

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 USDA 1989–1992 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