

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.191) for the residues of folpet, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from folpet 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-Food Commodity Intake Database (DEEM-FCIDTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 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: Anticipated residues for most commodities and percent crop treated for many commodities. For hop, the dietary exposure analysis assumed tolerance level residues and 100 percent crop treated.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM FCID) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998] 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 chronic exposure assessments: Anticipated residues for most commodities and percent crop treated for many commodities. For hop, the dietary exposure analysis assumed tolerance level residues and 100 percent crop treated.

iii. *Cancer.* In conducting this cancer dietary risk assessment the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCIDTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 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 chronic exposure assessments: Anticipated residues for most commodities and percent crop treated for many commodities. For hop, the dietary exposure analysis assumed

tolerance level residues and 100 percent crop treated.

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.

The Agency did use anticipated residue calculations in conducting its risk assessment. These calculations are based upon submitted field trial data and could be further refined through the use of monitoring data.

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. The only registered food use of folpet in the United States is avocados grown in Florida. According to data available from the United States Department of Agriculture's National Agricultural Statistics Service, California accounted for 89 percent of avocado production in the United States, followed by Florida at nearly 11 percent and Hawaii at approximately 0.1 percent. Therefore, the Agency has assumed that only 11 percent of the U.S. avocado crop is treated with folpet. As

stated earlier, for the hop use, the Agency assumed 100 percent crop treated even though imports of hop accounted for less than 50 percent of the crop consumed in the United States, based upon data available from the Hop Growers of America 2001 Statistical Report. For all other commodities (except hops and avocados), the Agency assumed a maximum percent crop treated value of 1% for each commodity (i.e., apple, cranberry, cucumber, grape, lettuce, melon, onion, strawberry, and tomato) based upon information derived through an analysis of import and domestic production data available from the United States Department of Agriculture for the years 1995 through 1999 and adjusted for the countries in which folpet is registered.

The Agency believes that the three conditions listed in Unit III. 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. In using these data, the Agency also took into account the specific countries where folpet is registered. In the case of avocados, the Agency based its PCT estimate on the volume of the avocado crop grown in the United States, utilizing data from the U.S. Department of Agriculture. For all potentially-treated commodities, EPA used estimated maximum PCT assumptions in conducting both the acute and chronic dietary exposure assessments. 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