

II. Background and Statutory Findings

In the **Federal Register** of April 16, 2003 (68 FR 18582) (FRL-7302-3), EPA issued a proposed rule pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), EPA, in cooperation with university extension specialists, and DuPont Crop Protection, pursuant to sections 408(e) and (r) of FFDCA, proposed to establish a tolerance for combined residues of the reduced risk pesticide, Indoxacarb in or on peaches. This temporary tolerance supports a non-crop destruct 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 time-limited tolerances for pesticide residues from FIFRA experimental use permits.

The proposed rule requested that 40 CFR 180.564 be amended by establishing a tolerance for combined residues of the insecticide, Indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl) 4-(trifluoromethoxy)phenyl] amino] carbonyl] indeno[1,2-e] [1,3,4]oxadiazine-4a(3H)-carboxylate] + its R-enantiomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl) 4-(trifluoromethoxy)phenyl] amino] carbonyl] indeno[1,2-e] [1,3,4]oxadiazine-4a(3H)-carboxylate] + its R-enantiomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl) 4-(trifluoromethoxy)phenyl] amino] carbonyl] indeno[1,2-e] [1,3,4]oxadiazine-4a(3H)-carboxylate, in or on peaches at 10.0 parts per million (ppm). The tolerance will expire on May 15, 2006.

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

no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of Indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl) 4-(trifluoromethoxy)phenyl] amino] carbonyl] indeno[1,2-e] [1,3,4]oxadiazine-4a(3H)-carboxylate] + its R-enantiomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl) 4-(trifluoromethoxy)phenyl] amino] carbonyl] indeno[1,2-e] [1,3,4]oxadiazine-4a(3H)-carboxylate on peaches at 10 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 the proposed rule, as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

Refer to the April 16, 2003, **Federal Register** document (68 FR, 18582) for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon that risk assessment and the findings made in the **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment, including this use on peaches.

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 tolerances already established for: Apple at 1.0 ppm, apple, wet pomace at 3.0 ppm, brassica, head and stem, subgroup at 5.0 ppm, cattle, goat, horse, sheep, and hog fat at 0.75 ppm, cattle, goat, horse, sheep, and hog meat at 0.03 ppm, cattle, goat, horse, sheep, and hog meat byproducts at 0.02 ppm, corn, sweet, forage at 10 ppm, corn, sweet, kernel plus cob with husk removed at 0.02 ppm, corn, sweet stover at 15 ppm, cotton gin byproducts at 15 ppm, cotton, undelinted seed at 2.0 ppm, lettuce, head at 4.0 ppm, lettuce, leaf at 10.0 ppm, milk at 0.10 ppm, and milk, fat at 3.0 ppm, pear at 0.20 ppm, and vegetables, fruiting, group at 0.50 ppm. Risk assessments were conducted by EPA to assess dietary exposures from Indoxacarb in food as follows:

An acute dietary endpoint for females 13 years and older and for the general population, including infants and children has been identified. 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 a "not likely" to be carcinogenic to humans. It has been determined 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. Currently, indoxacarb is not registered for use in residential settings.

For the chronic exposure estimates, it was assumed that all commodities had tolerance level residues and 100% of all RACs were treated with indoxacarb. Refined processing factors were used in the chronic analysis for several commodities, in place of the Dietary Exposure Evaluation Model (DEEM®) default processing factors. The Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models provided the estimated environmental concentrations (EECs) of indoxacarb. The EECs 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