

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.535) for the combined residues of fluroxypyr, in or on a variety of raw agricultural commodities. Tolerances have also been established for the combined residues of fluroxypyr on meat and milk. Risk assessments were conducted by EPA to assess dietary exposures from fluroxypyr 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 one-day or single exposure.

No adverse effect attributable to a single exposure (dose) of fluroxypyr was observed in the oral toxicity studies. Therefore, EPA did not identify an acute dietary endpoint and a quantitative acute dietary assessment was not performed because no acute risk is expected.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID<sup>†</sup>), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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 chronic exposure assessments: 100% crop treated (PCT) and tolerance-level residues for fluroxypyr on all treated crops. This assessment was Tier I analysis. The exposures from fluroxypyr residues are below EPA's level of concern (<100% of the chronic population adjusted dose (cPAD)) for the general U.S. population (<1% of the cPAD) and all population subgroups.

iii. *Cancer.* Fluroxypyr is classified as “not likely” a human carcinogen and there was no concern for its mutagenicity potential.

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

The Agency used the Pesticide Root Zone Model/Exposure Analysis

Modeling System (PRZM/EXAMS), a Tier 2 model, to estimate pesticide concentrations in surface water. PRZM/EXAMS incorporates an index reservoir environment and includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin. The Tier 1 Screening Concentration In Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water.

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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 fluroxypyr they are further discussed in the aggregate risk sections in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of fluroxypyr for acute exposures are estimated to be 32.9 parts per billion (ppb) for surface water and 0.04 ppb for ground water. The EECs for chronic exposures are estimated to be 3.3 ppb for surface water and 0.062 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).

Fluroxypyr is currently registered for use on the following residential non-dietary sites: Residential turfgrass and recreational sites such as golf courses and sports fields. The risk assessment was conducted using the following residential exposure assumptions:

Adults and children may be exposed to fluroxypyr residues from dermal contact with turf during postapplication activities. Toddlers may receive short- and intermediate-term oral exposure from incidental ingestion during postapplication activities. Residential handlers may receive short-term dermal and inhalation exposure to fluroxypyr when mixing, loading and applying the formulations.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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 fluroxypyr 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 fluroxypyr and any other substances and fluroxypyr 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 fluroxypyr 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 OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at <http://www.epa.gov/pesticides/cumulative/>.

### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of 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 based on reliable data 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