

exposures from pyraflufen-ethyl 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. No adverse effect attributable to a single exposure dose of pyraflufen-ethyl was observed in the oral toxicity studies, including the developmental toxicity studies in rats and rabbits. Therefore, EPA did not identify an acute dietary endpoint and an acute dietary assessment was not performed because no acute risk is expected.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) nationwide Continuing Surveys of Food Intake by Individuals (CSFII) 1994–1996 and 1998, 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 pyraflufen-ethyl on all treated crops. This assessment was Tier I analysis. The exposure from pyraflufen-ethyl residues in food occupies less than 1% of the chronic percent adjusted dose (cPAD) for all population subgroups and is not a concern.

iii. *Cancer.* The cancer dietary exposure assessment was conducted using the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA nationwide CSFII 1994–1996 and 1998, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the cancer assessments: 100% crop treated and tolerance-level residues for pyraflufen-ethyl on all treated crops. This assessment was Tier I analysis. The exposure from pyraflufen-ethyl residues in food results in a cancer risk of 10^{-6} and is not a concern.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyraflufen-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 chemical and physical characteristics of pyraflufen-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 ground water (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 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 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 %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 pyraflufen-ethyl they are further discussed in the aggregate risk sections below.

Based on the FIRST and SCI-GROW models the EECs of pyraflufen-ethyl for acute exposures are estimated to be 1.25 parts per billion (ppb) for surface water and 0.002 ppb for ground water. The EECs for chronic exposures are estimated to be 0.28 ppb for surface water and 0.002 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).

Pyraflufen-ethyl is currently registered for use on the following residential non-dietary sites: Airports, nurseries, ornamental turf, golf courses, roadsides, and railroads. The risk assessment was conducted using the following residential exposure assumptions: Adults and children may be exposed to residues of pyraflufen-ethyl through post-application contact with treated areas which may include residential/recreational areas.

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 pyraflufen-ethyl 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, pyraflufen-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 pyraflufen-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 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