

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 for both the acute and chronic dietary risk assessment as follows:

A routine acute and chronic dietary exposure analysis for thiacloprid was based on 61% of apple crop treated, 51% of pear crop treated and 1% of cotton crop 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 in the preceding paragraph for thiacloprid used on these crops is reliable and has a valid basis. The PCT estimates are based on use of existing alternate insecticides against insects that thiacloprid will control. As per Agency practice, the PCT estimates are what the Agency expects to be likely upper bound market penetrations for various crop/pest niches. Maximal percent crop treated estimates were projected for apples, pears, and cotton. 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 thiacloprid 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 thiacloprid 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 thiacloprid.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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.

The Tier II screening model, PRZM/EXAMS, was used to estimate residues of thiacloprid and one of its major degradates, YRC 2984 amide in surface water. The SCI-GROW model was used to estimate the ground water residues.

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 estimated environmental concentrations (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 estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to thiacloprid they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models the estimated

environmental concentrations (EECs) of thiacloprid and one of its major degradates, YRC 2894 amide for acute exposures are estimated to be 10.2 parts per billion (ppb) for surface water and 0.06 ppb for ground water. The EECs for chronic exposures are estimated to be 2.36 ppb for surface water and 0.06 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Thiacloprid is not registered or proposed for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity.

EPA does not have, at this time, available data to determine whether thiacloprid has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to thiacloprid and any other substances and thiacloprid does not appear to produce a toxic metabolite produced by other substances. Thiacloprid does produce 6-CNA, a metabolite also produced by another registered chloronicotinoid pesticide. However, the limiting toxic endpoints used in this assessment for thiacloprid are not based upon the toxicity of 6-CNA. For the purposes of this tolerance action, therefore, EPA has not assumed that thiacloprid has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.