

Surveys of Food Intake by Individuals (CSFI) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

The chronic dietary (food only) assessment is based on Tier 2 assumptions (tolerance-level residues and 25% crop treated estimates). For all population subgroups, the estimated dietary (food only) risks are less than 1% of the chronic PAD.

iii. *Cancer.* The cancer dietary (food only) assessment is based on Tier 2 assumptions (tolerance-level residues and 25% crop treated estimates). Based on these assumptions, the estimated dietary exposure for the U.S. Population is  $0.000013 \text{ mg/kg/day}$ . Applying a  $Q^{1*}$  of  $4.85 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$  results in a cancer risk estimate of  $6.5 \times 10^{-7}$ . Generally the Agency is not concerned with cancer risk less than the range of  $1 \times 10^{-6}$ .

iv. *Anticipated residue and percent crop treated (PCT) information.* 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:

For the acute dietary risk assessment, the Agency assumed 100% crop treated i.e., that the entire crop was treated. For chronic (non-cancer and cancer) dietary analyses it was assumed that 25% of the corn was treated.

For assessing chronic dietary risk, the Agency believes that the three conditions listed above have been met. With respect to condition 1, it was assumed that 25% of the corn was treated. The information was based on the percent crop treated data for acetochlor since 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane can be used as a safener with acetochlor to treat

corn. This 25% crop treated estimate is likely to significantly overestimate the percentage of corn treated with 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane. According to information supplied by the USDA, Economic Research Service, the total production of corn in the United States was 239.55 and 251.85 million metric tons for the growing seasons of 1999–2000 and 2000–2001 respectively. United States corn imports were 328.393 and 195.603 metric tons for the years 1999 and 2000 respectively. Thus, treated amount of imported corn is less than 1% of domestic U.S. corn production.

As to conditions 2 and 3, regional consumption information and the consumption information for significant subgroups 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 procedure 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.

2. *Dietary exposure from drinking water.* Residues in drinking water (either ground water or surface water) are not expected to result as a consequence of establishing an import tolerance for 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane residues in or on corn commodities. There are currently no registered products containing 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane being distributed or sold in the United States. The one registered product containing 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane is pending request for cancellation (October 16, 2002, 67 FR 63909; FRL–7276–6). Therefore, exposure through drinking water is unlikely.

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). 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane is not registered in the United States and the petition is for import tolerances only, therefore, there would be no residential exposure.

4. *Cumulative exposure to 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 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 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that 4-(dichloroacetyl)-1-oxa-4-azaspiro[4.5]decane 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There are two developmental toxicity studies in the rat. In a 1995 study, fetal malfunctions were observed at 200 mg/kg/day in the presence of minimal maternal toxicity (clinical signs). Both maternal and developmental OAEL's are 80 mg/kg/day. In a 1989 study, resorption and malfunctions were observed in the presence of a maternal clinical signs including decreased body