methylethyl)-5-phenyl-4*H*-1,3,5-thiadiazin-4-one, in the commodity.

Commodity	Parts per million
* * * * *	
Brassica, head and stem, subgroup 5A	12.0
* * * * *	
Coffee, green bean	0.35
* * * * *	
Pomegranate	1.9
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0271; FRL–8424–9]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of indoxacarb and its metabolites and degradates, to be determined by measuring only indoxacarb and its R-enantiomer, in or on beet, garden, roots; beet, garden, tops; and bushberry subgroup 13–07B. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 10, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0271. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of 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–2008–0271 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 8, 2009.

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 that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0271, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of May 16, 2008 (73 FR 28461) (FRL–8361–6), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7324) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.564 be amended by establishing tolerances for combined 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 beet, garden, roots at 0.30 parts per million (ppm); beet, garden, tops at 6.0 ppm; and bushberry subgroup 13–07B at 1.5 ppm. That notice referenced a summary of the petition prepared on behalf of IR–4 by E.I. du Pont de Nemours and Company, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for tolerances for combined residues of indoxacarb and its metabolites and degradates, to be determined by measuring only indoxacarb and its R-enantiomer, on beet, garden, roots at 0.30 ppm; beet, garden, tops at 6.0 ppm; and bushberry subgroup 13–07B at 1.5 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances 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 is the S-enantiomer of an isomeric compound containing two enantiomers, the S-enantiomer (DPX–KN128, the insecticidally active component) and its R-enantiomer (DPX–KN127, the insecticidally inactive component). DPX–MP062 is an enantiomeric mixture containing the 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.

DPX–KN128, DPX–MP062 and DPX–JW062 appear to be of similar toxicity acutely. DPX–KN128 and DPX–MP062 were moderately acutely toxic by the oral route while DPX–JW062 was practically non-toxic due to its poor solubility in the corn oil vehicle. However, it was equally toxic orally, when tested using a solvent where it had a higher solubility, such as polyethylene glycol (PEG). By the dermal route, they had low toxicity. DPX–MP062 and DPX–JW062 had low acute inhalation toxicity. DPX–MP062 and DPX–JW062 had moderate to low ocular irritant properties, while DPX–KN128 was practically non-irritating to the rabbit's eyes. By the maximization test, DPX–KN128 and DPX–MP062 were considered dermal sensitizers, while DPX–JW062 was not a sensitizer.

There was possible evidence of lung damage in the acute inhalation studies with both DPX–MP062 and DPX–JW062. ''Lung noise,'' observed with JW062, may indicate the development of acute lung injury and high permeability pulmonary edema. This was not unexpected since an oxidant was generated during indoxacarb metabolism. ''Hunched over back and gasping'' were also present and suggested arterial hypoxemia that accompanies alveolar flooding. The acute inhalation study report with indoxacarb 70% manufacturing use product noted that a ''red nasal discharge'' was detected for 2 days after exposure. This may be indicative of a lung exudate, a sign of lung injury. Subchronic (28 days) inhalation toxicity of indoxacarb in rats was characterized by increased spleen weights, increased pigmentation and hematopoiesis in the spleen, and hematological changes.

The toxicity profiles for DPX–KN128, DPX–MP062, and DPX–JW062 in rats, mice, and dogs with both subchronic and chronic oral exposures were similar. Dermal subchronic exposure in the rat also resulted in a similar profile. The toxic signs occurred at similar doses and with a similar magnitude of response, with females generally being more sensitive than males. The endpoints that most frequently defined the lowest-observed-adverse-effect-level (LOAEL) were non-specific, and included decreased 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. It was frequently accompanied by an increase in reticulocytes in all three species and an increase in Heinz bodies (dogs and mice only). None of these signs of toxicity appeared to get worse over time. In one subchronic rat study, the parameters appeared to return to normal levels following a four-week recovery period. High doses in the rats and mice also sometimes caused mortality.

There was no evidence of increased susceptibility of fetuses or offspring from either *in utero* or neonatal exposure to DPX–MP062 or DPX–JW062. There was no evidence of increased susceptibility from *in utero* exposure of rats to DPX–KN128. There was no evidence of increased susceptibility in the developmental neurotoxicity study in rats with DPX–KN128. No evidence of teratogenicity was observed in rats and rabbits with

DPX–MP062 or DPX–JW062. No evidence of teratogenicity was observed in rats with DPX–KN128. There was no evidence of reproductive effects in the 2-generation reproduction study in rats.

Neurotoxicity was observed in both rats and mice; however, it did not occur in the absence of other signs of toxicity. Neurotoxicity 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 and ataxia. Acute and subchronic neurotoxicity screening batteries were performed using DPX–MP062 in rats. Neurotoxicity was characterized by clinical signs (depression, abnormal gait, head shake, salivation) and functional-observation battery (FOB) effects (circling behavior, incoordination, slow righting reflex, decreased forelimb grip strength, decreased foot splay, decreased motor activity). However, there was no evidence of neurohistopathology in any study. Learning and memory parameters were affected in the pups in the developmental neurotoxicity study in rats with DPX–KN128.

There was no evidence of carcinogenicity in either the rat or mouse in acceptable studies using DPX–JW062. DPX–JW062 was not mutagenic in a complete battery of mutagenicity studies. There was also no evidence of mutagenicity with either DPX–KN128, or DPX–MP062.

Both DPX–JW062 and DPX–MP062 were rapidly absorbed and eliminated following oral administration. The absorption of DPX–JW062 was dose dependent and appeared to be saturated at the high dose. Both urine and feces represented major routes of excretion (35–45% and 33–47%, respectively). The distribution pattern did not vary with dosing regimen and overall tissue burden was limited to only 3.4–12.9% of the administered dose. The red blood cells of rats dosed with the trifluoromethoxyphenyl label consistently contained much greater levels of radioactivity than did plasma. Fat tissue contained the greatest level of radioactivity (1.76–8.76% of the administered dose) and, for both compounds, was greater in female rats. The finding also demonstrates a greater propensity for accumulation by female rats than by male rats. Both DPX–MP062 and DPX–JW062 were extensively metabolized and the metabolites were eliminated in the urine, feces, and bile. With the exception of parent compound (DPX–JW062, which accounted for 19.2% of a single low dose in the feces of female rats), none of the metabolites from any source represented more than 12.3% of the administered dose. The metabolite profile for DPX–JW062 was dose dependent and varied quantitatively between males and females. Differences in metabolite profiles were also observed for the different label positions. All of the biliary metabolites appear to undergo further biotransformation in the gut.

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 LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document *Indoxacarb. Health Effects Division (HED) Human Health Risk Assessment for Bushberry Crop Subgroup 13–07B and Beets (Garden)*, page 13 in docket ID number EPA–HQ–OPP–2008–0271.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which the NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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 can be found at *http://www.regulations.gov* in the document *Indoxacarb. Health Effects Division (HED) Human Health Risk Assessment for Bushberry Crop Subgroup 13–07B and Beets (Garden)*, page 18 in docket ID number EPA–HQ–OPP–2008–0271.

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.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, for most currently registered commodities, EPA used anticipated residues derived from field trial data and maximum percent crop treated (PCT) estimates. EPA assumed tolerance-level residues and 100 PCT for the new commodities associated with this petition (garden beets and bushberries). Available processing data for indoxacarb were used to refine anticipated residues for apples/pears (juice), potato (dry, chips), cotton (oil), tomato (paste and puree), peanut (oil), soybean (oil), grapes (raisin and juice), prunes (dried), mint (oil), and other commodities where translation was appropriate. For all other processed commodities, DEEM–FCID™ (ver. 7.81) default processing factors were assumed.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA relied upon anticipated residues derived from field trial data for most of the registered and new commodities and an anticipated residue value for milk derived from monitoring data collected by the United States Department of Agriculture's Pesticide Data Program

(PDP). Residue estimates were further refined using average PCT data and available processing data, as described in Unit III.C.i. EPA assumed 100 PCT for the new commodities, garden beets and bushberries.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified indoxacarb as ''not likely'' to be carcinogenic to humans via relevant routes of exposure. Therefore, an exposure assessment for evaluating 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, 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 used PCT information as follows:

Acute dietary exposure assessment: Apple 5%, broccoli 50%, cabbage 25%, cauliflower 55%, cherry 2.5%, corn (sweet) 2.5%, lettuce (head) 25%, lettuce (leaf) 11%, peach 2.5%, peanut 2.5%, pear 2.5%, pepper 15%, potato 2.5%, soybean 1%, spinach 5%, and tomato 25%.

Chronic dietary exposure assessment: Apple 1%, broccoli 40%, cabbage 15%, cauliflower 35%, cherry 1%, lettuce (head) 18%, lettuce (leaf) 9%, peach 1%, peanut 1%, pear 1%, pepper 10%, potato 1%, soybean 1%, spinach 5%, and tomato 15%.

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 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. 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*. 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 Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of indoxacarb for acute exposures are estimated to be 25.1 parts per billion (ppb) for surface water and 0.21 ppb for ground water. The EDWCs of indoxacarb for chronic exposures for non-cancer assessments are estimated to be 5.37 ppb for surface water and 0.21 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 25.1 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 5.37 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 several uses that could result in residential, non-dietary exposures. Indoxacarb is registered for use as a fire ant bait, which may be applied as a mound treatment or as a broadcast application to lawns, golf courses, and other recreational areas. Indoxacarb is also registered as a mole cricket bait applied as a broadcast treatment to lawns, golf courses, parks, recreational areas, and athletic fields. Finally, indoxacarb is registered as a foliar or broadcast spray to control lepidopterous larvae on landscape and recreational (including golf courses) turfgrass and ornamentals. EPA assessed residential exposure using the following assumptions:

Based on the residential use patterns, commercial and private (i.e., grower/homeowner) pesticide handlers are expected to have short-term (1–30 days) dermal and inhalation exposures to indoxacarb. Commercial handlers may also have intermediate-term exposures (1–6 months). The short- and intermediate-term toxicological points of departure are the same; therefore, the

risk estimates for intermediate-term exposures are the same as those for short-term exposures.

There is also the potential for short- and intermediate-term postapplication exposure of adults and children from entering areas previously treated with indoxacarb. The postapplication exposure scenarios assessed include: Dermal exposure from treated lawns due to high contact lawn activities (adult and toddler); Dermal exposure from treated turf due to golfing (adults and youths); Hand-to-mouth transfer of pesticide residues on lawns (toddler); Episodic incidental ingestion of granules from pesticide-treated residential areas (toddler); Incidental ingestion of soil from pesticide-treated residential areas (toddler); and Incidental oral object-to-mouth exposure from pesticide-treated residential areas (toddler).

Postapplication inhalation exposures are expected to be negligible and, therefore, were not assessed.

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 *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 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 a developmental neurotoxicity (DNT) study in rats with DPX–KN128. In these studies, developmental toxicity was observed 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. With the exception of an immunotoxicity study, now mandatory under the 40 CFR part 158 Data Requirements for Pesticides, the toxicological database for indoxacarb is complete. The available data do not indicate that indoxacarb is immunotoxic. 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 (75.6 mg/kg/day). Increased spleen weights were also observed in the 28–day dermal rat study at 500 mg/kg/day. The increase in spleen weights is not considered immunological in origin but can be considered a result of the hemolytic effects, which is the mode of action of indoxacarb. Indoxacarb is currently regulated based on a NOAEL of 1.5 mg/kg/day for chronic dietary exposure (protective of hemolytic effects) and 9 mg/kg/day for acute dietary exposure. EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in NOAELs lower than those currently identified for indoxacarb, and an additional uncertainty factor is not needed to account for immunotoxicity.

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. The study has been submitted and reviewed. 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 utilize anticipated residues that are based on reliable field trial and monitoring data. They also utilize PCT data that have been verified by the Agency for most existing uses. 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute 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 63% of the aPAD for children 3 to 5 years 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 6.6% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of indoxacarb is not expected.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposures take into account short- or intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Indoxacarb is currently registered for uses that could result in short- and intermediate-term residential exposures and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to indoxacarb.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short-/intermediate-term food, water, and residential exposures aggregated result in aggregate MOEs of 320 for adults and 102 for children (toddlers). The aggregate MOE for adults includes dietary exposures from food and drinking water, as well as dermal handler and postapplication exposures from the residential use of indoxacarb on turf for mole cricket control, the residential scenario resulting in the highest estimated exposures. Similarly, the aggregate MOE for toddlers includes dietary (food and drinking water) and residential exposures. The residential exposure estimate for toddlers is also based on the worst-case turf scenario (mole cricket control) and includes dermal and incidental oral postapplication exposures. The highest estimated incidental oral exposures for toddlers are from hand-to-mouth activities on treated turf; therefore, the oral hand-to-mouth exposures were used to calculate the aggregate MOE for toddlers.

5. *Aggregate cancer risk for U.S. population*. EPA has classified indoxacarb as ''not likely'' to be carcinogenic to humans via relevant routes of exposure. Indoxacarb is not expected to pose a cancer risk.

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; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no established or proposed Codex, Canadian or Mexican maximum residue limits (MRLs) for indoxacarb on bushberries or garden beets.

C. Changes to Proposed Tolerances

Tolerances for indoxacarb are currently expressed in terms of ''combined 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(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.'' EPA is revising the tolerance expression for existing tolerances and the proposed tolerances on garden beets and bushberries to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the tolerance covers ''residues of indoxacarb, including its metabolites and degradates,'' and that compliance with the tolerance levels will 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(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.

EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of indoxacarb, including its metabolites and degradates, in or on beet, garden, roots at 0.30 ppm; beet, garden, tops at 6.0 ppm; and bushberry subgroup 13–07B at 1.5 ppm. Compliance with these tolerance levels 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(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.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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) (Public Law 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: July 1, 2009.

G. Jeffrey Herndon,

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. Section 180.564 is amended in paragraph (a) by revising the introductory text and by alphabetically adding the following commodities to the table to read as follows:

§180.564 Indoxacarb; tolerances for residues.

(a) *General.* Tolerances are established for residues of indoxacarb, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified 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(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.

Commodity	Parts per million
* * * * *	
Beet, garden, roots	0.30
Beet, garden, tops	6.0
Bushberry subgroup 13–07B	1.5
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[FR Doc. E9–16368 Filed 7–9–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0461; FRL–8422–5]

Mandipropamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of mandipropamid in or on hops, dried cones. Syngenta Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 10, 2009. Objections and requests for hearings must be received on or before September 8, 2009, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0461. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rose Mary Kearns, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5611; e-mail address: *kearns.rosemary@epa.gov*.