

3.7 ppb for surface water and 0.02 ppb for ground water.

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 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 II (partially refined analysis) dietary assessment was performed with use of anticipated residues (ARs) from field trial data, processing factors (where applicable), assumed 100% crop treated (CT) for all crops other than peaches, and 1% CT for the peach EUP (300 acres). 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 body weight (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 I).

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.

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 ARs 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 percent crop treated (PCT) as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

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 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 EECs from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model