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[FR Doc. 03–12359 Filed 5–20–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0151; FRL–7305–2]

Indoxacarb; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of indoxacarb and its R-enantimomer in or on collards. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on collards. This regulation establishes a maximum permissible level for residues of indoxacarb in this food commodity. The tolerance will expire and is revoked on June 30, 2006.

DATES: This regulation is effective May 21, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0151, must be received on or before July 21, 2003.

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

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *Madden.Barbara@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 a federal or state government agency (NAICS 9241) involved in administration of environmental quality programs (i.e., Departments of Agriculture, Environment, etc).

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–2003–0151. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is 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 collards at 3.0 parts per million (ppm). This tolerance will expire and is revoked on June 30, 2006. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18-related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State

agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Indoxacarb on Collards and FFDCA Tolerances

The State of Georgia requested an emergency exemption use for indoxacarb (Avaunt®) for control of the diamondback moth in collards, since this pest appears to have developed resistance to almost all available chemical alternatives. Although spinosad has provided satisfactory diamondback moth control until recently, field failures were detected in 2002, suggesting that resistance may be involved. According to the State, potential yield losses tend to be either 0% or 100%, since in affected fields the damage level may be considered either acceptable or a cause for rejection, in which case the crop would not be harvested. The State estimated an overall 10% decrease in yield in the absence of effective insecticides and a doubling of insecticide costs from $24.50 to $49.00 because of a lack of efficacy leading to repeated applications. The 10% estimate represents anticipated total losses in a few fields and minor losses in fields with manageable moth populations. EPA has authorized under FIFRA section 18 the use of indoxacarb on collards for control of diamond back moth in Georgia. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of indoxacarb in or on collards. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on June 30, 2006, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on collards after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether indoxacarb meets EPA's registration requirements for use on collards or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of indoxacarb by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Georgia to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for indoxacarb, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

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 indoxacarb and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of indoxacarb [(S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy) phenyl] amino] carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate] and its R-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 collards at 3.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by indoxacarb and the endpoints used in risk assessment are discussed in Unit III.A. and B. of the final rule on indoxacarb pesticide tolerances published in the **Federal Register** of July 18, 2002 (67 FR 47299) (FRL–7186–2). Please refer to that document should you desire detailed toxicological information on indoxacarb.

The Agency has identified an acute dietary endpoint for females 13 years and older and for the general population, including infants and children. The acute population adjusted dose (aPAD) for females is 0.02 milligrams/kilogram/day (mg/kg/day). The acute dietary endpoint for the general population including infants and children is 0.12 mg/kg/day. The chronic population adjusted dose (cPAD) for all populations is 0.02 mg/kg/day. Indoxacarb has been classified as ''not likely'' to be carcinogenic to humans.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.564) for the combined residues of indoxacarb, in or on a variety of raw agricultural commodities including alfalfa, head lettuce, peanuts, potatoes, and soybeans. Additionally, there are tolerances for milk, milk fat, meat, fat and meat by-products of cattle, goat, hog, horse, and sheep. 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® version 7.76) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1989–1992 nationwide Continuing

Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Acute Tier II assessment, a partially refined analysis with use of anticipated residues (ARs) from field trial data, refined processing factors, and 100% crop treated.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM® (version 7.76) 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: Tolerance level residues for all commodities and assumed all raw agricultural commodities were 100% treated with indoxacarb. Refined processing factors were used in the chronic analysis for several commodities, in place of the DEEM® default processing factors.

iii. *Cancer*. Indoxacarb has been classified as ''not likely'' to be carcinogenic to humans. Therefore, cancer risk was not assessed.

iv. *Anticipated residue 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.

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

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use 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 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).

C. Safety Factor for Infants and Children

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.

The prenatal and postnatal toxicology data base for indoxacarb is complete with respect to FQPA considerations. The nature of the toxic effects caused by indoxacarb are discussed in Unit III.D. of the final rule on indoxacarb pesticide tolerances published in the **Federal Register** of July 18, 2002 (67 FR 47299) (FRL–7186–2). Please refer to that document should you desire detailed toxicological information on indoxacarb regarding FQPA considerations.

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. EPA did require a developmental neurotoxicity study as confirmatory data. 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.

D. Aggregate Risks and Determination of Safety

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

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

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to indoxacarb 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 indoxacarb on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to indoxacarb will occupy 12% of the aPAD for the U.S. population, 64% of the aPAD for females 13 years and older, 67% of the aPAD for all infants (<1 year old) and 79% of the aPAD for children 1–5 years old, the children subpopulations at greatest exposure. In addition, despite the potential for acute dietary exposure to indoxacarb in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of indoxacarb in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1. below:

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

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.12	12	13.7	0.02	3,700
All Infants (< 1year old)	0.12	67	13.7	0.02	400
Children (1–5 years old)	0.12	79	13.7	0.02	760
Females (13–40 years old)	0.02	64	13.7	0.02	218

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 all infants (<1 year old) and 79% of the cPAD for children (1–2 years old), the children subpopulation at greatest exposure. There are no residential uses for indoxacarb that result in chronic residential exposure to indoxacarb. In addition, despite the potential for chronic dietary exposure to indoxacarb in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of indoxacarb in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2. below:

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

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

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

Population Subgroup	cPAD mg/ kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children (1–2 years old)	0.02	79	3.7	0.02	30

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

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational 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 were previously addressed.

5. *Aggregate cancer risk for U.S. population*. Indoxacarb has been classified as ''not likely'' to be carcinogenic to humans. Therefore, cancer risk was not assessed.

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.

V. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has submitted a method for enforcing tolerances of indoxacarb in/on plant commodities, a high-performance liquid chromatography (HPLC)/column switching/ultraviolet (UV) detector method (AMR 2712–93). This method has been radiovalidated and undergone a successful independent laboratory validation (ILV) and a successful petition method validation (PMV) trial by the Analytical Chemistry Laboratory (ACL). The HPLC/UV Method AMR 2712–93 was forwarded to the Food and Drug Administration for inclusion in the Pesticide Analytical Manual (PAM), Vol. II). The Agency has determined that this method is suitable for enforcement of the tolerances associated with this petition.

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

B. International Residue Limits

There are no Mexican, Canadian or Codex Maximum Residue Limits (MRLs) established for indoxacarb on collards. Therefore, no compatibility problems exist for the proposed tolerance.

VI. Conclusion

Therefore, the tolerance is established 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 collards at 3.0 ppm.

VII. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0151 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 21, 2003.

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

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

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

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

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

3.*Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by the docket ID number OPP–2003–0151, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. 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 FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final

rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 9, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

§ 180.564 Indoxacarb; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Collards	3.0	06/30/06
* * * * *		

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[FR Doc. 03–12480 Filed 5–20–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7499–8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of partial deletion of Cecil Field Naval Air Station (Site) From the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency, Region 4, announces the partial deletion of the Cecil Field Naval Air Station Superfund Site (the ''Site'') (EPA ID# FL 5170022474) from the National Priorities List (NPL). The portion to be deleted is described below. The NPL is codified as appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300, which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended, 42 U.S.C. 9605. The EPA has determined, with the concurrence of the State of Florida through its Department of Environmental Protection, that the parcels to be deleted under this action do not pose a significant threat to public health or the environment, as defined by CERCLA, and therefore, further remedial measures pursuant to CERCLA are not appropriate for these parcels.

The remaining parcels comprising the Cecil Field Naval Air Station Superfund Site will remain on the NPL. Response actions are either underway at these parcels or the parcels do not require any further response action other than operation and maintenance activities and enforcement.

EFFECTIVE DATE: June 20, 2003.

FOR FURTHER INFORMATION CONTACT: Deborah A. Vaughn-Wright, Remedial Project Manager, Federal Facilities Branch, Waste Management Division, U.S. Environmental Protection Agency, 61 Forsyth Street, Atlanta, Georgia 30303, 404–562–8539, fax 404–562–8518, e-mail *vaughn-wright.debbie@epa.gov.*

SUPPLEMENTARY INFORMATION: The portions of Cecil Field to be deleted from the NPL include OU 4 (site 10), OU 5 (site 14), OU 12 (sites 44, 42 and the Old Golf Course) and an additional 16,527 acres which are not associated with an operable unit that have been evaluated as not posing a risk to human health and the environment (BRAC environmental condition of property 1, 2, 3 and 4).

The boundaries of the base are within the following coordinates: 30.3012 North Latitude, 81.9306 West Longitude; 30.3012 North Latitude, 81.9244 West Longitude; 30.3063 North Latitude, 81.8781 West Longitude; 30.2468 North Latitude, 81.8445 West Longitude; 30.1784 North Latitude, 81.8676 West Longitude; 30.1783 North Latitude, 81.8847 West Longitude. Within these coordinates are several areas which are not part of this partial deletion. The areas not included are Building 635, Building 605, Potential Source of Contamination (PSC) 51 (Current golf Course), Operable Unit (OU) 1 (Sites 1—Old Landfill and Site 2—recent landfill), OU 2 (Site 5—Oil Disposal Area Northwest and Site 17—Oil and Sludge Disposal Pit Southwest), OU 3 (Site 7—Old Firefighter Training Area and Site 8—Boresite Range/Hazardous Waste Storage/Firefighting Area), OU 5 (Site 15—Blue 10 Ordnance Disposal Area, Site 49—Recent Skeet Range), OU 6 (site 11—Golf Course Pesticide Disposal Area), OU 7, (Site 16—AIMD Seepage Pit/NDI Holding Tank), OU 8 (Site 3—Oil and Sludge Disposal Pit), OU 9 (Site 36—Control Tower TCE Plume, Site 37—Hangars 13 and 14 DCE Plume, Site 57—Building 824A/Day Tank 1 Area, and Site 58—Building 312 Area), OU 10 (Site 21—Golf Course Maintenance Area and Site 25—Former Transformer Storage Area), OU 11 (Site 45—Former Steam Generating Plant), and OU 12 (Site 32—Former DRMO Area). A Notice of Intent to Delete for this site was published in the **Federal Register** on January 29, 2003 (68 FR 4429). The closing date for comments on the Notice of Intent to Delete was March 31, 2003. EPA received no comments during this period.

The EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Deletion from the NPL does not necessarily preclude further remedial action. Federal Facilities are not subject of the Hazardous Substances Response Fund (Fund) financed remedial actions. However, all federal facilities have a continuing statutory duty to conduct further remediation, if required even after the federal property is transferred to non-federal owners.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: April 18, 2003.

A. Stanley Melburg,

Acting Regional Administrator, Region 4.

■ For the reasons set out in the preamble, 40 CFR part 300, Title 40 of Chapter 1 of