

proposed commodities. The submitted corn grain, soybean, and sugarcane processing studies indicate that flufenpyr-ethyl residues do not concentrate in corn, soybean, and sugarcane processed commodities. Therefore, processing factors were set to 1 for all corn, soybean, and sugarcane processed commodities.

The chronic dietary exposure estimates are below EPA's level of concern (<100% cPAD) for the general U.S. population and all population subgroups (<1% of the cPAD). The chronic assessment was highly conservative, using several upper-end assumptions. Additional refinements, such as inclusion of anticipated residues (ARs) and %CT data, could be made in order to refine the chronic assessment.

iii. *Cancer.* A quantitative cancer aggregate risk assessment was not performed because flufenpyr-ethyl is classified as "not likely" to be carcinogenic based on lack of evidence of carcinogenicity in mice and rats.

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

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 Screening Concentration in Groundwater (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 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 (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 percent reference dose (%RfD) or percent population adjusted dose (%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.

Based on FIRST and SCI-GROW models, the EECs of flufenpyr-ethyl and its metabolite S-3153 acid 4-OH for acute exposures are estimated to be 3.76 parts per billion (ppb) for surface water and 0.05 ppb for ground water. The EECs for chronic exposures are estimated to be 1.504 ppb for surface water and 0.05 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).

Flufenpyr-ethyl 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 flufenpyr-ethyl 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 flufenpyr-ethyl and any other substances, and flufenpyr-ethyl 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 flufenpyr-ethyl 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 margin of exposure (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 no evidence of quantitative and/or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure to flufenpyr-ethyl. There is no evidence of increased qualitative and/or quantitative evidence of increased susceptibility to flufenpyr-ethyl following prenatal exposure in a 2-generation reproduction study(s) in rats or 1-generation reproduction studies.

3. *Conclusion.* There is a complete toxicity data base for flufenpyr-ethyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

The FQPA Safety Factor (SF) was reduced to 1x based on toxicological considerations, the conservative residue assumptions used in the chronic dietary exposure risk assessment, the completeness of the toxicity, residue chemistry and environmental fate data base and the lack of the potential for residential exposures.

#### *E. Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model