du Pont de Nemours and Company, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based on available information, EPA is establishing some tolerances that vary from what the petitioner requested. The reasons for these changes are discussed 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 indoxacarb including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with indoxacarb follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The most common effects resulting from exposure to indoxacarb (defined by the lowest-observed-adverse-effect-level (LOAEL)) were non-specific, and included decreases in body weight, food consumption, and food efficiency. Indoxacarb also affected the hematopoietic system by decreasing the red blood cell count, hemoglobin, and hematocrit in rats, dogs, and mice.

There was no evidence of reproductive effects in rats resulting from exposure to indoxacarb. There was no evidence of increased susceptibility in developing fetuses or in 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. Neurotoxicity was observed in rats and mice, but at doses much higher than those selected for points of departure (PoDs) (which are based on changes in body weight, food consumption and changes in hematology). There is no evidence indoxacarb is carcinogenic, teratogenic, mutagenic, or immunotoxic.

Specific information on the studies received and the nature of the adverse effects caused by indoxacarb as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the documents, Indoxacarb: Human Health Risk Assessment for Indoxacarb to Support the Proposed New Uses on Corn (Field, Pop, and Grown for Seed) in docket ID number EPA–HQ–OPP–2017–0095 and Indoxacarb: Human Health Draft Risk Assessment for Indoxacarb to Support Registration Review and the Proposed New Use for Controlling Ants at Ornamental Nurseries, Sod Farms, and Livestock Corrals of non-Food Bearing Animals in docket ID number EPA–HQ–OPP–2013–0367.

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://www.epa.gov/pesticides/factsheets/riskassess.htm.*

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

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR INDOXACARB 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 (All populations)	NOAEL = 12 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.12 mg/kg/day. aPAD = 0.12mg/kg/day.	Acute oral rate neurotoxicity study LOAEL = 50 mg/kg/day based on decreased body weight and body-weight gain in females (MP062).
Chronic dietary (All populations)	NOAEL= 2.0 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.02 mg/kg/day. cPAD = 0.02 mg/kg/day.	Weight of evidence approach was used from four studies: (1) Subchronic toxicity study—rat (MP062). MRID 44477129. LOAEL = 6.0 (M), 3.8 (F) mg/kg/day based on decreased body weight, body-weight gain, food consumption and food efficiency.
			(2) Subchronic neurotoxicity study—rat (MP062). MRID 44477135. LOAEL = 5.6 (M), 3.3 (F) mg/kg/day based on decreased body weight and alopecia. (3) Chronic/carcinogenicity study—rat (JW062). MRID 44477145. LOAEL = 10 (M), 3.6 (F) mg/kg/day based on decreased body weight, body-weight gain, and food consumption and food efficiency; decreased HCT, HGB and RBC at 6 months in F only. (4) Two-generation rat reproduction study (JW062). MRID 44477144. LOAEL = 4.4 mg/kg/day based on decreased body weights, body-weight gain, food consumption and food efficiency and increased spleen weights in the F_0 and F_1 females.
Incidental oral short-term (1 to 30 days)	NOAEL= 2.0 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100.	Weight of evidence approach was used from four studies: (1) Subchronic toxicity study—rat (MP062). MRID 44477129. LOAEL = 6.0 (M), 3.8 (F) mg/kg/day based on decreased body weight, body-weight gain, food consumption and food efficiency.
			(2) Subchronic neurotoxicity study—rat (MP062). MRID 44477135. LOAEL = 5.6 (M), 3.3 (F) mg/kg/day based on decreased body weight and alopecia. (3) Chronic/carcinogenicity study—rat (JW062). MRID 44477145. LOAEL = 10 (M), 3.6 (F) mg/kg/day based on decreased body weight, body-weight gain, and food consumption and food efficiency; decreased HCT, HGB and RBC at 6 months in F only. (4) Two-generation rat reproduction study (JW062). MRID 44477144. LOAEL = 4.4 mg/kg/day based on decreased body weights, body-weight gain, food consumption and food efficiency and increased spleen weights in the F_0 and F_1 females.
Short-Term Dermal (1 to 30 days) ..... Intermediate-Term Dermal (1–6 months)	A quantitative dermal assessment is not required for indoxacarb, since the calculated human dermal LOAEL exceeds the limit dose of 1,000 mg/kg/day.		
Inhalation short-term (1 to 30 days)	Inhalation NOAEL= 23 μg/L/day. UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	28-day rat inhalation toxicity study (MP062). MRID 45870001.
Inhalation (1–6 months)			The LOAEL of 290 μg/L/day is based on increased spleen weights, pigmentation and hematopoiesis in the spleen, hematological changes, mortality (females), and nasal ulceration and inflammation.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR INDOXACARB FOR USE IN—Continued HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Cancer (Oral, dermal, inhalation)	"Not likely" to be carcinogenic to humans since no evidence of carcinogenicity in either the rat or mouse studies, and no evidence of mutagenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. µg/L/day = microgram/liter/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 indoxacarb, EPA considered exposure under the petitioned-for tolerances 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. Such effects were identified for indoxacarb. In conducting the acute dietary exposure assessment EPA used food consumption information from the 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). In estimating acute dietary exposure, EPA used maximum residue levels based on 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 food consumption information from the 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). In estimating chronic dietary exposure, 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 summarized in Unit III.A., EPA has concluded that indoxacarb 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.* Average or maximum residues and PCT values were used for food commodities.

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, 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 maximum and average PCT values for the acute and chronic dietary assessments, 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 the three conditions discussed in Unit III.C.1.iv.

have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which 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 *http://www.epa.gov/oppefed1/models/water/index.htm.*

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 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 the acute dietary risk assessment, a time series distribution of ground water modeled residues was used to assess the contribution to drinking water. For the 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, crack and crevice applications indoors, outdoor broadcast (*i.e.,* turf), perimeter and foundations, spot (*i.e.,* direct mount applications for fire ants), and crack and crevice.

Based on these use scenarios, EPA assessed residential exposure using the following assumptions:

- Spot and crack and crevice exposures were not assessed due to formulation types that minimize the potential for handler and post-application exposures (*i.e.,* gels or bait stations). Risks from spot and crack and crevice were not assessed 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 assessed due to the lack of a dermal endpoint. Residential handler inhalation and dermal exposures are considered negligible for applying ready-to-use arenas (*i.e.,* baits or stations).
- *Residential post-application dermal and incidental oral exposure:* Post-application 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 assessed for gels or bait stations; exposure is considered negligible. A golfer assessment was not conducted, due to the lack of a dermal endpoint. Post-application inhalation exposure is generally not assessed following application to pets and turf. The combination of low vapor pressure (1.9x10–10 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, inhalation exposures cannot be aggregated 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 *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional 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 10 times;, 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.* 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 determined 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 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, respectively, as shown in unit III.C.i., and unit III.C.ii.

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 (RDF) in the Monte Carlo analysis. For food commodities, RDFs were constructed for the probabilistic acute dietary assessment as appropriate, and average residues were computed for blended commodities and for the chronic dietary assessment.

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.

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 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 less than 1-year old, the population group receiving the greatest exposure. EPA has concluded the combined long-term food, water, and residential exposures result in aggregate MOEs of 260 (food, water, and residential) for children aged 1–2. Because EPA's level of concern for indoxacarb is a MOE of 100 or below, this MOEs 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 because they are based on different effects than for oral exposures. Therefore, short-term aggregate risk for adults is equivalent to the chronic risk noted in unit III.E.2.

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 a MOE of 100 or below, this MOEs 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 aged 1–2 years through food and water with intermediate-term residential exposures to indoxacarb. For adults, residential inhalation exposures cannot be aggregated because they are based on different effects than for oral exposures. Therefore, intermediate-term aggregate risk for adults is equivalent to the chronic risk noted above in unit III.E.2.

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 aggregate MOEs of 260. Because EPA's level of concern for indoxacarb is a 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.

IV. 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.

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 in field corn for indoxacarb.

C. Revisions to Petitioned-For Tolerances

Based on available data and using the Organisation for Economic Co-operation and Development (OECD) maximum residue limit (MRL) calculation procedures, EPA determined that the appropriate tolerance level for corn, field, forage is 6.0 ppm. Based on the corn processing studies, the Agency determined that there is a low level of residue concentration from processing; therefore, separate tolerances are not needed for the processed corn commodities of flour, meal, or oil because these commodities are covered by the tolerance for corn, field, grain. The ''grain, aspirated fractions'' tolerance does not need to be modified for field corn because 40 CFR 180.564(a) currently lists a tolerance level of 45 ppm for ''grain, aspirated fractions,'' and this tolerance covers potential indoxacarb residues in aspirated grain fractions derived from corn.

V. Conclusion

Therefore, tolerances are established for residues of indoxacarb, [(S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)-phenyl] amino]carbonyl] indeno[1,2e][1,3,4]oxadiazine-4a(3H)-carboxylate], and [(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 corn, field, forage at 6.0 ppm; corn, field, stover at 15 ppm; and corn, field, grain at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 22, 2017.

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. In § 180.564, add alphabetically the entries for ''Corn, field, forage'', ''Corn, field, grain'', and ''Corn, field, stover'' to the table in paragraph (a)(1) to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Corn, field, forage	6.0
Corn, field, grain	0.02
Corn, field, stover	15
* * * * *	

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[FR Doc. 2017–26517 Filed 12–7–17; 8:45 am]

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