

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 highly refined chronic exposure assessment was conducted which incorporated the most recent PDP monitoring data, field trial data and processing factor data (for grapes and pending uses). It assumed 100% crop treated for the new and existing uses.

iii. *Cancer.* Bifenthrin has been classified as a Category C (possible human) carcinogen. The Agency has determined that the reference dose (RfD) approach should be used for quantification of human risk. For further discussion of the weight-of-the-evidence considered by EPA in making this determination, see the proposed rule for Bifenthrin tolerances (59 FR 9167, February 25, 1994) (FRL–4756–1). Under this approach, chronic dietary exposures that are less than the RfD (or cPAD) are assumed to be protective for cancer dietary exposure as well. Therefore, a separate cancer dietary risk assessment was not conducted.

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.

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 did not use percent crop treated information for assessing dietary risk from bifenthrin.

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

The Agency uses the FQPA 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.

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 bifenthrin they are further discussed in the aggregate risk sections in Unit III.E.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of bifenthrin for acute exposures are estimated to be 0.1 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.1 ppb for surface water and 0.006 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).

Bifenthrin is currently registered for use on the following residential non-dietary sites: ornamental gardens, lawns, turf, and general insect control in, around and on buildings, structures, and immediate surroundings. There are also uses for spot treatments and crack and crevice treatments for insects in, on, and around homes, buildings, and other structures and for subsoil treatment around structures for control of termites (termite use). The risk assessment was conducted using the following residential exposure assumptions: Adults and children are potentially exposed to bifenthrin residues after application of bifenthrin products in residential settings. Short- and intermediate-term post-application dermal exposures for adults, and short- and intermediate-term post-application dermal and incidental oral exposures for children are anticipated. Risk estimates were generated for potential contact with lawn, soil, and treated indoor surfaces using EPA's Draft Standard Operating Procedures for Residential Exposure Assessment; and for the lawn exposure scenarios, dissipation data from a chemical specific turf transferable residue (TTR) study. Indoor surface residues in homes were based on crack and crevice data collected for bifenthrin and another insecticide, malathion. These estimates are considered conservative screening level estimates, since the study data were adjusted to reflect maximum application rates.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA