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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0420; FRL-9903-92]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indoxacarb in or on multiple commodities and removes previously established commodities that will be superseded by tolerances established in this action, which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0420, 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), EPA West 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; 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-2012-0420 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0420, 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 July 25, 2012 (77 FR 43562) (FRL-9353-6), 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 2E8029) by IR-4, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.564 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[1,2-e][1,3,4][oxadiazine-4a(3*H*)-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(3*H*)-carboxylate, in or on bean, dry, seed at 0.07 parts per million (ppm); bean, forage at 37 ppm; bean, succulent at 0.64 ppm; berry, low growing, except strawberry, subgroup 13-07H at 0.9 ppm; small fruit, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm. The petition additionally requested to remove established tolerances of indoxacarb in or on grape at 2.0 ppm and cranberry at 0.90 ppm, upon approval of the updated crop groups or subgroups. That document referenced a summary of the petition prepared on behalf of IR-4 by DuPont Crop

Protection, 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 upon review of the data supporting the petition, EPA has revised several proposed tolerances, has corrected the commodity terminology for bean forage to cowpea forage, and has determined that a tolerance should be established on cowpea hay. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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.

Indoxacarb products are frequently formulated as a mixture of the insecticidally active S-enantiomer (DPX–KN128) and the insecticidally inactive R-enantiomer (DPX–MP062). DPX–MP062 is an formula mixture containing the indoxacarb S-enantiomer and its R-enantiomer at approximately a 75:25 ratio. DPX–JW062 is the racemic mixture of the enantiomers at a 50:50 ratio. EPA has determined that it is appropriate to use data from DPX-JW062 (50:50) to satisfy the requirements for dietary subchronic, chronic, oncogenicity and reproductive studies and that toxicology data using DPX-JW062 and DPX-MP062 may be bridged to DPX-KN128 formulations.

The toxicity profile for KN128, MP062, and JW062 in rats, mice, and dogs with both subchronic and chronic oral exposures were qualitatively similar. Dermal subchronic exposure in the rat also resulted in a similar profile. Signs of toxicity occurred at similar doses and with a similar magnitude of response (females generally being more sensitive than males), and included decreases in body weight, weight gain, food consumption, and food efficiency. These compounds also affected the hematopoietic system by decreasing the red blood cell count, hemoglobin, and hematocrit

in rats, dogs, and mice. Exposure to indoxacarb was frequently accompanied by an increase in reticulocytes in all three species and an increase in Heinz bodies in dogs and mice only. These signs of toxicity did not appear to increase in severity over time.

Neurotoxicity was observed in rats and mice, and was characterized by one or more of the following symptoms in both male and female rats and mice: Weakness, head tilting, and abnormal gait or mobility with inability to stand or ataxia. There was possible evidence of lung damage in the acute inhalation studies with both MP062 and JW062.

The immunotoxicity study in mice did not indicate toxicity to the immune system at the highest dose tested. In the 28-day inhalation study in rats, increased spleen weights, pigmentation, and hematopoiesis in the spleen, and hematological changes were observed at the highest dose tested. Increased spleen weights were also observed in the 28-day dermal rat study. The increase in spleen weights are not considered immunological in origin but can be considered a result of the hemolytic effects, which is the mode of action of indoxacarb.

There was no evidence of carcinogenicity in either the rat or mouse in acceptable studies (JW062). JW062 was not mutagenic in a complete battery of mutagenicity studies. There was also no evidence of mutagenicity with either KN128 or MP062. Therefore, all formulations (KN128, MP062, and JW062) were classified as not likely to be carcinogenic in humans by all relevant routes of exposure.

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 document: "Indoxacarb**.** Human Health Risk Assessment

for the Proposed New Use on Dry Beans, Succulent Beans, Small Fruit Vine Climbing Subgroup (except kiwifruit) 13-07F and Low Growing Berry Subgroup (except strawberry) 13-07H" at pp. 50-55 in docket ID number EPA-HQ-OPP-2012-0420.

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 (General population including infants and children and females 13-49 years old)	NOAEL = 12 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.12 mg/kg/day aPAD = 0.12 mg/kg/day	Acute oral rat neurotoxicity study. LOAEL = 50 mg/kg 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). 2. Subchronic neurotoxicity study - rat (MP062). 3. Chronic/carcinogenicity study - rat (JW062). 4. 2-generation rat reproduction study (JW062). LOAEL = 3.3 mg/kg/day based on decreased body weight, body-weight gain, food

			consumption, and food efficiency; decreased hematocrit, hemoglobin, and red blood cells only at 6 months.
Incidental oral short-term (1 to 30 days), intermediate-term (1 to 6 months), and long-term (> 6 months)	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). 2. Subchronic neurotoxicity study - rat (MP062). 3. Chronic/carcinogenicity study - rat (JW062). 4. Two generation rat reproduction study (JW062). LOAEL = 3.3 mg/kg/day based on decreased body weight, body-weight gain, food consumption, and food efficiency; decreased hematocrit, hemoglobin and red blood cells only at 6 months.

Inhalation short-term (1 to 30 days)	Inhalation study NOAEL= 6 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	28-day rat inhalation toxicity study (MP062). The LOAEL of 75.69 mg/kg/day is based on increased spleen weights, pigmentation, and hematopoiesis in the spleen, hematological changes and mortality (females).
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. 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_H = potential variation in sensitivity among members of the human population (intraspecies).

*The LOAEL of 50 mg/kg was based on a 7% body weight decrease in females only on day 8. No significant differences were noted for days 1, 2, or 15. Currently, a 10% decrease in adult body weight is the threshold for an adverse effect, thus this study NOAEL is considered to be conservative.

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 estimating acute dietary exposure, EPA utilized Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) from 2003 to 2008. Anticipated residues (ARs) for most registered and proposed food commodities were based on field trial data, and in some crops tolerance-level residues were used. Residue estimates for some current uses were further refined using percent crop treated (PCT) data, and 100 PCT estimates were assumed for the remaining uses. .

Available processing data for indoxacarb were used to refine ARs for apples/pears (juice), cotton (oil), grapes (raisin and juice), peanut (oil), potato (dry, chips), prunes (dried), mint (oil), soybean (oil), and tomato (paste and puree), and other commodities where translation was applicable. DEEM-FCID™ (ver. 7.81) default processing factors were assumed for all other processed commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the same assumptions as described in Unit III.C.1.i.

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*.

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 the PCT for existing uses as follows for the acute dietary assessment: Apples, 10%; broccoli, 70%; cabbage, 35%; cauliflower, 60%; cherries, 2.5%; lettuce, 40%; peaches, 2.5%; peanuts, 10%; pears, 2.5%; potatoes, 2.5%; soybeans, 2.5%; spinach, 5%; sweet corn, 10%; and tomatoes, 40%.

The Agency estimated the PCT for existing uses as follows for the chronic dietary risk assessment: Apples, 5%; broccoli, 50%; cabbage, 25%; cauliflower, 40%; celery, 5%; cherries, 1%; grapes, 1%; lettuce, 10%; peaches, 2.5%; peanuts, 2.5%; pears, 1%; potatoes, 1%; soybeans, 1%; spinach, 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 6-7 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 one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. In cases where the average PCT is less than 2.5, 2.5% is used as the average PCT. Similarly, in cases where the maximum PCT is less than 2.5, 2.5% is used as the maximum PCT. 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%.

The Agency believes that 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*. A Total Toxic Residue (TTR) approach was used for the parent indoxacarb and the degradation products with toxicological concern (IN-JT333, IN-KG4333, IN- KT413, IN-ML437-0H) for the drinking water assessment. Therefore, the Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for indoxacarb and its metabolites 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 Provisional Cranberry Model and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of indoxacarb and its metabolites for surface water are expected to be 59.26 parts per billion (ppb) for acute exposures and 18.48 for chronic exposures. For ground water, the EDWC is estimated to be 0.33 ppb for acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration values of 59.26 ppb and 18.48 ppb were used to assess the contribution to drinking water for the acute and chronic dietary risk assessments, respectively.

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 several uses that could result in residential exposures:

• Ready- to-use (RTU) bait stations.

• Spot-on applications of gels (crack and crevices and indoor spot directed treatments) for household insect control (indoor treatments).

• Spot-on treatments for the control of fleas and ticks on dogs and cats.

• Broadcast, perimeter and ant mound treatment on ornamentals, trees, and lawns/turf, utilizing granular and liquid formulations (outdoor treatments).

• Indoor spray applications with granular and liquid formulations for insect control on households/domestic dwellings (crack and crevice and spot directed treatments).

Adult handlers were assessed for potential short-term inhalation toxicity from mixing/loading/applying the following:

• Granular formulation for insect control on lawns/turf.

• Liquid flowable formulation for insect control on lawns/turf.

• Water-soluble packaging formulation for indoor spray applications with manually pressurized hand wand (crack and crevice and spot directed treatments) for insect control in households/domestic dwellings.

• Liquid flowable formulation for indoor spray applications with manually pressurized hand wand (crack and crevice and spot directed treatments) for insect control on households/domestic dwellings. Residential handler exposure is expected to be short-term in duration only, as intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.

Potential postapplication exposures to indoxacarb were considered for adults and children (1-<2 years old), based on the following scenarios:

• Treated pets (dogs and cats) to children from short-, intermediate-, and long-term incidental oral exposures.

• Physical activities on turf to children from short-term incidental oral exposures.

• Crack and crevice and indoor spot-directed spray applications, including short-term inhalation exposures to adults and both short-term inhalation and short-term incidental oral exposures to children.

Since there is no expectation of non-dietary oral exposures to adults from contact with treated pets, that aggregate risk is not quantified.

Since inhalation and incidental oral exposure routes share a common toxicological endpoint (i.e., hematological changes), risk estimates have been combined for those routes. Therefore, the postapplication exposure scenarios that were combined for children 1 < 2 years old are the inhalation and hand-to-mouth (the highest incidental oral exposure assessment) for the indoor surfaces directed spray applications. This combination is considered protective of children's exposure to indoxacarb from residential uses.

Because of the preventative nature of pet products and the potential for extended use in more temperate parts of the country, the residential postapplication exposures to treated pets may be short-, intermediate-, or long-term in duration. Postapplication incidental oral exposures from treated golf courses were not quantified since youth old enough to play golf are not expected to exhibit significant hand-to-mouth behavior. Furthermore, the residential lawn assessment provides the highest estimate of potential exposure from turf applications and is protective of any exposures to children from indoxacarb turf treatment scenarios. Finally, the residential handler and postapplication assessments consider inhalation and/or oral exposures only, since a dermal toxicity endpoint has not been identified for indoxacarb.

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, an oxadiazine class insecticide, 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 *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 Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no quantitative or qualitative

evidence of increased prenatal or postnatal sensitivity in the two developmental toxicity studies in rats with DPX–JW062, one developmental toxicity study in rats with DPX–MP062 and DPX–KN128, one developmental toxicity study in rabbits with DPX–JW062, one 2-generation reproduction studies in rats with DPX–JW062, and the developmental neurotoxicity (DNT) study in rats with DPX–KN128. In these studies, developmental toxicity was observed only in the presence of maternal toxicity.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for indoxacarb is complete.

ii. EPA has determined that an additional uncertainty factor is not needed to account for neurotoxicity. Neurotoxicity was seen in animal studies in rats and mice, but at higher doses than the hematologic effects on which EPA's risk assessments are based. To evaluate the potential for increased sensitivity of infants and children to neurotoxic effects, EPA required a rat developmental neurotoxicity (DNT) study. There was no evidence of increased sensitivity of offspring in the submitted study. Clinical observations, motor activity, acoustic startle habituation, and learning and memory testing were all comparable between the control and treated groups. Mean brain weight, gross and microscopic examinations, and morphometric measurements of the brain were also comparable between the controls and treated groups.

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 acute and chronic dietary food exposure assessments utilized anticipated residues that are based on reliable field trial, as well as PCT data. For the new uses, a conservative estimate of 100 PCT is assumed. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to indoxacarb in drinking water. EPA used similarly conservative assumptions to assess postapplication 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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to indoxacarb will occupy 49% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to indoxacarb from food and water will utilize 12% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Long-term (chronic) aggregate risk for indoxacarb also includes the contribution from dietary (food and drinking water) exposure plus the long-term postapplication exposure to treated pets. EPA has concluded the combined long-term food, water, and residential exposures result in an aggregate MOE of 420 for children 1-<2 years old. Because EPA's level of concern for indoxacarb is a MOE of 100 or below, this MOE is not of concern.

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 through food and water with short-term residential exposures to indoxacarb.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the aggregate short-term exposure (food, water, and residential exposures) result in the lowest aggregate MOEs of 110 for children 1-<2 years old (resulting from the postapplication crack and crevice and spot directed treatment indoor spray) and 1,600 for adults (resulting from the handler turf use). Because EPA's level of concern for indoxacarb is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water

(considered to be a background exposure level). 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 through food and water with intermediate-term residential exposures to 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 (from pet treatments) result in an aggregate MOE of 420 for children 1-<2 years old 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

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)/column switching/ultraviolet (UV) method AMR 2712-93 with confirmation/specificity provided by gas chromatography (GC)/mass-selective detector method AMR 3493-95, Supplement No. 4) is available to enforce the tolerance expression.

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

B. International Residue Limits

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

The Codex has established MRLs for indoxacarb in or on cranberries at 1 ppm, dry chickpea at 0.2 ppm, dry cowpea at 0.1 ppm, dry mung bean at 0.2 ppm, and grapes at 2 ppm, based on measurement of indoxacarb and its R-enantiomer. U.S. tolerances for subgroup 13-07F (represented by grape) at 2 ppm and subgroup 13-07H (represented by cranberry) at 1 ppm are harmonized with the corresponding Codex MRLs. Additionally, the U.S. tolerance level for dry bean is being established at 0.2 ppm, in order to harmonize with the Codex MRLs for dry chickpea and dry mung bean. The Codex has not established MRLs for the other commodities associated with this action.

C. Revisions to Petitioned-For Tolerances

Based on the data submitted with the petition, EPA revised the proposed tolerances for several commodities, as follows: Succulent bean from 0.64 ppm to 0.9 ppm; and low growing berry, except strawberry, subgroup 13–07H from 0.9 ppm to 1 ppm. EPA also determined that the proposed tolerance in or on bean forage at 37 ppm should be revised to 50 ppm, and the Agency determined that the commodity should be listed as cowpea forage because the cowpea forage and hay are the only significant feedstuffs associated with dry beans. Because of that reason, EPA also determined that a tolerance is necessary for cowpea hay at 100 ppm. Finally, EPA revised the tolerance on bean, dry, seed from 0.07 ppm to 0.2 ppm in order to harmonize with Codex MRLs. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization of Economic Cooperation and Development (OECD) tolerance calculation procedures.

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[1,2-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(3*H*)-carboxylate, in or on bean, dry seed at 0.2 ppm; bean, succulent at 0.9 ppm; cowpea, forage at 50 ppm; cowpea, hay at 100 ppm; berry, low growing, except strawberry, subgroup 13-07H at 1 ppm; and fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2 ppm. This regulation additionally removes the established tolerances in or on cranberry at 0.90 ppm and grape at 2.0 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: December 16, 2013.

Lois Rossi,

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:

a. Remove the commodities "Cranberry" and "Grape" in the table in paragraph (a)(1).

b. Add alphabetically the following commodities to the table in paragraph (a)(1).

The amendments read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * *	* *
Bean, dry, seed	0.2
Bean, succulent	0.9
* * *	* *
Berry, low growing, except strawberry, subgroup 13-07H	1
* * *	* *
Cowpea, forage	50
Cowpea, hay	100

* * *	* *
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2
* * *	* *

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