ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301064; FRL–6747–8]

RIN 2070–AB78]

Indoxacarb; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for the 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 a 75:25 mixture (DPX–MP062), respectively, in or on the raw agricultural commodities as follows: apples, pears, *Brassica* (head and stem subgroup), cotton, leaf lettuce, head lettuce, fruiting vegetable group, sweet corn, milk, and the meat, meat byproducts and fat of cattle, goats, horses, hogs and sheep. E. I. du Pont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301064, must be received by EPA on or before November 28, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301064 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Jane Smith, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703 305–7378; e-mail address: smith.jane-scott@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301064. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of April 16, 1998 (63 FR 18912–18919) (FRL–5782–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) 8F4948, for tolerance by E. I. du Pont de Nemours and Company, P.O. Box 80038, Wilmington, DE 19880–0038. This notice included a summary of the petition prepared by DuPont, the registrant. There were three comments in response to the Notice of Filing from members of the cotton industry. They expressed concern for the use of terminology associated with cotton in the Notice of Filing. These cotton terminology comments were forwarded within the Agency to the evaluators of the cotton portion of the submission which ultimately did not impact the interpretation of the submission.

The petition (8F4948) requested that 40 CFR 180.564 be amended by establishing permanent tolerances for residues of the insecticide DPX–MP062 (75:25 enantiomeric mixture of indoxacarb and its R-enantiomer), [R,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] in/on the raw agricultural commodities as follows: pome fruit at 2.0 parts per million (ppm), apple pomace at 6.0 ppm, *Brassicas*, head and stem at 10.0 ppm, cottonseed at 3.0 ppm, cotton gin trash at 15.0 ppm, leaf lettuce at 20.0 ppm, head lettuce at 7.0 ppm, fruiting vegetables at 0.70 ppm, sweet corn kernel at 0.02 ppm, sweet corn forage at 20.0 ppm, and sweet corn stover at 25.0 ppm, meat 0.02 ppm, milk at 0.10 ppm, cattle kidney at 0.05 ppm; and by establishing a tolerance for residues of the insecticide DPX–MP062, (R,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 metabolite (IN-JT333), methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadi azine- 4a(3H)-carboxylate, in/on milk fat at 0.75 ppm and cattle fat at 0.75 ppm.

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) 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) 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 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), 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), for a tolerance for the combined residues of indoxacarb and its R-enantiomer in/on the following: 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 ppm; milk at 0.10 ppm; milk fat at 3.0 ppm; pear at 0.20 ppm; vegetables, fruiting, group at 0.50 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 and its R-enantiomer are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed. DPX–MP062 is a 75:25 mixture of the two enantiomers: indoxacarb which is insecticidally active, and its R-enantiomer, which is insecticidally inactive. DPX–JW062 is a mixture of these same two enantiomers; however, they are in a 50:50 ratio. Toxicology data submitted on DPX–JW062 were considered relevant and included in the evaluation.

The technical DPX–MP062 (75:25) is toxicity category I for acute oral (rat); IV for acute dermal (rat), inhalation (rats) and primary dermal irritation (rabbit); and III for primary eye irritation (rabbit). The technical is considered a dermal sensitizer (guinea pig).

TABLE 1. — SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents — rats	DPX—MP062 (75% indoxacarb / 25% enantiomer) NOAEL = Male (M) 3.1 mg/kg/day, Female (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.
870.3100	90–Day oral toxicity rodents—rats	DPX—JW062 (50% indoxacarb / 50% enantiomer) / NOAEL = M 8.0, F 4.6 mg/kg/day LOAEL = M 16, F 9.5 mg/kg/day based on mortality (F only), decreased. body weight, body weight gain, food consumption and food efficiency in rats.
870.3100	90–Day oral toxicity rodents— rats	DPX—JW062 / NOAEL = M 3.7, F 4.9 mg/kg/day LOAEL = M 7.5, F 12 mg/kg/day based on decreased in absolute body weight, body weight gain and food efficiency in rats.
870.3100	90–Day oral toxicity rodents— mice	DPX—JW062 / NOAEL = M23, F 16 mg/kg/day LOAEL = M 44, F 30 mg/kg/day based on mortality (M only); increased reticulocytes and Heinz bodies and decreased body weight, weight gain, food consumption, food efficiency; and increased clinical signs (leaning to one side and/or with abnormal gait or mobility) (F only) in mice.
870.3150	90–Day oral toxicity in nonrodents—dogs	DPX—JW062 / NOAEL = 5.0 mg/kg/day LOAEL = 19 mg/kg/day based on hemolytic anemia, as indicated by decreased 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); increased in splenic EMH; and RBC hyperplasia in bone marrow in dogs.

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

Guideline No.	Study Type	Results
870.3200	28–Day dermal toxicity — rats	DPX—MP062 / NOAEL = 2,000 mg/kg/day LOAEL = >2,000 mg/kg/day in rats.
870.3200	28–Day dermal toxicity — 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.
870.3700a	Prenatal developmental in rodents—rats	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.
870.3700a	Prenatal developmental in rodents—rats	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.
870.3700a	Prenatal developmental in rodents—rats	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.
870.3700b	Prenatal developmental in nonrodents—rabbits	DPX—JW062 / 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 decr. fetal body weights and reduced ossification of the sternebrae.
870.3800	Reproduction and fertility effects—rats	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 F_0 females, and increased spleen weights in the F_0 and F_1 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 decreased in the body weights of the F_1 pups during lactation.
870.4100a	Chronic toxicity rodents—rats	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
870.4100b	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 870.4100a no evidence of carcinogenicity
870.4300	Carcinogenicity—mice	DPX—JW062 / NOAEL = M 2.6, F4.0 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 *S. typhimurium* and strain WP2(uvrA) of *E. coli* were negative for mutagenic activity both with and without S9 activation for the concentration range 10–5000 μg/plate
870.5100	Gene mutation	DPX—JW062 / strains TA97a, TA98, TA100 and TA1535 of *S. typhimurium* and strain WP2(uvrA) of *E. coli* were negative for mutagenic activity both with and without S9 activation for the concentration range 10–5000 μg/plate.

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

Guideline No.	Study Type	Results
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)
870.5300	Gene mutation	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)
870.5375	Cytogenetics	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
870.5395	Cytogenetics	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
870.5550	Other effects	DPX—JW062 / No evidence of mutagenic activity at the following concentration range: 0.1–50 µg/mL, cytotoxicity observed at ≥50 µg/mL
870.6200a	Acute neurotoxicity screening battery — rat	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
870.6200a	Acute neurotoxicity screening battery —rats	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
870.6200b	Subchronic neurotoxicity screening battery — rats	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 pharmacokinetic — rats	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.

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 intraspecies differences.

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.

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 1×10^{-6} 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 and its R-enantiomer used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, Uncertainty Factor (UF)	FQPA Safety Factor (SF)* and Endpoint 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	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.02 mg/kg/day	Developmental rat toxicity study. developmental LOAEL = 4.0 mg/kg/day based on decreased fetal body weight.
Acute dietary general population including infants and children	NOAEL= 12.5 mg/kg UF = 100 Acute RfD = 0.12 mg/kg	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.12 mg/kg/day	Acute oral rat neurotoxicity study. LOAEL = 50 mg/kg based on decreased body weight and body weight gain in females.
Chronic dietary all populations	NOAEL= 2.0 mg/kg/day UF = 100 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1 cPAD = chr 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, alopecia, 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 NOAEL/LOAEL of the 3 studies.
Short-term oral (1–7 days) (Residential)	Oral study NOAEL= 2.0 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	Developmental rat toxicity study. maternal LOAEL = 4.0 mg/kg/day based on decreased mean maternal body weights, body weight gains, and food consumption.
Intermediate- term oral (1 week - several months) (Residential)	Oral study NOAEL= 2.0 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	90–day rat subchronic toxicity study. LOAEL = 3.8 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency.
Short- (1–7 days), intermediate- (1 week—several months), and long- (several months—lifetime) term dermal (Occupational/ Residential)	Dermal study NOAEL= 50 mg/kg/day	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	28–day rat dermal toxicity study. LOAEL = 500 mg/kg/day 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/ Residential)	Oral study NOAEL= 2.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	Rat developmental toxicity study. maternal LOAEL = 4.0 mg/kg/day based on decreased mean maternal body weights, body weight gains, and food consumption.
Intermediate- term inhalation (1 week—several months) (Occupational/ Residential)	Oral study NOAEL= 2.0 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	90–day rat subchronic toxicity study. LOAEL = 3.8 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency.

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

Exposure Scenario	Dose Used in Risk Assessment, Uncertainty Factor (UF)	FQPA Safety Factor (SF)* and Endpoint for Risk Assessment	Study and Toxicological Effects
Long-term inhalation (several months—lifetime) (Occupational/ Residential)	Oral study NOAEL= 2.0 mg/kg/day (inhalation absorption rate =100%)	LOC for MOE = 100 (Occupational) LOC for MOE = 100 (Residential, includes the FQPA SF)	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.
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 Safety Factor 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 or residues of indoxacarb and its R-enantiomer, in or on a variety of raw agricultural commodities including apples, pears, *Brassica* (head and stem subgroup), cotton, leaf lettuce, head lettuce, fruiting vegetable group, sweet corn, milk, and the meat, meat byproducts and fat of cattle, goats, horses, hogs and sheep. Risk assessments were conducted by EPA to assess dietary exposures from indoxacarb and its R-enantiomer 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 one day or single exposure. The Dietary Exposure Evaluation Model (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: acute Tier 1 analysis assuming tolerance level residues and 100% crop treated (CT) information was performed; however, dietary risk estimates from residues in food exceeded Agency's level of concern (> 100% aPAD). An acute Tier 2 (partially refined analysis) dietary assessment was performed with use of anticipated residues (ARs) from field trial data, processing factors (where applicable), and 100% CT. Note that the Tier 2 assessment is deterministic in that point estimates were used for all residues and the conservative assumption of 100% CT was made. Additional refinement using % CT data would result in even lower exposure estimates from residues in food.

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: tolerance level residues and 100% CT (Tier 1). Additional refinement using less than 100% CT data would result in even lower exposure estimates from residues in food.

iii. *Anticipated residue and percent crop treated Information.* Section 408(b)(2)(E) 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), 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.

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 and its R-enantiomer 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 and its R-enantiomer.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and the Screening Concentration in Ground Water Model (SCI–GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 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 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 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 and its R-enantiomer they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI–GROW models the estimated environmental concentrations (EECs) of indoxacarb and its R-enantiomer for acute exposures are estimated to be 3.81 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.56 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 and its R-enantiomer 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) 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 and its R-enantiomer 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 and its R-enantiomer 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 and its R-enantiomer 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).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. FFDCA section 408 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. There is no evidence of susceptibility from either *in utero* or neonatal exposure to both rat and rabbit young with either DPX—MP062 or DPX—JW062.

iii. *Conclusion*. There is a complete toxicity data base for indoxacarb and its R-enantiomer and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA safety factor is 1X. EPA determined that the 10X safety factor to protect infants and children should be removed 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 SF; the dietary (food and drinking water) exposure assessments will not under estimate the potential exposures for infants and children; and 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 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 the U S EPA Office of Water are used to calculate DWLOCs: 2L/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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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 only to indoxacarb and its R-enantiomer will occupy < or = 10% of the aPAD for the U.S. population, 33% of the aPAD for females 13 years and older, 6% of the aPAD for infants < 1 year and 10% of the aPAD for children 1–6 years old. In addition, there is potential for acute dietary exposure to indoxacarb and its R-enantiomer 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 the following Table 3:

TABLE 3. — AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO INDOXACARB AND ITS R-ENANTIOMER.

Scenario / Population Subgroup	aPAD (mg/kg/day)	% aPAD	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–50 years old	0.02	33	3.81	0.02	3,400
General U.S. Population	0.12	6	3.81	0.02	4,000
All Infants < 1 year old	0.12	6	3.81	0.02	1,100
Children 1–6 years old	0.12	10	3.81	0.02	1,100
Children 7–12 years old	0.12	7	3.81	0.02	1,100

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to indoxacarb and its R-enantiomer from food will utilize 28% of the cPAD for the U.S. population, 37% of the cPAD for infants <1 year old, and 73% of the cPAD for children 1–6 years old. There are no residential uses for indoxacarb and its R-enantiomer that result in chronic residential exposure to indoxacarb and its R-enantiomer. In addition, there is potential for chronic dietary exposure to indoxacarb and its R-enantiomer in drinking water. After calculating the 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 the following Table 4:

TABLE 4. — AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO INDOXACARB AND ITS R-ENANTIOMER

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.12	28	0.56	0.02	500
All Infants <1 year old	0.12	37	0.56	0.02	130
Children 1–6 years old	0.12	73	0.56	0.02	53
Children 7–12 years old	0.12	40	0.56	0.02	120
Females 13–50 years old	0.12	22	0.56	0.02	540

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 and its r- enantiomer 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 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 and its R-enantiomer 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. *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 and its R-enantiomer residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example: gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

No other international residue limits have been established at this time.

C. Conditions

The following toxicology studies are required as confirmatory: a developmental neurotoxicity study in the rat (Guideline #870.6300) and a 90–day inhalation toxicity study in the rat (Guideline #870.3465).

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 the following raw agricultural commodities: 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 ppm; milk at 0.10 ppm; milk fat at 3.0 ppm; pear at 0.20 ppm; and vegetables, fruiting, group at 0.50 ppm.

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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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 FFDCA sections 408 and 409. 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 control number OPP–301064 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 November 28, 2000.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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) 260–4865.

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.

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.

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.2. Mail your copies, identified by docket control number OPP–301064, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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: September 21, 2000.

Susan B. Hazen,

Acting Director, 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 added to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

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

Commodity	Parts per million
Apple	1.0
Apple, wet pomace	3.0
Brassica, head and stem, subgroup	5.0
Cattle, goat, horse, sheep and hog fat	0.75
Cattle, goat, horse, sheep and hog meat	0.03
Cattle, goat, horse, sheep and hog meat byproducts	0.02
Corn, sweet, forage	10
Corn, sweet, kernel plus cob with husk removed	0.02
Corn, sweet, stover	15
Cotton gin byproducts	15
Cotton, undelinted seed	2.0
Lettuce, head	4.0
Lettuce, leaf	10
Milk	0.10
Milk fat	3.0
Pear	0.20
Vegetables, fruiting, group	0.50

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

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00–25052 Filed 9–28–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301058; FRL–6746–2]

RIN 2070–AB78

Halosulfuron–methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of halosulfuron–methyl in or on the squash/cucumber subgroup. The Interregional Research Project 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings,identified by docket control number OPP–301058, must be received by EPA on or before November 28, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301058 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7610; and e-mail address: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing