

incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The 1994–96 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment. Risk assessments were conducted by EPA to assess dietary exposures from imidacloprid 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. DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996/1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A Tier 1, deterministic acute dietary exposure assessment was conducted using tolerance-level residues, 100 PCT information for registered and proposed commodities; and modified DEEM™ (vision 7.76) processing factors for some commodities based on guideline processing studies. EPA estimated exposure based on the 95th percentile value from this deterministic exposure assessment.

In its objections to a separate imidacloprid tolerance action, NRDC asserts that EPA erred by relying on the exposure value for the 95th percentile of the population in estimating exposure. NRDC claims that this approach leaves 5% of the population unprotected. These comments by NRDC represent a misunderstanding of EPA's exposure assessments. Although EPA estimated exposure using the 95th percentile, EPA most definitely was not, however, acting in a manner designed to protect only 95% of the population. To the contrary, EPA's exposure estimates were designed to reasonably capture the full range of exposures in each population subgroup. As explained in its science policy paper on this subject, EPA, in estimating exposure for population subgroups, generally considers various population percentiles of exposure between 95 and 99.99, depending on the extent of overestimation in the residue data used

in the assessment. In each exposure assessment EPA is attempting to reasonably estimate the full range of exposures in a subgroup. Accordingly, as EPA noted in its policy paper, just as when EPA uses the 95th percentile with non-probabilistic exposure assessments EPA is not suggesting that EPA is leaving 5% of the population unprotected, EPA is not by choosing the 99.9th percentile for probabilistic exposure assessments concluding that only 99.9% of the population deserves protection. Rather, it is EPA's view that, with probabilistic assessments, the use of the 99.9th percentile generally produces a reasonable high-end exposure such that if that exposure does not exceed the safe level, EPA can conclude there is a reasonable certainty of no harm to the general population and all significant population groups. (Office of Pesticide Programs, EPA, Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern 31 (March 22, 2000)). Importantly, EPA generally uses a population percentile of 95 when EPA relies on worst-case residue values - i.e., all crops covered by the tolerance contain residues at the tolerance value. Even at the 95th percentile of estimated exposure, actual exposure, when based on this assumption tends to be significantly overstated. For example, EPA has found that when it uses realistic residue information (e.g., data from monitoring of the food supply), that exposure estimates are generally substantially lower even at the 99.99th percentile.

As noted above, EPA did use the worst-case assumption that all food covered by imidacloprid tolerances would bear residues at the tolerance level. Hence, EPA believes its exposure estimate is unlikely to understate exposure; rather, in all likelihood, the estimate probably substantially overstates exposure.

ii. *Chronic exposure.* The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure assessment was performed using published and proposed tolerance levels, DEEM™ default processing factors, and percent crop treated (PCT) information on some commodities.

iii. *Cancer.* A quantitative cancer aggregate risk assessment was not performed because imidacloprid is not carcinogenic.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) of the FFDCFA 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 FFDCFA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: For the acute assessment, 100 PCT was assumed for all registered and proposed commodities. For the chronic assessment, average weighted PCT information was used for the following commodities: Apple 34%; Brussels sprouts 56%; broccoli 35%; cabbage 14%; cantaloupe 31%; cauliflower 52%; collards 10%; corn, field 1%; cotton 3%; cucumber 2%; eggplant 36%; grapefruit 3%; grape 32%; mustard greens 16%; honeydew 26%; kale 30%; lemon 1%; lettuce, head 49%; lime 5%; orange 1%; pear 16%; pepper 62%; pumpkin 7%; spinach 15%; squash 7%; sugarbeet 1%; tangerine 9%; tomato 9%; watermelon 6%; wheat 1%. A default value of 1% was used for all commodities which were reported as having >1% CT.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to