

all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of hexythiazox on date, dried fruit at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile and Endpoints

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by hexythiazox and the endpoints used in risk assessment are discussed in Unit III. A. and B. of the final rule on hexythiazox pesticide tolerances published in the **Federal Register** of April 18, 2001 (66 FR 19879) (FRL-6778-8). Please refer to this document should you desire detailed toxicological information on hexythiazox.

The Agency has identified an acute dietary endpoint for females 13 years and older. The acute population adjusted dose (aPAD) for females is 2.4 milligrams/kilograms/day (mg/kg/day).

No acute dietary endpoint was identified for the general population including infants and children; a dose and endpoint attributable to a single exposure were not identified from the available oral toxicity studies, including maternal toxicity in the developmental toxicity studies. The chronic population adjusted dose (cPAD) for all populations is 0.025 mg/kg/day. Hexythiazox has been classified as a category C, possible human carcinogen, for cancer. The calculated Q* for hexythiazox is 2.22×10^{-2} .

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.448) for the combined residues of hexythiazox, trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide and its metabolites containing the 4-chlorophenyl-4-methyl-2-oxo-3-thiazolidine moiety in or on a variety of raw agricultural commodities (RAC) including tolerances for milk, fat, and meat byproducts of cattle, goat, horse, sheep, and swine. Risk assessments were conducted by EPA to assess dietary exposures from hexythiazox 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. The dietary exposure evaluation model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the Department of Agriculture (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: Default processing factors were used, and 100 percent crop treated (PCT) information for all commodities.

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: A partially-refined dietary analysis was performed using anticipated residue levels for most crops (calculated from field trial data) and PCT or anticipated market-share information for all crops.

iii. *Cancer.* A partially-refined dietary-exposure analysis was performed using anticipated residue (AR) levels for most crops, processing factors where applicable, and PCT or anticipated market share information for all crops.

iv. *Anticipated residue and 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.

The following Table 1 provides a summary of the anticipated residue (AR) and PCT information used for the chronic and cancer exposure assessments. The Agency has issued emergency exemptions to the state of California for use of hexythiazox on dates since 1998. The PCT information for dates is based on applications made under these emergency exemptions. The majority of dates grown in the United States are grown in California.