final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by May 16, 2003.

ADDRESSES: Written comments should be mailed to Kristeen Gaffney, Acting Chief, Permits and Technical Assessment Branch, Mailcode 3AP11, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103 and District of Columbia Department of Public Health, Air Quality Division, 51 N Street, NE., Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Paresh R. Pandya, (215) 814–2167, or by e-mail at *pandya.perry@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: April 9, 2003.

James W. Newsom,

Acting Regional Administrator, Region III.

[FR Doc. 03–9344 Filed 4–15–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0125; FRL–7302–3]

Indoxacarb; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish a temporary tolerance for combined residues of Indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxy carbonyl) [4-(trifluor omethoxy)phenyl]amino]carbonyl] indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate + its R-enantiomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoro methoxy)phenyl]amino]carbonyl]indeno [1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate in or on peaches under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This action is in response to university extension specialists, DuPont Crop Protection, and EPA's combined efforts to generate the information necessary for use of the reduced risk pesticide, Indoxacarb, on peaches for control of oriental fruit moth and plum cuculio. This proposed temporary tolerance supports a non-crop destruct experimental use permit (EUP) under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of Indoxacarb on peaches in Georgia, Michigan, New Jersey, Pennsylvania, South Carolina, and West Virginia. This regulation proposes to establish a maximum permissible level for residues of Indoxacarb in this food commodity pursuant to section 408(e) of FFDCA, as amended by FQPA.

DATES: Comments, identified by docket ID number OPP–2003–0125, must be received on or before May 1, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0125. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not

included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0125. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2003–0125. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0125.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Attention: Docket ID Number OPP–2003–0125. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background and Statutory Findings

EPA, in cooperation with DuPont Crop Protection and university extension specialists, under section 408(e) of the FFDCA, 21 U.S.C. 346a, is proposing to establish a tolerance for combined residues of the insecticide Indoxacarb, in or on peaches at 10.0 parts per million (ppm). This action is in response to university extension specialists, DuPont, and EPA's combined efforts to generate the information necessary for registration of the reduced risk pesticide, Indoxacarb, on peaches for control of oriental fruit moth and plum curculio. This proposed temporary tolerance supports a non-crop destruct experimental use permit (EUP) under section 5 of FIFRA authorizing use of Indoxacarb on peaches in Georgia, Michigan, New Jersey, Pennsylvania, South Carolina, and West Virginia. Section 5 of FIFRA authorizes EPA to issue an experimental use permit for a pesticide. This provision was not amended by FQPA. EPA has established regulations governing such experimental use permits in 40 CFR part 172. Section 408(r) of FFDCA authorizes EPA to issue temporary tolerances for pesticide residues from FIFRA experimental use permits.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of Indoxacarb on peaches at 10.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by Indoxacarb are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity rodents	DPX-MP062 NOAEL = M 3.1 mg/kg/day F 2.1 mg/kg/day LOAEL = M 6.0 mg/kg/day, F 3.8 mg/kg/day based on decreased body weight, body weight gain, food consumption and food efficiency.
870.3150	90–Day oral toxicity in nonrodents	DPX-JW062 NOAEL = 5.0 mg/kg/day LOAEL = 19 mg/kg/day based on hemolytic anemia, as indicated by decrease in HGB, RBCs; increases in platelets, increased reticulocytes; and secondary histopathologic findings indicative of blood breakdown (pigment in Kupffer cells, renal tubular epithelium, and spleen and bone marrow macrophages); increase in splenic EMH; and RBC hyperplasia in bone marrow in dogs.
870.3200	21/28–Day dermal toxicity	DPX-MP062 NOAEL = 2,000 mg/kg/day LOAEL = >2,000 mg/kg/day in rats. DPX-MP062 NOAEL = 50 mg/kg/day LOAEL = 500 mg/kg/day based on decreased body weights, body weight gains, food consumption, and food efficiency in F*, and changes in hematology parameters (increased reticulocytes), the spleen (increased absolute and relative weight M* only, gross discoloration), clinical signs of toxicity in both sexes in rats.

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

Guideline No.	Study Type	Results
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 kg/day LOAEL = 2.2 mg/kg/day based on decreased fetal body weights.
870.3700	Prenatal developmental in nonrodents	DPX-JW062 - rabbits Maternal NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on slight decreases in maternal body weight gain and food consumption. Developmental NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on decreased fetal body weights and reduced ossification of the 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 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 decrease in the body weights of the F_1 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 decr. 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 decr. HCT, HGB and RBC; increased Heinz bodies and reticulocytes and associated secondary microscopic changes in the liver, kidneys, spleen, and bone marrow; increased absolute and relative liver weights.
870.4200	Carcinogenicity rats	DPX-JW062 see 870.4100. No evidence of carcinogenicity
870.4300	Carcinogenicity mice	DPX-JW062 NOAEL = M 2.6, 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 10–5,000 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.

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) DPX-JW062 negative for mutagenic activity for the following concentration ranges: Negative;100–1,000 μg/mL (-S9); 100–1,000 μg/mL (+S9), precipitate ≥1,000 μg/mL
870.5375	Cytogenetics	DPX-MP062 no evidence of chromosomal aberrations induced by the test article over background for the following concentration ranges: 15.7–1,000 μg/mL (±S9) DPX-JW062 no evidence of chromosomal aberrations induced by the test article over background for the following concentration ranges: 19–300 μg/mL (- S9), 19–150 μg/mL (+S9); partial insoluble and cytotoxicity ≥150 μg/mL
870.5395	Cytogenetics	DPX-MP062 no evidence of mutagenicity for the following dose ranges: 3,000–4,000 mg/kg - males; 1,000–2,000 mg/kg - females DPX-JW062 no evidence of mutagenicity at 2,500 or 5,000 mg/kg
870.5550	Other Effects	DPX-MP062 no evidence of mutagenic activity at the following concentration range: 1.56–200 μg/mL; cytotoxicity was seen at concentrations of ≥100 μg/mL DPX-JW062 No evidence of mutagenic activity at the following concentration range: 0.1–50 μg/mL, cytotoxicity observed at ≥50 μg/mL
870.6200	Acute neurotoxicity screening battery	DPX-MP062 NOAEL = M 100, F 12.5 mg/kg LOAEL = M 200 mg/kg based on decreased body weight gain, decreased food consumption, decreased forelimb grip strength, and decreased foot splay. F 50 mg/kg based on decreased body weight, body weight gain, and food consumption DPX-JW062 NOAEL= M > 2,000 mg/kg = F < 500 mg/kg LOAEL > M 2,000 mg/kg F < 500 mg/kg based on clinical signs, decreased body weight gains and food consumption, and FOB effects
870.6200	Subchronic neurotoxicity screening battery	DPX-MP062 NOAEL = M 0.57, F 0.68 mg/kg/day LOAEL = M 5.6, F 3.3 mg/kg/day based on decreased body weight and alopecia
870.7485	Metabolism and pharmacokinetics	Both DPX-MP062 and DPX-JW062 were extensively metabolized and the metabolites were eliminated in urine, feces, and bile. The metabolite profile for DPX-JW062 was dose dependent and varied quantitatively between males and females. Differences in metabolite profiles were also observed for the different label positions (indanone and trifluoromethoxyphenyl rings). All biliary metabolites undergo further biotransformation in the gut. The proposed metabolic pathway for both DPX-MP062 and DPX-JW062 has multiple metabolites bearing one of the two ring structures (see 870–4100 chronic toxicity rodents above).

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

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

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

The linear default risk methodology (Q*) is the primary method currently

used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (*e.g.,* risk is expressed as 1 x 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 Table 2 of this unit:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13–50 years of age)	NOAEL = 2.0 mg/kg/day UF = 100 Acute RfD = 0.02 mg/kg	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 = chronic RfD÷FQPA SF = 0.02 mg/kg/day	90–day rat subchronic toxicity study, 90–day rat neurotoxicity study, chronic/carcinogenicity rat study. LOAEL = 3.3 mg/kg/day based on decreased body weight, 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) (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.
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.

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
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: alfalfa, forage at 10 ppm; alfalfa, hay at 50 ppm; 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 1.5 ppm; cattle, goat, horse, sheep, and hog meat at 0.05 ppm; cattle, goat, horse, sheep , and hog meat byproducts at 0.03 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, head at 5.0 ppm; lettuce, leaf at 10.0 ppm; milk at 0.15 ppm; and milk, fat at 4.0 ppm; peanut at 0.01 ppm; peanut, hay at 40 ppm; pear at 0.20 ppm; potato at 0.01 ppm; soybean, seed at 0.8 ppm; soybean, aspirated grain fractions at 45 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 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: 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) for all crops. ARs for meat, milk, poultry, and eggs (MMPE) raw agricultural commodities (RACs) were calculated also.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Chronic exposure estimates are expressed in mg/kg bw/day and as a percent of the cPAD. The chronic dietary assessment assumed tolerance level residues, DEEM® default processing factors, assumed 100% CT for all crops other than peaches, and 1% CT for the peach EUP (300 acres)(Tier 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 (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

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

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described 1% for Indoxacarb used on peaches is reliable and has a valid basis. A 2–year EUP has been issued for this use, which will allow for use of Indoxacarb on 300 acres of peaches in some eastern states. Before the use can be expanded for treatment of greater than 300 acres per year, permission from the Agency must be obtained. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk

assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which Indoxacarb may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for Indoxacarb in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of Indoxacarb.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW (screening concentration in ground water), which predicts pesticide concentrations in groundwater. 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 percent reference dose (%RfD) or percent population adjusted dose (%PAD). Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to Indoxacarb they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of Indoxacarb for acute exposures are estimated to be 13.7 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 3.7 ppb for surface water and 0.02 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Indoxacarb is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether Indoxacarb has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, Indoxacarb does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that Indoxacarb has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There is no evidence for either qualitative or quantitative susceptibility. In all developmental studies, the developmental endpoint occurs at the maternal LOAEL or above. Although there is no rabbit developmental toxicity study with indoxacarb, a study is not required since: (1) studies both using methyl cellulose comparing JW062 in the rabbit and rat demonstrate that the toxicity profiles for the rat and rabbit are similar and that the rat is the more sensitive species; (2) range finding studies in the rat comparing indoxacarb and JW062 indicate that the maternal and external developmental toxicity are comparable; (3) a dietary developmental toxicity study in the rat with JW062 had comparable toxicity to the gavage indoxacarb rat developmental toxicity study. Developmental toxicity only occurred at levels at or above maternal toxicity.

The reproduction toxicity study with JW062 can be used to satisfy the requirement for an indoxacarb study because: 1) systemic toxicity is at similar doses and of similar magnitude to that observed in subchronic feeding studies with both indoxacarb and JW062; 2) based on the data base, the HIARC determined that there was support for using data from dietary studies conducted with JW062 to satisfy the data requirements for indoxacarb.

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

- Clinical signs of neurotoxicity in several studies, males and females, mice and rats, at some doses that do not cause mortality;
- Signs of neurotoxicity in the acute neurotoxicity study rat with indoxacarb (males and females), no mortality in males at neurotoxic doses;

- Clinical signs of neurotoxicity in the 90–day toxicity study rat indoxacarb (females), mortality;
- Clinical signs of neurotoxicity in the 90–day toxicity study mouse with the racemic mixture, JW062 (males and females), no mortality in females at neurotoxic doses, mortality in males;
- Clinical signs of neurotoxicity in the 18 month carcinogenicity study mouse with JW062 (males and females) high and mid dose, mortality at the high but no mortality at the mid dose; and
- Clinical signs of neurotoxicity in the developmental toxicity study rat with JW062 (using methyl cellulose as the vehicle), at doses causing mortality.

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

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

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 drinking water level of comparison (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: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to Indoxacarb will occupy 12% of the aPAD for the U.S. population, 69% of the aPAD for females 13 years and older, 67% of the aPAD for infants less than 1 year old and 36% of the aPAD for children 1 to 2 years old. In addition, there is potential for acute dietary exposure to Indoxacarb in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPad, as shown in Table 3 of this unit:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO INDOXACARB

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.12	7	13.7	0.02	3,700
Females 13 +	0.02	69	13.7	0.02	180
All infants less than 1 year	0.12	67	13.7	0.02	400
Children 1 to 2	0.12	36	13.7	0.02	760

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to Indoxacarb from food will utilize 30% of the cPAD for the U.S. population, 29% of the cPAD for infants less than 1 year old and 79% of the cPAD for children 1 to 2 years old. There are no residential uses for Indoxacarb that result in chronic residential exposure to Indoxacarb. Based the use pattern, chronic residential exposure to residues of Indoxacarb is not expected. In addition, there is potential for chronic dietary exposure to Indoxacarb in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit:

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

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.02	30	3.7	0.02	490
All infants less than 1 year old	0.02	29	3.7	0.02	140
Children 1 to 2	0.02	79	3.7	0.02	43

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 carcinogenic risk when used as directed.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography HPLC/UV Method AMR 2712–93) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, 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

A 15–day comment period is being allowed for this proposed rule because of the speed of growth and the pest pressure, and the Agency's desire to be suportive of efforts by peach growers and researchers to find alternatives to organophosphates for control of oriental fruit moth and plum curculio in peaches. Additionally, the Agency feels that there is strong evidence in support of the safety of this proposed action.

Therefore, a temporary tolerance for 3 years is proposed for combined residues of Indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxy carbonyl) [4-(trifluoromethoxy)phenyl] amino]carbonyl] indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate + its R-enantiomer] (R)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoro methoxy)phenyl]amino]carbonyl]indeno [1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate in peaches at 10.0 ppm.

VI. Statutory and Executive Order Reviews

This proposed rule is establishing a tolerance under section 408(d) of the FFDCA. EPA is proposing this regulation in cooperation with Research Extension Specialists at the University of Georgia, Rutgers University, Clemson University, Pennsylvania State University, Michigan State University, University of West Virginia, and DuPont de Nemours and Company. 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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 proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this proposed 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 proposed rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 10, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 03–9340 Filed 4–15–03; 8:45 a.m.]

BILLING CODE 6560–50–S