

residues of methoxyfenozide, in or on a variety of raw agricultural commodities including pome fruit, cottonseed, and animals (except poultry). Residues in plants, milk, meat and fat are regulated in terms of parent compound only. Residues in liver and meat byproducts (except liver) are regulated in terms of combined residues of methoxyfenozide and its glucuronide metabolite (RH-141,518). Risk assessments were conducted by EPA to assess dietary exposures from methoxyfenozide 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 United States 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: No appropriate endpoint was identified in the oral toxicity studies including the acute neurotoxicity study in rats and the developmental toxicity studies in rats and rabbits.

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 or 1994–1996, nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A Tier 1 (assumptions: Tolerance level residues and 100 percent crop treated) chronic dietary risk assessment was conducted via DEEM™. The established tolerances of 40 CFR 180.544 and the proposed tolerances were included in the analysis. DEEM™ default processing factors (from DEEM™ Version 7.76) were used for all processed commodities that do not have individual tolerances.

iii. *Cancer.* Methoxyfenozide is classified as a “not likely” human carcinogen.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and 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 (PC) area factor as an adjustment to account for the maximum PC 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 concentrations 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 methoxyfenozide they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS model, the EECs of methoxyfenozide for surface water are estimated to be 43 parts per billion (ppb) for acute, and 30 ppb for chronic. Based on the SCI-GROW model the EEC of methoxyfenozide for acute

and chronic exposures for ground water are estimated to be 3.5 ppb.

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).

Methoxyfenozide 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 methoxyfenozide 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 methoxyfenozide and any other substances and methoxyfenozide 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 methoxyfenozide 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