dismissing the pending DPM litigation upon completion of the rulemakings described in the settlement above (Case Nos. 01–1046, 01–1124, and 01–1146 (D.C. Cir.)) pursuant to Fed. R. App. P. 42(b). Each party will bear its own costs and fees.

IV. Stay of Effectiveness

As a result of the parties' settlement negotiations, MSHA has determined that the provisions subject to a stay should be revised and has developed an enforcement policy for the interim concentration limit that involves extensive compliance assistance. A stay of the provisions is necessary to prevent confusion while MSHA carries out this enforcement policy. A stay should not decrease protection of miners and may further a full settlement of the court challenge. Accordingly, this stay meets the requirements of 5 U.S.C. 705 which states, ''When an agency finds that justice so requires, it may postpone the effective date of action taken by it pending judicial review.'')

By a separate document in the **Federal Register**, MSHA will initiate rulemaking on these provisions.

Dated: July 16, 2002.

Dave D. Lauriski,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 02–18310 Filed 7–17–02; 1:49 pm]

BILLING CODE 4510–43–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–02–004]

RIN 2115–AA97

Security Zones; Captain of the Port Detroit Zone, Selfridge Air National Guard Base, Lake St. Clair

AGENCY: Coast Guard, DOT.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard published a final rule on June 7, 2002, creating a permanent security zone on the navigable waters of Lake St. Clair to protect the Selfridge Air National Guard Base from possible acts of terrorism. The location of the security zone designated by some of the coordinates in that rule was incorrect. This document corrects the description of the location and the section number of the security zone.

DATES: This correction becomes effective July 18, 2002.

FOR FURTHER INFORMATION CONTACT: LTJG Brandon Sullivan, U.S. Coast Guard Marine Safety Office Detroit, at (313) 568–9580.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Coast Guard published a permanent security zone in the **Federal Register** on June 7, 2002 (67 FR 39294). This rule added § 165.908 to title 33 of the Code of Federal Regulations.

Need for Correction

As published, the location of the security zone was described incorrectly. While the landmarks included in the final rule were correct, some of the coordinates were incorrect. In addition, the section number used in the amendatory instruction for the rule was incorrect. This rule corrects the coordinates and section number.

Correction of Publication

In rule FR Doc. 02–14268 published on June 7, 2002 (67 FR 39294) make the following corrections:

1. On page 39294, in the third column, on line 65, remove both latitude figures ''42°37.8′ N'' and add, in their respective places, latitude figure ''42°37.7′ N''.

2. On page 39295, in the first column, on lines 2 and 3, remove the coordinates and words ''42°36.8′ N, 082°47.2′ W; then southwest to 42°36.4′ N, 082°47.9′ W'' and add, in their place, the coordinates and words ''42°37.05′ N, 082°48.3′ W; then southwest to 42°36.6′ N, 082°48.7′ W''.

§ 165.908 [Corrected]

3. On page 39296, in the first column, in lines 3 and 4, remove both latitude figures ''42°37.8′ N'' and add, in their respective places, latitude figure ''42°37.7′ N''. On the same page and in the same column, in lines 7 through 9, remove the coordinates and words ''42°36.8′ N, 082°47.2′ W; then southwest to 42°36.4′ N, 082°47.9′ W'' and add, in their place, the coordinates and words ''42°37.05′ N, 082°48.3′ W; then southwest to 42°36.6′ N, 082°48.7′ W''.

4. On page 39295, in the third column, on line 56, remove section number ''165.910'' and add, in its place, section number ''165.908''.

Dated: July 9, 2002.

P.G. Gerrity,

Commander, Coast Guard, Captain of the Port Detroit.

[FR Doc. 02–18011 Filed 7–17–02; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0105; FRL–7186–2]

Indoxacarb; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of indoxacarb in or on alfalfa forage, alfalfa hay, peanut, peanut hay, potato, soybean seed, soybean aspirated grain fractions, and soybean hulls. Additionally, this regulation is increasing the tolerance levels for head lettuce, milk, milk fat, meat, fat, and meat by-products of cattle, goat, hog, horse, and sheep. E. I. Du Pont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective July 18, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0105, must be received on or before September 16, 2002.

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 ID number OPP–2002–0105 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Geri McCann, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605–0716; e-mail address: *mccann.geri@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	Crop production

Categories	NAICS codes	Examples of potentially affected entities
	112 311 32532	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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0105. 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 (67 FR 3700, January 25 2002) (FRL–6819–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996 (Public Law 104–170), announcing the filing of a pesticide petition (PP 1F6301) by E. I. Du Pont de Nemours and Company. This notice included a summary of the petition prepared by E. I. Du Pont de Nemours and Company, the registrant. The Agency received one e-mail letter from consumers/growers that believe there should be zero pesticide levels on human and animal foods.

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-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 alfalfa, forage at 10 parts per million (ppm), alfalfa, hay at 50 ppm, peanut at 0.01 ppm, peanut, hay at 40 ppm, potato at 0.01 ppm, soybean, seed at 0.80 ppm, aspirated grain fractions at 45 ppm, and soybean, hulls at 4.0 ppm. Additionally, the petition requested an increase in tolerance levels for head lettuce, milk, milk fat, meat, fat, and meat by-products of cattle, goat, hog, horse, and sheep based on a proposed increase in the labeled use rate for head lettuce and on potential changes in residue levels in livestock diets. The proposed increases are for head lettuce at 5.0 ppm, meat of cattle, goat, hog, horse, and sheep at 0.05 ppm, fat of cattle, goat, hog, horse, and sheep at 1.5 ppm, meat by-products of cattle, goat, hog, horse, and sheep at 0.03 ppm, milk at 0.15 ppm, and milk, fat at 4.0 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 combined residues of indoxacarb on alfalfa, forage at 10 ppm, alfalfa, hay at 50 ppm, peanut at 0.01 ppm, peanut, hay at 40 ppm, potato at 0.01 ppm, soybean, seed at 0.80 ppm, aspirated grain fractions at 45 ppm, soybean, hulls at 4.0 ppm, lettuce, head at 5.0 ppm, meat of cattle, goat, hog, horse, and sheep at 0.05 ppm, fat of cattle, goat, hog, horse, and sheep at 1.5 ppm, meat by-products of cattle, goat, hog, horse, and sheep at 0.03 ppm, milk at 0.15 ppm, and milk, fat at 4.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance(s) follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the

toxic effects caused by indoxacarb are discussed in the 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.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	DPX-MP062 NOAEL = M 3.1 milligrams/kilogram/day (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

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

Guideline No.	Study Type	Results
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 sternebrae
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 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 decrease in the body weights of the F1 pups during lactation
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 nd 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—Chronic toxicity rodents above) 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 *S. typhimurium* and strain WP2(uvrA) of *E. coli* were negative for mutagenic activity both with and without S9 activation for the concentration range 10–5,000 μg/plate 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 10–5,000 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

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

Guideline No.	Study Type	Results
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
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 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 used for human risk assessment is shown in the following Table 2:

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	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 LOAEL of the three 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), and long (several months—lifetime) (Occupational/ 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

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
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
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 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 by-products 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 by-products at 15 ppm, cotton, undelinted seed at 2.0 ppm, lettuce, head at 4.0 ppm, lettuce, leaf at 10.0 ppm, milk at 0.10 ppm, and milk, fat at 3.0 ppm, pear at 0.20 ppm, and vegetables, fruiting, group at 0.50 ppm. Risk assessments were conducted by EPA to assess dietary exposures from indoxacarb in food as follows:

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 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: An acute Tier 2 (partially refined analysis) dietary assessment was performed with use of anticipated residues (ARs) from field trial data, processing factors (where applicable), and assumed 100% crop treated (CT). 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 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 chronic exposure assessments: Chronic exposure estimates are expressed in mg/kg bwt/day and as a percent of the cPAD. The chronic dietary assessment assumed tolerance level residues, DEEM™ default processing factors, and 100% CT (Tier 1).

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.

iv. *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, 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, chemical, and environmental fate characteristics of indoxacarb.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and 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 meta-model of the PRZM/EXAMS model that uses a specific high-end runoff scenario

for pesticides. PRZM/EXAMS incorporate an index reservoir environment in place of the 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 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 they are further discussed in the aggregate risk sections.

Based on the PRZM/EXAMS and SCI-GROW models, the estimated environmental concentrations (EECs) of indoxacarb for acute exposures are estimated to be 13.86 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 2.47 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) 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).

D. Safety Factor for Infants and Children

1. *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.

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: 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; range finding studies in the rat comparing indoxacarb and JW062 indicate that the maternal and external developmental toxicity are comparable; 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: Systemic toxicity is at similar doses and of similar magnitude to that observed in subchronic feeding studies with both indoxacarb and JW062; based on the data base, the 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), 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.

- 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; central nervous system malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) and therefore, does not warrant an FQPA safety factor; and
- The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children There are no registered residential uses at the current time.

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 USEPA 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, 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 7% of the aPAD for the U.S. population, 41% of the aPAD for females 13 years and older, 6% of the aPAD for all infants less than 1 year old and 12% of the aPAD for children 1 to 6 years old, the children population at greatest exposure. 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 water 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

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.12	7	13.86	0.02	3,900
Females 13 +	0.12	41	13.86	0.02	350
All infants less than 1 year	0.12	6	13.86	0.02	1,100
Children 1 to 6	0.12	12	13.86	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 from food will utilize 33% of the cPAD for the U.S. population, 48% of the cPAD for infants less than 1 year old and 85% of the cPAD for children 1 to 6 years old, the subpopulation at greatest exposure. There are no residential uses for indoxacarb that result in chronic residential exposure to indoxacarb. Based on the use pattern, chronic residential exposure to residues of indoxacarb is not expected. In addition, there is potential for chronic dietary exposure to indoxacarb in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water 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

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.02	33	3.65	0.02	470
All infants less than 1 year old	0.02	48	3.65	0.02	100
Children 1 to 6	0.02	85	3.65	0.02	30

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

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Indoxacarb is not

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

5. *Aggregate cancer risk for U.S. population*. There is no evidence for mutagenicity and there is no evidence of carcinogenicity in either the 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 a carcinogenic risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to indoxacarb residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (HPLC/UV Method AMR 2712–93) 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

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, tolerances are established for combined residues of indoxacarb [(S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate] and its R-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 alfalfa, forage at 10 ppm, alfalfa, hay at 50 ppm, peanut at 0.01 ppm, peanut, hay at 40 ppm, potato at 0.01 ppm, soybean, seed at 0.80 ppm, aspirated grain fractions at 45 ppm, soybean, hulls at 4.0 ppm. Additionally, the petition requested an increase in tolerance levels for head lettuce, milk, milk fat, meat, fat, and meat by-products of cattle, goat, hog, horse, and sheep based on a proposed increase in the labeled use rate for head lettuce and on potential changes in residue levels in livestock diets. The proposed increases are for head lettuce at 5.0 ppm, meat of cattle, goat, hog, horse, and sheep at 0.05 ppm, fat of cattle, goat, hog, horse, and sheep at 1.5 ppm, meat by-products of cattle, goat, hog, horse, and sheep at 0.03 ppm, milk at 0.15 ppm, and milk, fat at 4.0 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 ID number OPP–2002–0105 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 September 16, 2002.

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 ID number OPP–2002–0105 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 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). 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 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). 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. 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: July 3, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 is revised to read as follows:

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

2. Section 180.564 is amended by revising the table in paragraph (a) to read as follows:

§ 180.564 Indoxacarb, tolerances for residues.

(a) * * *

Commodity	Parts per million
Apple	1.0
Apple, wet pomace	3.0
Brassica, head and stem, subgroup	5.0
Alfalfa, forage	10
Alfalfa, hay	50
Cattle, fat	1.5
Cattle, meat	0.05
Cattle, meat byproducts	0.03
Corn, sweet, forage	10
Corn, sweet, kernel plus cob with husk removed	0.02
Corn, sweet, stover	15
Cotton gin byproducts	15
Cotton, undelinted seed	2.0
Goat, fat	1.5
Goat, meat	0.05
Goat, meat byproducts	0.03
Hog, fat	1.5
Hog, meat	0.05
Hog, meat byproducts	0.03
Horse, fat	1.5
Horse, meat	0.05
Horse, meat byproducts	0.03
Lettuce, head	5.0
Lettuce, leaf	10
Milk	0.15
Milk, fat	4.0
Pear	0.20
Peanut	0.01
Peanut, hay	40
Potato	0.01
Sheep, fat	1.5
Sheep, meat	0.05
Sheep, meat byproducts	0.03
Soybean, aspirated grain fractions	45
Soybean, hulls	4.0
Soybean, seed	0.80
Vegetable, fruiting, group	0.50

* * * * *

[FR Doc. 02–18173 Filed 7–17–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[FRN–7247–4]

RIN 2090–AA30

Project XL Site-Specific Rulemaking for Implementing Waste Treatment Systems at Two Virginia Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today EPA is promulgating a site-specific rule proposed on December 28, 2001, to implement a project under the EPA's Project eXcellence and Leadership Program (Project XL). The rule provides site-specific regulatory flexibility under the Resource Conservation and Recovery Act (RCRA) for two Virginia landfills (referred to collectively as the ''Virginia Project XL Landfills''): The Maplewood Recycling and Waste Disposal Facility, located in Amelia County, Virginia (Maplewood Landfill); and the King George County Landfill and Recycling Facility, located in King George County, Virginia (King George Landfill). On September 29, 2000, EPA, USA Waste of Virginia, Inc., and King George Landfills, Inc., signed the Final Project Agreement (FPA) for this project, which would allow for the addition of liquids to these landfills.

The addition of liquids to landfills accelerates the biodegradation of landfill waste and is allowed for certain prescribed liner designs under current RCRA municipal solid waste landfill (MSWLF) regulations. The principal objectives of this XL project are two-fold: To demonstrate that the alternative liner designs at the Virginia Project XL Landfills will also safely accelerate the biodegradation of landfill waste and thereby decrease the time it takes for the waste to reach stabilization in the landfill, facilitate the management of leachate and other liquid wastes, and promote recovery of landfill gas; and to assess the effects of applying differing amounts of liquids to landfills.

The Virginia Project XL Landfills comprise two of several landfills, located in different geographic and climactic regions across the country, that under Project XL are testing this bioreactor technology over alternative liner designs. In order to carry out this project, the Virginia Project XL Landfills need relief from certain requirements in EPA regulations which set forth design and operating criteria for MSWLFs, requirements which would otherwise preclude the addition of liquids at these landfills. Today's rule will allow the Virginia Project XL Landfills to apply collected, non-containerized non-hazardous bulk liquids (including landfill leachate) to the landfills.

DATES: This regulation is effective on July 18, 2002.

ADDRESSES: A docket containing supporting information used in developing this final rule is available for public inspection and copying at EPA's RCRA docket office located at Crystal Gateway, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia. The public is encouraged to phone in advance to review docket materials. Appointments can be scheduled by