

opportunity to revise their SIPs before MPOs must use the model's new emissions factors."

In consultation with the DOT, EPA considers many factors in establishing the length of the grace period, including the degree of change in emissions models and the effects of the new model on the transportation planning process (40 CFR 93.111).

Upon consideration of all of these factors, EPA is establishing a 2-year grace period, which begins today and ends on May 19, 2006, before MOBILE6.2 and AP-42 are required for new PM₁₀ conformity analyses in most cases. During this grace period, areas should use the interagency consultation process to examine how MOBILE6.2 and AP-42 will affect their future conformity determinations.

However, the grace period will be shorter than 2 years for PM₁₀ if an area revises its SIP and budgets with MOBILE6.2 and AP-42 and such budgets become applicable for conformity purposes prior to the end of the 2-year grace period. For example, if an area revises a previously submitted (but not approved) PART5-based PM₁₀ SIP with MOBILE6.2 and AP-42 and EPA finds the revised budgets adequate for conformity, such budgets would apply for conformity on the effective date of the **Federal Register** notice announcing EPA's adequacy finding.

During the grace period, areas can use earlier models such as PART5 for PM₁₀ conformity determinations or choose to use MOBILE6.2 and AP-42 on a faster time frame. When the grace period ends on May 19, 2006, MOBILE6.2 will become the only approved motor vehicle emissions model for new PM₁₀ transportation conformity analyses outside of California and AP-42 will become the approved method for estimating re-entrained road dust unless an alternate method is approved as described in section III above. In general, this means that all new PM₁₀ conformity analyses started after the end of the 2-year grace period must be based on MOBILE6.2 and AP-42, even if the SIP is based on PART5. As discussed above, the grace period for new conformity analyses would be shorter for PM₁₀ if an area revised its SIP and budgets with MOBILE6.2 and AP-42 and such budgets became applicable for conformity purposes prior to the end of the 2-year grace period. EPA strongly encourages areas to use the consultation process to examine how MOBILE6.2 and AP-42 will affect future conformity determinations, so, if necessary, PM₁₀ SIPs and budgets can be revised with MOBILE6.2 and AP-42 or transportation plans and programs can be revised as

appropriate prior to the end of the grace period.

Finally, the conformity rule provides some flexibility for analyses that are started before or during the grace period. Regional conformity analyses that began before the end of the grace period may continue to rely on earlier models such as PART5. Conformity determinations for transportation projects may also be based on an earlier model if the regional analysis was begun before the end of the grace period, and if the final environmental document for the project is issued no more than three years after the issuance of the draft environmental document (see 40 CFR 93.111(c)). The interagency consultation process should be used if it is unclear whether an analysis based on an earlier model was begun before the end of the grace period.

The release of MOBILE6.2 and AP-42 does not trigger the need for quantitative conformity hot-spot modeling to estimate concentrations of PM₁₀ at this time. However, qualitative hot spot analyses are still required in PM₁₀ nonattainment and maintenance areas.

VI. PM_{2.5} SIP and Transportation Conformity Policy for MOBILE6.2 and AP-42

EPA has not yet finalized implementation policy for the PM_{2.5} National Ambient Air Quality Standards (NAAQS). However, when that policy is finalized and PM_{2.5} nonattainment areas have been designated, MOBILE6.2 (except in California) and AP-42 (except in areas where another dust methodology has been approved) will be the approved models for estimating motor vehicle exhaust, brake and tire wear, and re-entrained road dust emissions in PM_{2.5} SIPs and conformity determinations, until they are replaced by newer models or methods. No PM_{2.5} SIPs have previously been done using other models and therefore, the release of MOBILE6.2 and AP-42 does not constitute a change in models which might result in inconsistencies between the SIP and transportation analyses. As a result, there is no need for a PM_{2.5} conformity grace period for MOBILE6.2 and AP-42. MOBILE6.2 (except in California) and AP-42 (except in areas where another dust methodology has been approved) must be used in all PM_{2.5} conformity analyses, until they are replaced by newer approved methods or models.

Dated: May 11, 2004.

Margo Tsirigotis Oge,

Director, Office of Transportation and Air Quality.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0130; FRL-7359-1]

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, 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 cherry, sweet and cherry, tart. E.I. DuPont de Nemours and Company, DuPont Crop Protection requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerance will expire on May 21, 2007.

DATES: This regulation is effective May 19, 2004. Objections and requests for hearings must be received on or before July 19, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP-2004-0130. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy 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.

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. 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 and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), 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 E-CFR

Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm/>.

II. Background and Statutory Findings

In the **Federal Register** of March 17, 2004 (69 FR 12664-12670) (FRL-7345-2), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3G6797) by E.I. DuPont de Nemours and Company, DuPont Crop Protection, Wilmington, DE. This notice included a summary of the petition prepared by DuPont, the registrant.

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 cherry, sweet and cherry, tart at 1.0 part per million (ppm). The tolerance will expire on May 21, 2007. One comment was received from a private citizen objecting to this tolerance. This commenter opposes all residues, tolerances, exemptions from tolerance, animal testing, or the Agency's risk assessment process, and has objected to numerous Agency actions over the past several months.

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, 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, on cherry, sweet and cherry, tart at 1.0 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 Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—ACUTE, SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity in rodents	DPX-MP062 NOAEL = M 3.1 mg/kg/day, F 2.1 mg/kg/day LOAEL = M 6.0 mg/kg/day, F 3.8 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency
870.3150	90-Day oral toxicity in nonrodents	DPX-JW062 NOAEL = 5.0 mg/kg/day LOAEL = 19 mg/kg/day based on hemolytic anemia, as indicated by decrease in HGB, RBCs; increases in platelets, increased reticulocytes; and secondary histopathologic findings indicative of blood breakdown (pigment in Kupffer cells, renal tubular epithelium, and spleen and bone marrow macrophages); increase in splenic EMH; and RBC hyperplasia in bone marrow in dogs
870.3200	21/28-Day dermal toxicity	DPX-MP062 NOAEL = 2,000 mg/kg/day LOAEL = >2,000 mg/kg/day in rats DPX-MP062 NOAEL = 50 mg/kg/day LOAEL = 500 mg/kg/day based on decreased body weights, body weight gains, food consumption, and food efficiency in F, and changes in hematology parameters (increased reticulocytes), the spleen (increased absolute and relative weight M only, gross discoloration), clinical signs of toxicity in both sexes in rats
870.3700	Prenatal developmental in rodents	DPX-MP062 Maternal NOAEL = 2.0 mg/kg/day LOAEL = 4.0 mg/kg/day based on decreased mean body weights, body weight gains, food consumption Developmental NOAEL = 2.0 mg/kg/day LOAEL = 4.0 mg/kg/day based on decreased fetal weights DPX-JW062 Maternal NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on mortality, clinical signs, and decreased mean body weights, body weight gains, and food consumption Developmental NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on decreased numbers of live fetuses/litter. DPX-JW062 Maternal NOAEL = 1.1 mg/kg/day LOAEL = 2.2 mg/kg/day based on decreased mean body weights, body weight gains, food consumption, and food efficiency. Developmental NOAEL = 1.1 mg/kg/day LOAEL = 2.2 mg/kg/day based on decreased fetal body weights
870.3700	Prenatal developmental in nonrodents	DPX-JW062 - rabbits Maternal NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on slight decreases in maternal body weight gain and food consumption. Developmental NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on decreased fetal body weights and reduced ossification of the sternbrae.
870.3800	Reproduction and fertility effects	DPX-JW062 Parental/Systemic NOAEL = 1.5 mg/kg/day LOAEL = 4.4 mg/kg/day based on decreased body weights, body weight gains, and food consumption of F0 females, and increased spleen weights in the F0 and F1 females Reproductive NOAEL = 6.4 mg/kg/day LOAEL = 6.4 mg/kg/day Offspring NOAEL = 1.5 mg/kg/day LOAEL = 4.4 mg/kg/day based on decrease in the body weights of the F1 pups during lactation.

TABLE 1.—ACUTE, SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4100	Chronic toxicity rodents	DPX-JW062 NOAEL = M 5, F 2.1 mg/kg/day LOAEL = M 10, F 3.6 mg/kg/day based on decreased body weight, body weight gain, and food consumption and food efficiency; decreased HCT, HGB and RBC at 6 months in F only. No evidence of carcinogenic potential
870.4100	Chronic toxicity dogs	DPX-JW062 NOAEL = M 2.3, F 2.4 mg/kg/day LOAEL = M 18, F 19 mg/kg/day based on decreased HCT, HGB and RBC; increased Heinz bodies and reticulocytes and associated secondary microscopic changes in the liver, kidneys, spleen, and bone marrow; increased absolute and relative liver weights.
870.4200	Carcinogenicity rats	DPX-JW062 see 870.4100 No evidence of carcinogenicity
870.4300	Carcinogenicity mice	DPX-JW062 NOAEL = M 2.6, F 4.0 mg/kg/day LOAEL = M 14, F 20 mg/kg/day based on decreased body weight, body weight gain, and food efficiency and clinical signs indicative of neurotoxicity. No evidence of carcinogenicity
870.5100	Gene mutation	DPX-MP062 strains TA97a, TA98, TA100 and TA1535 of <i>S. typhimurium</i> and strain WP2(uvrA) of <i>E. coli</i> were negative for mutagenic activity both with and without S9 activation for the concentration range 10-5,000 µg/plate DPX-JW062 strains TA97a, TA98, TA100 and TA1535 of <i>S. typhimurium</i> and strain WP2(uvrA) of <i>E. coli</i> were negative for mutagenic activity both with and without S9 activation for the concentration range 10-5,000 µg/plate.
870.5300	Gene mutation	DPX-MP062 negative for mutagenic activity for the following concentration ranges: 3.1-250 µg/mL (-S9); 3.1-250 µg/mL (+S9) DPX-JW062 negative for mutagenic activity for the following concentration ranges: Negative; 100-1,000 µg/mL (-S9); 100- 1,000 µg/mL (+S9), precipitate ≥1,000 µg/mL
870.5375	Cytogenetics	DPX-MP062 No evidence of chromosomal aberrations induced by the test article over background for the following concentration ranges: 15.7-1,000 µg/mL (+S9) DPX-JW062 No evidence of chromosomal aberrations induced by the test article over background for the following concentration ranges: 19-300 µg/mL (-S9), 19-150 µg/mL (+S9); partial insoluble and cytotoxicity ≥ 150 µg/mL
870.5395	Cytogenetics	DPX-MP062 No evidence of mutagenicity for the following dose ranges: 3,000-4,000 mg/kg - males; 1,000-2,000 mg/kg - females DPX-JW062 No evidence of mutagenicity at 2,500 or 5,000 mg/kg
870.5550	Other effects	DPX-MP062 No evidence of mutagenic activity at the following concentration range: 1.56-200 µg/mL; cytotoxicity was seen at concentrations of ≥100 µg/mL DPX-JW062 No evidence of mutagenic activity at the following concentration range: 0.1-50 µg/mL, cytotoxicity observed at ≥50 µg/mL

TABLE 1.—ACUTE, SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.6200	Acute neurotoxicity screening battery	DPX-MP062 NOAEL = M 100, F 12.5 mg/kg LOAEL = M 200 mg/kg based on decreased body weight gain, decreased food consumption, decreased forelimb grip strength, and decreased foot splay. F 50 mg/kg based on decreased body weight, body weight gain, and food consumption DPX-JW062 NOAEL >= M 2,000 mg/kg = F < 500 mg/kg LOAEL > M 2,000 mg/kg F < 500 mg/kg based on clinical signs, decreased body weight gains and food consumption, and FOB effects
870.6200	Subchronic neurotoxicity screening battery	DPX-MP062 NOAEL = M 0.57, F 0.68 mg/kg/day LOAEL = M 5.6, F 3.3 mg/kg/day based on decreased body weight and alopecia
870.7485	Metabolism and pharmacokinetics	Both DPX-MP062 and DPX-JW062 were extensively metabolized and the metabolites were eliminated in urine, feces, and bile. 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 (indanone and trifluoromethoxyphenyl rings). All biliary metabolites undergo further biotransformation in the gut. The proposed metabolic pathway for both DPX-MP062 and DPX-JW062 has multiple metabolites bearing one of the two ring structures (see 870.4100 chronic toxicity rodents above)

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences. Discuss any additional UFs (other than the FQPA SF) used in the assessment.

For dietary risk assessment (other than cancer) the Agency uses the UF to

calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify

carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10⁶ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a “point of departure” is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for indoxacarb used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR INDOXACARB FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age)	NOAEL = 2.0 mg/kg/day UF = 100 Acute RfD = 0.02 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/ FQPA SF = 0.02 mg/kg/day	Developmental rat toxicity study LOAEL = 4.0 mg/kg/day based on decreased fetal body weight

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR INDOXACARB FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (general population including infants and children)	NOAEL = 12 mg/kg/day UF = 100 Acute RfD = 0.12 mg/kg/day	FQPA SF = 1 aPAD = acute RfD/ FQPA SF = 0.12 mg/kg/day	Acute oral rat neurotoxicity study LOAEL = 50 mg/kg/day based on decreased body weight and body weight gain in females
Chronic dietary (all populations)	NOAEL = 2.0 mg/kg/day UF = 100 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD/FQPA SF = 0.02 mg/kg/day	90-day rat subchronic toxicity study, 90-day rat neurotoxicity study, chronic/carcinogenicity rat study LOAEL = 3.3 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency; decreased hematocrit, hemoglobin and red blood cells only at 6 months. 3.3 mg/kg/day is the lowest LOAEL of the three studies
Short-term dermal (1 to 7 days) (Occupational)	Dermal (or oral) study NOAEL = 50 mg/kg/day	LOC for MOE = 100 (Occupational)	28-day rat dermal toxicity study LOAEL = 500 mg/kg/day based on based on decreased body weights, body weight gains, food consumption, and food efficiency in females, and changes in hematology parameters (increased reticulocytes), the spleen (increased absolute and relative weight males only, gross discoloration), and clinical signs of toxicity in both sexes
Short-term inhalation (1-7 days) (Occupational)	oral study NOAEL = 2.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational)	Rat developmental toxicity study. Maternal LOAEL = 4.0 mg/kg/day based on decreased mean maternal body weights, body weight gains, and food consumption
Cancer (oral, dermal, inhalation)	"Not likely" to be carcinogenic to humans	N/A	No evidence of carcinogenicity in either the rat or mouse in acceptable carcinogenicity studies and no evidence of mutagenicity

*The reference to the FQPA SF refers to any additional safety factor retained due to concerns unique to the FQPA.

C. 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, Vegetables, fruiting, group at 0.50 ppm, and a time-limited tolerance for peach at

10.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures from indoxacarb in food as follows:

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 Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 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: A partially refined, acute dietary exposure assessment was performed with use of some anticipated residues (ARs) from field trial data, processing factors (where applicable), and assuming 100%

crop treated. 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 1994–1996 and 1998 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 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 cherries and peaches, and 1% CT for the peach EUP (300 acres) and cherry EUP (180) acres.

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 anticipated residues 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% CT for peaches and cherries. This PCT of 1% was based on the fact that the 2-year experimental use permits were issued for only 300 acres of peaches, and 180 acres of cherries to be treated annually, which amounts to 0.2% of the total peach and cherry acreages 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 and cherries is reliable and has a valid basis. A 2-year EUP has been issued for both of these uses, which will allow for use of indoxacarb on 300 acres of peaches and 180 acres of cherries in some eastern states. Before these uses can be expanded for treatment of greater than 300 or 180 acres respectively 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 First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment. FIRST and PRZM/EXAMS models include 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 screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would 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 estimated environmental concentrations (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 high-end to bounding estimates 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).

D. 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: (1) 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; (2) range finding studies in the rat comparing indoxacarb and JW062 indicate that the maternal and external developmental toxicity are comparable; (3) 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: (1) systemic toxicity is at

similar doses and of similar magnitude to that observed in subchronic feeding studies with both indoxacarb and JW062; (2) based on the data base, EPA 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.
- 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 reduced 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.
- 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.

E. 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 high-end to bounding estimates 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 the USEPA 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 36% 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 3 of this unit:

TABLE 3.—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	3700
Females 13 +	0.12	64	13.7	0.02	220
All infants (less than 1 year)	0.12	67	13.7	0.02	400
Children (1 to 2 years)	0.12	36	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 31% of the cPAD for the U.S. population, 29% of the cPAD for infants less than 1 year old and 80% 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. 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 water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 if this unit:

TABLE 4.—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	31	3.7	0.02	480
All infants (less than 1 year) old	0.02	29	3.7	0.02	140
Children (1 to 2 years)	0.02	80	3.7	0.02	40

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 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 (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of indoxacarb; therefore, international harmonization is not an issue at this time.

V. Conclusion

Therefore, the 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, 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 cherry, sweet and cherry, tart at 1.0 ppm. This tolerance will expire and is revoked on May 21, 2007.

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-2004-0130 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 19, 2004.

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 (1900L), 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 Suite 350, 1099 14th St., NW., Washington, DC 20005. 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 (202) 564-6255.

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 **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2004-0130, 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 **ADDRESSES**. 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. 801et 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: May 6, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.564 is amended by alphabetically adding the following commodities to the table in paragraph (a)(2) to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) * * * P≤(2) * * *

Commodity	Parts per million	Expiration/revocation date
Cherry, sweet	1.0	May 21, 2007
Cherry, tart	1.0	May 21, 2007
* * *	* * *	* * *

* * * * *
[FR Doc. 04-11346 Filed 5-18-04; 8:45 am]
BILLING CODE 6560-50-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1003

RIN 0991-AB30

Medicare and State Health Care Programs; Fraud and Abuse: OIG Civil Money Penalties Under the Medicare Prescription Drug Discount Card Program

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: In accordance with section 1860D-31 of the Social Security Act,

this rule sets forth the OIG’s new authority for imposing civil money penalties (CMPs) against endorsed sponsors under the Medicare prescription drug discount card program that knowingly engage in false or misleading marketing practices; overcharge program enrollees; or misuse transitional assistance funds.

DATES: *Effective date:* These regulations are effective on June 18, 2004.

Comment date: We will consider comments if we receive them at the appropriate address, as provided in the address section below, no later than 5 p.m. on July 19, 2004.

ADDRESSES: In commenting, please refer to file code OIG-54-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG-54-FC, Room

5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

Please allow sufficient time for us to receive mailed comments on time in the event of delivery delays. Because access to the Cohen Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OIG drop box located in the main lobby of the building. For information on viewing public comments, see section IV. in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of Management and Policy, (202) 619-0089; or Nitesha Gupte, Office of Counsel to the Inspector General, (202) 619-1306.

SUPPLEMENTARY INFORMATION:

I. OIG Civil Money Penalties

In 1981, Congress enacted the civil money penalty statute, section 1128A of