

also been established under 40 CFR 180.503(b) in connection with EPA's granting of a section 18 emergency exemption. The time-limited tolerance for hops, dried cone was set to expire December 31, 2003. Tolerances for residues of cymoxanil per se in/on imported grapes and tomatoes at 0.1 ppm are established under 40 CFR 180.503(e). Risk assessments were conducted by EPA to assess dietary exposures from cymoxanil 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. In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Data base (FCDI DEEM™) which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996, and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute dietary exposure analyses assumed tolerance level residues, 100% crop treated and DEEM™ (ver. 7.76) default processing factors for all registered/proposed commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessments EPA used the DEEM™ software with the FCID which incorporates food consumption data as reported by respondents in the USDA 1994–1996, and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analyses assumed tolerance level residues, 100% CT, and DEEM™ (ver. 7.76) default processing factors for all registered/proposed commodities.

iii. *Cancer.* In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July 1999), the Agency classified cymoxanil as a “not likely” human carcinogen. Therefore, a cancer dietary exposure analysis was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cymoxanil 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 cymoxanil.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentration in Ground water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. 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.

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 cymoxanil they are further discussed in the aggregate risk sections in Unit II.E.

Cymoxanil appears to be mobile in soils. However, the rapid dissipation of cymoxanil in the environment precludes the possibility of extensive leaching. No detections of cymoxanil were observed below the 0–15 cm soil depth at any of the test sites. Though the degradates of cymoxanil are mobile, the aerobic soil metabolism study showed that the degradates are short-lived. Cymoxanil and its degradates should not pose a threat to ground water. Therefore, ground water EEC values were not included in the risk assessment.

Based on the GENEEC model the EECs of cymoxanil for surface water are estimated to be 4.13 parts per billion (ppb) for acute exposures and 0.19 ppb for chronic exposure.

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).

Cymoxanil is not registered for use on any sites that would result in 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 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 cymoxanil 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 cymoxanil and any other substances and cymoxanil 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 cymoxanil 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/>.

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