

Food Commodity Intake Database (DEEM-FCID®, Version 1.3), which incorporates consumption data from USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–96 and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods “as consumed” (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or not specified (N/S); baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg bwt/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

The DEEM-FCID® analyses estimate the dietary exposure of the U.S. population and various population subgroups. The analysis assumed tolerance-level residues. No processing studies were required due to the fact that field trials conducted at exaggerated rate (greater than 5X) showed no detectable residues in wheat and barley grains. Therefore, no tolerance is needed for processed commodities. A default processing factor of 1.92 was used for dried beef in this dietary exposure analysis. No other commodities in this analysis used DEEM default processing factors. No percent crop treated or anticipated residues were used.

iii. *Cancer.* The Agency has determined that mefenpyr-diethyl is “not likely to be a human carcinogen.” This was based on weight-of-the-evidence from negative rat and mouse carcinogenicity studies as well as negative mutagenicity studies. Therefore, a carcinogenic dietary assessment 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 mefenpyr-diethyl 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 mefenpyr-diethyl.

The Agency used the FQPA Index Reservoir Screening Tool (FIRST) to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in ground water (SCI-GROW2) model is used to predict pesticide concentrations in shallow ground water. FIRST is a tier 1 model that uses a specific high-end runoff scenario for pesticides. It incorporates an index reservoir environment, but does include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

Neither FIRST nor SCI-GROW2 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 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 FIRST and SCI-GROW2 is considered to be a screening tool 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 mefenpyr-diethyl, they are further discussed in the aggregate risk sections see Unit III.E.

The EECs for a single application of mefenpyr-diethyl at an exaggerated rate of 0.090 kg/hectare (ha) (0.080 lb/acre) results in the peak and chronic concentrations of combined parent and metabolites of 5 parts per billion (ppb) and 3 ppb, respectively for surface water and 4 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). Mefenpyr-diethyl 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 mefenpyr-diethyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, mefenpyr-diethyl 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 mefenpyr-diethyl 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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 level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* In the prenatal developmental toxicity study in rats, no evidence of developmental toxicity was seen, even in the presence of maternal toxicity. In the developmental toxicity study in