

result, a quantitative 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 etoxazole 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 etoxazole.

The Agency uses the First 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 ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier I model) before using PRZM/EXAMS (a Tier II 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 LOC.

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 etoxazole they are further discussed in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of etoxazole for

chronic exposures are estimated to be 1.77 parts per billion (ppb) for surface water and 0.242 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). Etoxazole is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from 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 etoxazole 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 etoxazole and any other substances and etoxazole 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 etoxazole 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 level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is qualitative evidence of increased susceptibility following exposure to etoxazole in the rat reproduction study. Therefore, EPA performed a Degree of Concern Analysis to determine the LOC for the effects observed when considered in the context of all available toxicity data, and to identify any residual uncertainties after establishing toxicity endpoints and traditional UF to be used in the risk assessment of this chemical. If residual uncertainties are identified, EPA examines whether these residual uncertainties can be addressed by a special FQPA safety factor and, if so, the size of the factor needed.

In performing the Degree of Concern Analysis, EPA noted that the effects in the pups in the rat reproduction study are well-characterized with a clear NOAEL. In addition, the pup effects occur at the same dose as maternal toxicity. Furthermore, the doses selected for various risk assessment scenarios are lower than the doses that caused off spring toxicity. There are no residual uncertainties for prenatal/postnatal toxicity in this study. Therefore, although there is evidence of increased qualitative susceptibility in the rat reproduction study, the concern is low.

For the reasons stated above, EPA has concluded that there is low concern for prenatal and/or postnatal toxicity resulting from exposure to etoxazole.

3. *Conclusion.* There is a complete toxicity data base for etoxazole and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed for the following reasons. The toxicological data base is complete for FQPA assessment and there is low concern for prenatal and/or postnatal toxicity resulting from exposure to etoxazole. The chronic dietary food exposure assessment assumed that 100% of the proposed crops were treated and that all treated crops and livestock had residues of concern at the tolerance level. By using these screening-level assumptions, actual exposures/risks will not be underestimated. In addition, the dietary drinking water assessment utilized modeling results which included conservative assumptions for the parent and all degradates of concern. Since conservative assumptions were used in the water models where environmental fate data are lacking, the water exposure assessment will not