

that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action is only a notice and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). This action also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely notifies the public of EPA's receipt of negative declarations for existing OSWI units from state agencies and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This action also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal Standard.

With regard to negative declarations for OSWI units received by EPA for states, EPA's role is only to notify the public of the receipt of such negative declarations. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to approve or disapprove a CAA section 111(d)/129 plan negative declaration submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a CAA section 111(d)/129 negative declaration, to use VCS in place of a section 111(d)/129 negative declaration that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection

burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### *B. Submission to Congress and the Comptroller General*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. This action is not a rulemaking, however, EPA will submit a report containing this action 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 rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### *C. Petitions for Judicial Review*

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 10, 2007. Filing a petition for reconsideration by the Administrator of this action does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such action.

This action approving the section 111(d)/129 negative declarations submitted by the States of Delaware, and West Virginia may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### **List of Subjects in 40 CFR Part 62**

Environmental protection, Administrative practice and procedure, Air pollution control, Aluminum, Fertilizers, Fluoride, Intergovernmental relations, Paper and paper products industry, Phosphate, Reporting and recordkeeping requirements, Sulfur oxides, Sulfur acid plants, Waste treatment and disposal.

Dated: June 28, 2007.

**William C. Early,**  
*Acting Regional Administrator, Region III.*

■ 40 CFR part 62 is amended as follows:

#### **PART 62—[AMENDED]**

■ 1. The authority citation for part 62 continues to read as follows:

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

#### **Subpart I—Delaware**

■ 2. Subpart I is amended by adding an undesignated center heading and § 62.1990 to read as follows:

##### **Emissions From Existing Other Solid Waste Combustion Units**

##### **§ 62.1990 Identification of plan—negative declaration.**

Letter from the Delaware Department of Natural Resources and Environmental Control submitted June 26, 2006, certifying that there are no existing other solid waste incinerator units within the State of Delaware that are subject to 40 CFR part 60, subpart FFFF.

#### **Subpart XX—West Virginia**

■ 3. Subpart XX is amended by adding an undesignated center heading and § 62.12165 to read as follows:

##### **Emissions From Other Solid Waste Incinerator Units**

##### **§ 62.12165 Identification of plan—negative declaration.**

Letter from the West Virginia Department of Environmental Protection submitted June 2, 2006, certifying that there are no existing other solid waste incinerator units within the State of West Virginia that are subject to 40 CFR part 60, subpart FFFF.

[FR Doc. E7-13426 Filed 7-10-07; 8:45 am]

**BILLING CODE 6560-50-P**

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

[EPA-HQ-OPP-2005-0149; FRL-8137-8]

#### **Indoxacarb; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for combined residues of indoxacarb and its R-enantiomer in or on cranberry; fruit, pome, except pear, group 11; fruit, stone, group 12; grape; grape, raisin; okra; pea, southern, seed; pear, oriental; peppermint, tops; spearmint, tops; turnip greens; vegetable, *Brassica*, leafy, group 5; vegetable, cucurbit, group 9; vegetable, leafy, except *Brassica*, group 4; and vegetable, tuberous and corm, subgroup 1-C. E.I. du Pont de Nemours and Company and the Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also removes existing

tolerances on apple; *Brassica*, head and stem, subgroup 5A; lettuce, head; lettuce, leaf; and potato, which are superseded by the new tolerances; and removes expired time-limited tolerances on cherry, sweet; cherry, tart; peach; and collards; and the time-limited tolerance on cranberry (set to expire December 31, 2007), which are no longer needed as a result of this action. Finally, this regulation corrects a typographical error in the spelling of the word "enantiomer" in the tolerance expression for indoxacarb given in 40 CFR 180.564(a)(1).

**DATES:** This regulation is effective July 11, 2007. Objections and requests for hearings must be received on or before September 10, 2007, 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-2005-0149. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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:** Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 an electronic copy of this **Federal Register** document through the electronic docket 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 pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, 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-2005-0149 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 10, 2007.

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-2005-0149, 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'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 July 2, 2003 (68 FR 39541) (FRL-7312-9), 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 3F6576) by E.I. du Pont de Nemours and Company, Newark, DE 19711. The petition requested that 40 CFR 180.564 be amended by establishing a tolerance 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(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, in or on grape at 2.0 parts per million (ppm) and raisin at 6.0 ppm. That notice

included a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant, which is available to the public in the docket EPA-HQ-OPP-2003-0212, <http://www.regulations.gov>. One comment was received on the notice of filing from a private citizen expressing support for the proposed tolerances.

In the **Federal Register** of May 5, 2004 (69 FR 25104) (FRL-7354-9), 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 2E6482) by the Interregional Research Project No. 4 (IR-4). The petition requested that 40 CFR 180.564 be amended by revoking *Brassica*, head and stem, subgroup at 5.0 ppm and establishing a tolerance 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(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[methoxycarbonyl]4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, in or on vegetable, leafy, group 5 at 12 ppm and turnip greens at 12 ppm. That notice included a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant, which is available to the public in the docket EPA-HQ-OPP-2004-0064, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of June 30, 2005 (70 FR 37852) (FRL-7718-9), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 5E6911 and 5E6926) by the Interregional Research Project No. 4 (IR-4). The petitions requested that 40 CFR 180.564 be amended by establishing a tolerance 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(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[methoxycarbonyl]4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, in or on leafy greens, except spinach, subgroup 4A at 10 ppm; spinach at 3.0 ppm; leaf petioles subgroup 4B at 1.5 ppm; fruit, pome, except pear, group 11 at 1.0 ppm; vegetable, tuberous and

corm, subgroup 1C at 0.01 ppm; okra at 0.5 ppm (all requested in PP 5E6911); pea (Southern) at 0.1 ppm; and mint at 10 ppm (both requested in PP 5E6926). That notice included a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant, which is available to the public in the docket EPA-HQ-OPP-2005-0149, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of April 12, 2006 (71 FR 18738) (FRL-7772-2), 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 5E6991) by the Interregional Research Project No. 4 (IR-4). The petition requested that 40 CFR 180.564 be amended by establishing a tolerance 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(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[methoxycarbonyl]4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, in or on vegetable, cucurbit, group 9 at 0.5 ppm; fruit, stone, group 12 at 1 ppm; and cranberry at 1 ppm. That notice referenced a summary of the petition prepared by E.I. du Pont de Nemours and Company, the registrant, which is available to the public in the docket EPA-HQ-OPP-2005-0149, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances. The reasons for these changes are explained in Unit V.

### III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the 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 the 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 the 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...." These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in 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 the petitioned-for tolerances for 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(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[methoxycarbonyl]4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, in or on cranberry at 0.90 ppm; fruit, pome, except pear, group 11 at 1.0 ppm; fruit, stone, group 12 at 0.90 ppm; grape at 2.0 ppm; grape, raisin at 5.0 ppm; okra at 0.50 ppm; pea, southern, seed at 0.10 ppm; pear, oriental at 0.20 ppm; peppermint, tops at 11 ppm; spearmint, tops at 11 ppm; turnip greens at 12 ppm; vegetable, *Brassica*, leafy, group 5 at 12 ppm; vegetable, cucurbit, group 9 at 0.60 ppm; vegetable, leafy, except *Brassica*, group 4 at 14 ppm; and vegetable, tuberous and corm, subgroup 1-C at 0.01 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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. 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>. The referenced

document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2005-0149 in that docket.

Indoxacarb is 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 (toxicity category II) while DPX-JW062 was practically non-toxic (toxicity category IV) 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 (toxicity category III and IV). DPX-MP062 and DPX-JW062 had low acute inhalation toxicity (IV). DPX-MP062 and DPX-JW062 had moderate to low ocular irritant properties (III and IV), 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 on 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 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 susceptibility from either *in utero* or neonatal exposure to both rat and rabbit young with either DPX-MP062 or DPX-JW062. There was no evidence of susceptibility from *in utero* exposure in rats with 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 present 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, 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) (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.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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 lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable uncertainty/safety factors. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure ("MOE") called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for indoxacarb used for human risk assessment can be found at [www.regulations.gov](http://www.regulations.gov) in document "PP#s: 2E6482, 3F6576, 5E6911, 5E6926, and 5E6991. Indoxacarb. Health Effects Division (HED) Risk Assessment for Grapes; Vegetable, *Brassica*, Leafy, Group 5; Turnip Greens; Vegetable, Leafy, Except *Brassica* (Group 4); Pome Fruits (Group 11, except pear); Tuberous and Corm Vegetables (Subgroup 1C); Cucurbit Vegetables (Group 9); Stone Fruits (Group 12); Cranberry; Mint; Okra; Southern Pea; and Fire Ant Bait." at pages 23–24 in Docket ID EPA–HQ–OPP–2005–0149.

### 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 USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues for most commodities and percent crop treated information for most currently registered commodities. EPA assumed 100 percent crop (PCT) treated for all of

the new commodities. Anticipated residues for all registered and new food commodities were based on field trial data.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide CSFII. As to residue levels in food, EPA relied upon anticipated residues for most commodities and PCT information for most currently registered commodities. EPA assumed 100 PCT for all of the new commodities. Anticipated residues for all registered and new food commodities were based on field trial data.

iii. *Cancer.* EPA has classified indoxacarb as "not likely" to be carcinogenic to humans via relevant routes of exposure using the Guidelines for Carcinogen Risk Assessment. Therefore, a cancer exposure assessment was not conducted.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the 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 pursuant to section 408(f)(1) require 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 the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- 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 such pesticide residue;
- The exposure estimate does not underestimate exposure for any significant subpopulation group; and
- 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 section 408(b)(2)(F) of FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

For the acute assessment, maximum PCT estimates were used for the following commodities: apple (5%), broccoli (50%), cabbage (25%), cauliflower and the remaining *Brassica* head and stem vegetables (55%), sweet corn (2.5%), head lettuce (25%), leaf lettuce (11%), peanut (2.5%), pear (2.5%), peppers (15%), potato (2.5%), soybean (1%), spinach (5%) and tomato (25%).

For the chronic assessment, average weighted PCT estimates were used for the following commodities: apple (1%), broccoli (40%), cabbage (15%), cauliflower and the remaining *Brassica* head and stem vegetables (35%), sweet corn (1%), head lettuce (18%), leaf lettuce (9%), peanut (1%), pear (1%), peppers (10%), potato (1%), soybean (1%), spinach (5%) and tomato (15%).

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. 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 Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, 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 2 and 3, 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 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 lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for indoxacarb in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate 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 EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) 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 EECs for chronic exposures 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 the following residential non-dietary sites: as a fire ant bait for turf, which may be applied as a mound treatment or as a broadcast application by "residential" (i.e., private persons) applicators as well as by commercial handlers.

EPA assessed residential exposure using the following assumptions: EPA has determined that residential handlers are likely to be exposed to indoxacarb residues via dermal and inhalation routes during handling and applying activities. Based on the current use pattern, EPA expects duration of exposure to be short-term (1–30 days). The broadcast treatment results in a higher handler exposure than the mound treatment and is, therefore, the scenario assessed by EPA. EPA assessed exposure of residential handlers applying indoxacarb with a push-type spreader using SOPs for Residential Exposure Assessments (DEC-1997) in conjunction with unit exposures developed by the Outdoor Residential Exposure Task Force (ORETF).

There is also the potential for short-term and intermediate-term post-application exposure of adults and children from entering areas previously treated with indoxacarb (i.e., turf treated for fire ants). The post-application scenarios assessed from exposure to treated turf 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); Incidental ingestion of granules from pesticide-treated residential areas (toddler); and Incidental ingestion of soil from pesticide-treated residential areas (toddler).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to indoxacarb and 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 not assumed that indoxacarb has 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 of FFDCA provides that EPA shall apply an additional ("10X") tenfold 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. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

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 that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

- i. The toxicity database for indoxacarb is complete.
- ii. 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 two-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 for most commodities that are based on reliable field trial data. They also utilize PCT data that have been verified by the Agency for most existing uses. For all new uses, 100 PCT is assumed. The acute and chronic assessments are somewhat refined and based on reliable data and will not underestimate exposure/risk. Conservative ground and surface water modeling estimates were used. Similarly conservative Residential SOPs were used to assess post-application exposure to 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*

Safety is assessed for acute and chronic risks by comparing aggregate 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 LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure ("MOE") called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to indoxacarb will occupy 84% of the aPAD for the population group (children, 3 to 5 years old) receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to indoxacarb from food and water will utilize 53% of the cPAD for the population group (children, 1 to 2 years old) with greatest exposure. Based on the use pattern, chronic residential exposure to residues of indoxacarb is not expected.

Indoxacarb is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for indoxacarb.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 620 for the general U.S. population and 190 for children, 1 to 2 years old. The aggregate MOE for the general U.S. population is based on the residential turf (fire ant control) scenario and includes combined residential applicator and post-application dermal exposures. EPA determined that it is not appropriate to include applicator inhalation exposure in the aggregate exposure assessment, since toxicological endpoints of concern for dermal and inhalation exposures are different. The aggregate MOE for children includes post-application dermal and incidental oral exposures from entering turf areas previously treated with indoxacarb for fire ants.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Indoxacarb is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for indoxacarb.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 620 for the general U.S. population and 190 for children, 1 to 2 years old. The aggregate MOE for the general U.S. population is based on the residential turf (fire ant control) scenario and includes combined residential applicator and post-application dermal exposures. EPA determined that it is not appropriate to include applicator inhalation exposure in the aggregate exposure assessment, since toxicological endpoints of concern for dermal and inhalation exposures are different. The aggregate MOE for children includes post-application dermal and incidental oral exposures from entering turf areas previously treated with indoxacarb for fire ants.

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 using the Guidelines for Carcinogen Risk Assessment. Therefore, a cancer aggregate exposure assessment was not conducted. 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 is available to enforce the tolerance expression (high-performance liquid chromatography (HPLC)/column switching/ultraviolet (UV) methods AMR 2712-93 and Du Pont 11978 with confirmation/specificity provided by gas chromatography (GC)/mass-selective detector method AMR 3493-95, Supplement No. 4). These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

There are no established or proposed Codex maximum residue limits (MRLs) for indoxacarb.

#### **V. Conclusion**

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as follows:

(1) PP 3F6576: Revised the commodity term and tolerance for "raisin" to read "grape, raisin" at 5.0 ppm;

(2) PP 5E6911: Replaced the proposed tolerances for "leafy greens, except spinach, subgroup 4A", "leaf petioles subgroup 4B" and "spinach" with a single tolerance in or on "vegetable, leafy, except Brassica, group 4" at 14 ppm; and added a tolerance for "pear, oriental" at 0.20 ppm;

(3) PP 5E 6926: Revised the commodity term "pea (southern)" to read "pea, southern, seed"; and revised the commodity term and tolerance level for "mint" to read "peppermint, tops" at 11 ppm and "spearmint, tops" at 11 ppm; and

(4) PP 5E6991: Revised the tolerances for "vegetable, cucurbit, group 9", "fruit, stone, group 12" and "cranberry" to 0.60 ppm, 0.90 ppm and 0.90 ppm, respectively. The reasons for these changes are discussed below.

EPA revised the commodity terms “raisin”, mint” and “pea (southern)” to agree with recommended commodity terms in the Office of Pesticide Program’s Food and Feed Commodity Vocabulary. Based on data submitted with PP 5E6911 and data previously submitted to support the existing tolerances on leaf and head lettuce, EPA determined that it was appropriate to establish a tolerance for the crop group “vegetable, leafy, except *Brassica*, group 4” instead of the proposed separate tolerances on “leafy greens, except spinach, subgroup 4A”, “spinach” and “leaf petioles subgroup 4B”. The crop group tolerance of 14 ppm is based on data for the crop with the highest field trial residues (spinach). EPA is establishing a tolerance for “pear, oriental” at 0.20 ppm. A tolerance for “pear” currently exists at this level. Although residue field trial data for pear may be translated to oriental pear, a separate tolerance must be established under current regulations. EPA is taking this action to clarify tolerances for all members of the pome fruit crop group. Based on the submitted grape processing data showing a maximum concentration in raisins of 2.7x and the highest average field trial (HAFT) residue on grapes of 1.52 ppm, EPA has determined that the proposed raisin tolerance of 6.0 ppm should be revised to 5.0 ppm. EPA also determined that the proposed tolerance levels for “peppermint, tops”, “spearmint, tops”, “vegetable, cucurbit, group 9”, “fruit, stone, group 12” and “cranberry” were inappropriate and should be revised as specified above based on analyses of the residue field trial data using the Agency’s Tolerance Spreadsheet in accordance with the Agency’s Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP).

Therefore, tolerances are established for 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(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)]4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, in or on cranberry at 0.90 ppm; fruit, pome, except pear, group 11 at 1.0 ppm; fruit, stone, group 12 at 0.90 ppm; grape at 2.0 ppm; grape, raisin at 5.0 ppm; okra at 0.50 ppm; pea, southern, seed at 0.10 ppm; pear, oriental at 0.20 ppm; peppermint, tops at 11 ppm; spearmint,

tops at 11 ppm; turnip greens at 12 ppm; vegetable, *Brassica*, leafy, group 5 at 12 ppm; vegetable, cucurbit, group 9 at 0.60 ppm; vegetable, leafy, except *Brassica*, group 4 at 14 ppm; and vegetable, tuberous and corm, subgroup 1-C at 0.01 ppm. Existing tolerances on apple; *Brassica*, head and stem, subgroup 5A; lettuce, head; lettuce, leaf; and potato, which are superseded by the new tolerances, are revoked.

Time-limited tolerances were established for combined residues of indoxacarb and its R-enantiomer in or on cherry, sweet; cherry, tart; and peach in connection with a FIFRA section 5 experimental use permit granted by EPA. Time-limited tolerances were established for combined residues of indoxacarb and its R-enantiomer in or on collards and cranberry in connection with FIFRA section 18 emergency exemptions granted by EPA. All of these time-limited tolerances have expired, except the time-limited tolerance on cranberry, which is set to expire on December 31, 2007. Because EPA is establishing tolerances on stone fruit, *Brassica* leafy vegetables and cranberry, these time-limited tolerances, most of which have already expired, are not needed. Therefore, the time-limited tolerances for residues of indoxacarb and its R-enantiomer under 40 CFR 180.564(a)(2) and 40 CFR 180.564(b) are revoked.

Finally, the word “enantiomer” is incorrectly spelled (“enantimomer”) in the tolerance expression for indoxacarb in 40 CFR 180.564(a)(1) and is being corrected in this regulation.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 6, 2000) do not apply to this rule. In addition, this 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 2, 2007.

**Donald R. Stubbs,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.564, paragraph (a) is revised and paragraph (b) is removed and reserved to read as follows:

**§ 180.564 Indoxacarb; tolerances for residues.**

(a) *General.* Tolerances are established for the 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(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4][oxadiazine-4a(3H)-carboxylate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Apple, wet pomace .....	3.0
Alfalfa, forage .....	10
Alfalfa, hay .....	50
Cattle, fat .....	1.5
Cattle, meat .....	0.05
Cattle, meat byproducts .....	0.03
Corn, sweet, forage .....	10
Corn, sweet, kernel plus cob with husk removed .....	0.02
Corn, sweet, stover .....	15
Cotton, gin byproducts ...	15
Cotton, undelinted seed .....	2.0
Cranberry .....	0.90
Fruit, pome, except pear, group 11 .....	1.0
Fruit, stone, group 12 ....	0.90
Goat, fat .....	1.5
Goat, meat .....	0.05
Goat, meat byproducts ...	0.03
Grape .....	2.0
Grape, raisin .....	5.0
Hog, fat .....	1.5
Hog, meat .....	0.05
Hog, meat byproducts ....	0.03
Horse, fat .....	1.5
Horse, meat .....	0.05
Horse, meat byproducts .....	0.03
Milk .....	0.15

Commodity	Parts per million
Milk, fat .....	4.0
Okra .....	0.50
Pea, southern, seed .....	0.10
Peanut .....	0.01
Peanut, hay .....	40
Pear .....	0.20
Pear, oriental .....	0.20
Peppermint, tops .....	11
Sheep, fat .....	1.5
Sheep, meat .....	0.05
Sheep, meat byproducts .....	0.03
Soybean, aspirated grain fractions .....	45
Soybean, hulls .....	4.0
Soybean, seed .....	0.80
Spearmint, tops .....	11
Turnip, greens .....	12
Vegetable, <i>Brassica</i> , leafy, group 5 .....	12
Vegetable, cucurbit, group 9 .....	0.60
Vegetable, fruiting, group 8 .....	0.50
Vegetable, leafy, except <i>Brassica</i> , group 4 .....	14
Vegetable, tuberous and corm, subgroup 1-C ....	0.01

(b) *Section 18 emergency exemptions.*  
[Reserved]

\* \* \* \* \*  
[FR Doc. E7-13339 Filed 7-10-07; 8:45 am]  
**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2006-0331; FRL-8130-5]**

**Cymoxanil; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of cymoxanil in or on grape, hop, and caneberry. The Interregional Research Project (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 11, 2007. Objections and requests for hearings must be received on or before September 10, 2007, 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-2006-0331. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert

the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [www.regulations.gov](http://www.regulations.gov) web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](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 Building), 2777 S. Crystal Drive, 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:** Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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