Constitution Avenue, NW., Washington DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, except on government holidays. You can reach the Reading Room by telephone at (202) 566–1742, and by facsimile at (202) 566–1741. The telephone number for the Air Docket is (202) 566–1742. You may be charged a reasonable fee for photocopying docket materials, as provided in 40 CFR part 2.

FOR FURTHER INFORMATION CONTACT: Robert Larson, U.S. EPA, National Vehicle and Fuel Emissions Laboratory, Transportation and Regional Programs Division, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone (734) 214–4277, fax (734) 214–4956, e-mail *larson.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: We stated in the direct final rule published at 68 FR 17741 (April 11, 2003) that if we received adverse comment on the amendment, by May 12, 2003, we would publish a timely withdrawal in the **Federal Register**. We have received adverse comments on the amendments to 40 CFR 89.2.

As a result of the adverse comments received, we are withdrawing the amendment to § 89.2. We intend to consider the issues raised by the comments in a final action based on the concurrent notice of proposed rulemaking (68 FR 17763).

List of Subjects in 40 CFR Part 89

Environmental protection, Administrative practice and procedure, Motor vehicle pollution.

Jeffrey R. Holmstead,

Assistant Administrator for Office of Air and Radiation.

[FR Doc. 03–12021 Filed 5–13–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0173; FRL–7307–6]

Indoxacarb; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues/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] + 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 peaches. This action is in response to university extension specialists, DuPont, and EPA's combined efforts to generate the information necessary for registration of the reduced risk pesticide, Indoxacarb, on peaches for control of oriental fruit moth and plum cuculio. This temporary tolerance supports a non-crop destruct experimental use permit (EUP) under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of Indoxacarb on peaches in Georgia, Michigan, New Jersey, Pennsylvania, South Carolina, and West Virginia. This regulation establishes a maximum permissible level for residues of Indoxacarb in this food commodity pursuant to section 408(e) of Federal Food Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerance will expire on May 15, 2006.

DATES: This regulation is effective May 14, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0173, must be received on or before July 14, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8291; e-mail address: kumar.rita@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:

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

This listing is not intended to be exhaustive, but rather provides 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 Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0173. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html,* a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of April 16, 2003 (68 FR 18582) (FRL–7302–3), EPA issued a proposed rule pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), EPA, in cooperation with university extension specialists, and DuPont Pont Crop Protection, pursuant to sections 408(e) and (r) of FFDCA, proposed to establish a tolerance for combined residues of the reduced risk pesticide, Indoxacarb in or on peaches. This temporary tolerance supports a non-crop destruct EUP under section 5 of FIFRA authorizing use of Indoxacarb on peaches in Georgia, Michigan, New Jersey, Pennsylvania, South Carolina, and West Virginia. Section 5 of FIFRA authorizes EPA to issue an experimental use permit for a pesticide. This provision was not amended by FQPA. EPA has established regulations governing such experimental use permits in 40 CFR part 172. Section 408(r) of FFDCA authorizes EPA to issue time-limited tolerances for pesticide residues from FIFRA experimental use permits.

The proposed rule 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] + 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 peaches at 10.0 parts per million (ppm). The tolerance will expire on May 15, 2006.

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. * * *''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the 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, consistent with section 408(b)(2) of the FFDCA, for a tolerance 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] + 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 on peaches at 10 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. The nature of the toxic effects caused by Indoxacarb are discussed in the proposed rule, as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

Refer to the April 16, 2003, **Federal Register** document (68 FR, 18582) for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon that risk assessment and the findings made in the **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment, including this use on peaches.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.564) for the combined residues of Indoxacarb, in or on a variety of raw agricultural commodities. Including tolerances already established for: Apple at 1.0 ppm, apple, wet pomace at 3.0 ppm, brassica, head and stem, subgroup at 5.0 ppm, cattle, goat, horse, sheep, and hog fat at 0.75 ppm, cattle, goat, horse, sheep, and hog meat at 0.03 ppm, cattle, goat, horse, sheep, and hog meat byproducts at 0.02 ppm, corn, sweet, forage at 10 ppm, corn, sweet, kernel plus cob with husk removed at 0.02 ppm, corn, sweet stover at 15 ppm, cotton gin byproducts at 15 ppm, cotton, undelinted seed at 2.0 ppm, lettuce, head at 4.0 ppm, lettuce, leaf at 10.0 ppm, milk at 0.10 ppm, and milk, fat at 3.0 ppm, pear at 0.20 ppm, and vegetables, fruiting, group at 0.50 ppm. Risk assessments were conducted by EPA to assess dietary exposures from Indoxacarb in food as follows:

An acute dietary endpoint for females 13 years and older and for the general population, including infants and children has been identified. The acute population adjusted dose (aPAD) for females is 0.02 milligrams/kilogram/day (mg/kg/day). The acute dietary endpoint for the general population including infants and children is 0.12 mg/kg/day. The chronic population adjusted dose (cPAD) for all populations is 0.02 mg/kg/day. Indoxacarb has been classified as a ''not likely'' to be carcinogenic to humans. It has been determined that the FQPA safety factor could be reduced to 1X for Indoxacarb. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure. Currently, indoxacarb is not registered for use in residential settings.

For the chronic exposure estimates, it was assumed that all commodities had tolerance level residues and 100% of all RACs were treated with indoxacarb. Refined processing factors were used in the chronic analysis for several commodities, in place of the Dietary Exposure Evaluation Model (DEEM®) default processing factors. The Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models provided the estimated environmental concentrations (EECs) of indoxacarb. The EECs for acute exposures are estimated to be 13.7 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be

3.7 ppb for surface water and 0.02 ppb for ground water.

i. *Acute exposure*. Acute dietary 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. The DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989—1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An acute Tier II (partially refined analysis) dietary assessment was performed with use of anticipated residues (ARs) from field trial data, processing factors (where applicable), assumed 100% crop treated (CT) for all crops other than peaches, and 1% CT for the peach EUP (300 acres). ARs for meat, milk, poultry, and eggs (MMPE) raw agricultural commodities (RACs) were calculated also.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989—1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Chronic exposure estimates are expressed in mg/kg body weight (bw)/day and as a percent of the cPAD. The chronic dietary assessment assumed tolerance level residues, DEEM® default processing factors, assumed 100% CT for all crops other than peaches, and 1% CT for the peach EUP (300 acres) (Tier I).

iii. *Cancer*. There is no evidence for mutagenicity and there is no evidence of carcinogenicity in either the rat or mouse. Indoxacarb has been classified as ''not likely to be carcinogenic in humans'' by the Agency; therefore, no carcinogenic dietary risk analysis was performed.

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 chemicals that have been measured in food. If EPA relies on such information, EPA must 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to ARs to be submitted no later than 5 years from the date of issuance of this tolerance.

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 Agency can make the following findings: Condition 1, that 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 percent crop treated (PCT) as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

Dietary exposure estimates were based on 1% PCT for peaches. This PCT of 1% was based on the fact that the 2–year experimental use permit was issued for only 300 acres of peaches to be treated annually, which amounts to 0.2% of the total peach acreage in the United States. The reason for using 1% instead of 0.2% is to allow for any uncertainties in the residue evaluation. Before making this tolerance permanent, reevaluation of dietary exposure will be performed using all available information. Other commodities were assumed to be 100% treated.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described 1% for Indoxacarb used on peaches is reliable and has a valid basis. A 2–year EUP has been issued for this use, which will allow for use of Indoxacarb on 300 acres of peaches in some eastern states. Before the use can be expanded for treatment of greater than 300 acres per year, permission from the Agency must be obtained. 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 exposure 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 physical characteristics of Indoxacarb.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the PRZM/EXAMS to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier I model) before using PRZM/EXAMS (a Tier II model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use EECs from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model

estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to Indoxacarb they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated EECs of Indoxacarb for acute exposures are estimated to be 13.7 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 3.7 ppb for surface water and 0.02 ppb for ground 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 not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to 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.''

EPA does not have, at this time, available data to determine whether Indoxacarb has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional 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 data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no evidence for either qualitative or quantitative susceptibility. In all developmental studies, the developmental endpoint occurs at the maternal LOAEL or above. Although there is no rabbit developmental toxicity study with indoxacarb, a study is not required since:

i. Studies-both using methyl cellulose-comparing JW062 in the rabbit and rat demonstrate that the toxicity profiles for the rat and rabbit are similar and that the rat is the more sensitive species;

ii. Range finding studies in the rat comparing indoxacarb and JW062 indicate that the maternal and external developmental toxicity are comparable;

iii. A dietary developmental toxicity study in the rat with JW062 had comparable toxicity to the gavage indoxacarb rat developmental toxicity study. Developmental toxicity only occurred at levels at or above maternal toxicity.

The reproduction toxicity study with JW062 can be used to satisfy the requirement for an indoxacarb study because:

iv. Systemic toxicity is at similar doses and of similar magnitude to that observed in subchronic feeding studies with both indoxacarb and JW062;

v. based on the data base, the HIARC determined that there was support for using data from dietary studies conducted with JW062 to satisfy the data requirements for indoxacarb.

The Agency has required a developmental neurotoxicity study as confirmatory data due to:

- Clinical signs of neurotoxicity in several studies, males and females, mice and rats, at some doses that do not cause mortality;
- Signs of neurotoxicity in the acute neurotoxicity study-rat with indoxacarb (males and females), no mortality in males at neurotoxic doses;
- Clinical signs of neurotoxicity in the 90-day toxicity study-rat indoxacarb (females), mortality;
- Clinical signs of neurotoxicity in the 90-day toxicity study-mouse with the racemic mixture, JW062 (males and females), no mortality in females at neurotoxic doses, mortality in males;
- Clinical signs of neurotoxicity in the 18 month carcinogenicity study-mouse with JW062 (males and females) high and mid dose, mortality at the high but no mortality at the mid dose; and
- Clinical signs of neurotoxicity in the developmental toxicity study-rat with JW062 (using methyl cellulose as the vehicle), at doses causing mortality.

3. *Conclusion*. The Agency concluded that the FQPA safety factor could be reducecd to 1X for Indoxacarb because:

- There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure;
- The requirement of a developmental neurotoxicity study is not based on the criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a DNT study—and a safety factor (e.g.: neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring)—and therefore does not warrant an FQPA safety factor; and
- The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children
- There are no registered residential uses at the current time.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPAs Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default

body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to Indoxacarb will occupy 12% of the aPAD for the U.S. population, 64% of the aPAD for females 13 years and older, 67% of the aPAD for infants less than 1 year old and 79% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to Indoxacarb in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1 of this Unit:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO INDOXACARB

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.12	12	13.7	0.02	3,700
Females 13+	0.12	64	13.7	0.02	218
All infants less than 1 year	0.12	67	13.7	0.02	400
Children 1 to 2	0.12	79	13.7	0.02	760

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to Indoxacarb from food will utilize 30% of the cPAD for the U.S. population, 29% of the cPAD for infants less than 1 year and 79% of the cPAD for children 1 to 2 years old. There are no residential uses for Indoxacarb that result in chronic residential exposure to Indoxacarb. Based on the use pattern, chronic residential exposure to residues of Indoxacarb is not expected. In addition, there is potential for chronic dietary exposure to Indoxacarb in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO INDOXACARB

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.02	30	3.7	0.02	490
All infants less than 1 year old	0.02	29	3.7	0.02	65
Children 1 to 2	0.02	79	3.7	0.02	30

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Indoxacarb is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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 not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. There is no evidence for mutagenicity and there is no evidence of carcinogenicity in either rat or mouse. Indoxacarb has been classified as ''not likely to be carcinogenic in humans'' by the Agency; therefore Indoxacarb is is not expected to pose carcinogenic risk when used as directed.

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, and 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/UV Method AMR 2712–93) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue., NW, Washington D.C. 20460; Telephone Number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of Indoxacarb; therefore, international

harmonization is not an issue at this time.

V. Conclusion

Therefore, the time-limited tolerance is 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] + 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 peaches at 10 ppm. This tolerance will expire and is revoked on May 15, 2006.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0173 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 on or before July 14, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0173, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the 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. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, 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 in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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. 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: April 30, 2003.

Debra Edwards

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), 346(a) and 371.

■ 2. Section 180.564 is amended by redesignating the existing text in paragraph (a) following the heading ''General'' as paragraph (a)(1) and by adding a new paragraph (a)(2) to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) * * *

(1) * * *

(2) Time-limited 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] + 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 connection with use of the pesticide under FIFRA section 5 experimental use permit granted by EPA. The tolerances are specified in the following table, and will expire and are revoked on the dates specified.

Commodity	Parts per million	Expiration/revocation date
Peach	10	May 15, 2006

[FR Doc. 03–11758 Filed 5–13–03; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0109; FRL–7305–9]

Pyriproxyfen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyriproxyfen in or on atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.20 parts per million (ppm); avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla and star apple at 1.0 ppm; okra at 0.02 ppm; fig at 0.30 ppm; and fig, dried at 1.0 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 14, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0109, must be received on or before July 14, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9368; e-mail address: *jamerson.hoyt@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:

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

This listing is not intended to be exhaustive, but rather provides 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 Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0109. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of March 7, 2003 (68 FR 11093) (FRL–7289–8), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP) 2E6416, 2E6425, 2E6428, and 2E6436) by IR-4, 681 US Highway #1 South, North Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.510 be amended by establishing tolerances for residues of the insecticide pyriproxyfen, 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine, in or on atemoya, biriba, cherimoya, custard apple, ilama, soursop, and sugar apple at 0.20 ppm (PP 2E6416); avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla and star apple at 1.0 ppm (PP 2E6428); okra at 0.02 ppm (PP 2E6436); fig at 0.30 ppm (PP 2E6425); and fig, dried at 1.0 ppm (2E6425).

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, *see* the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).