

## B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Currently established tolerances for residues of lambda-cyhalothrin are listed under 40 CFR 180.438 and include permanent tolerances on plants ranging from 0.01 ppm on soybeans to 6.0 ppm on alfalfa hay, corn forage, and tomato pomace (dry or wet). Tolerances are also established on animal commodities ranging from 0.01 ppm in eggs, poultry meat, and poultry meat by-products (mbyp) to 5.0 ppm in milk fat (reflecting 0.2 ppm in whole milk). The Agency has recently established additional tolerances for lambda-cyhalothrin on a number of commodities ranging from 0.05 ppm on sugarcane to 3.0 ppm on peanut hay. Risk assessments were conducted by EPA to assess dietary exposures from lambda-cyhalothrin 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<sup>TM</sup>) 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. A refined Tier 3 probabilistic acute dietary risk assessment was conducted for all currently registered and proposed lambda-cyhalothrin food uses. For the acute dietary risk analysis the entire distribution of residue field trial data was used for not-blended or partially-blended commodities; average residue field trial data was used for blended commodities; information from cooking and processing studies were used when available; and market share data for proposed and established tolerances was used.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) 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. For the chronic dietary risk analysis the average of the residue field trials, information from cooking and processing studies, and market share data were used.

iii. *Cancer.* The data base for carcinogenicity is considered complete,

and no additional studies are required at this time. The requirements for oncogenicity studies in the rat and the mouse with lambda-cyhalothrin have been satisfied by a combined chronic/ oncogenicity study in rats and an oncogenicity study in mice, both conducted with cyhalothrin. Lambda-cyhalothrin has been classified as a Group D chemical (not classifiable as to human carcinogenicity) with regards to its carcinogenic potential.

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.

A detailed description of how the Agency used PCT information in this assessment can be found in the lambda-cyhalothrin pesticide tolerance document published on September 27, 2002 (67 FR 60902; FRL-7200-1) in Unit III.C.1.iv.

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 underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. 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 lambda-cyhalothrin 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 lambda-cyhalothrin 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 lambda-cyhalothrin.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to