

produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will generally 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 %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 lambda-cyhalothrin they are further discussed in the aggregate risk sections below. The compounds to be regulated in drinking water are lambda-cyhalothrin and degradate XV (parent hydroxylated in the 4-position of the phenoxy ring).

Based on the FIRST, PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of lambda-cyhalothrin and its degradate XV for acute exposures are estimated to be 0.62 parts per billion (ppb) for surface water (0.51 ppb lambda-cyhalothrin and 0.11 ppb degradate XV) and 0.012 ppb (0.006 ppb lambda-cyhalothrin and 0.006 ppb degradate XV) for ground water. The EECs for chronic exposures are estimated to be 0.098 ppb for surface water (0.09 ppb lambda-cyhalothrin and 0.008 ppb

degradate XV) and 0.012 ppb for ground water (0.006 ppb lambda-cyhalothrin and 0.006 ppb degradate XV).

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). The residential exposure/risk assessment evaluated both proposed and existing uses for lambda-cyhalothrin. Existing uses on turf, in gardens, on golf courses, and for structural pest control were qualitatively assessed, but a quantitative calculation was only completed for postapplication exposure on treated turf because this scenario is expected to have the highest associated exposures. This screening level tool is protective for all residential exposures, even the handler scenarios, because the dose levels for children playing on treated lawns are thought to exceed those expected for all other scenarios. For postapplication exposure, all residential MOEs were well above the Agency target MOE of 100 for the inhalation, dermal, and oral routes and therefore do not exceed EPA's level of concern (range 700 to 14,700). Additionally, when total MOEs were aggregated, MOEs were still not of concern (MOEs for children = 500 and for adults = 3,000).

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 lambda-cyhalothrin 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, lambda-cyhalothrin 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 lambda-cyhalothrin 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).

C. 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. *Developmental toxicity studies.* In a developmental toxicity study in rats, the maternal NOAEL was 10 mg/kg/day and the LOAEL was 15 mg/kg/day based on uncoordinated limbs, reduced body weight gain and food consumption. The developmental NOAEL was 15 mg/kg/day, highest dose tested (HDT) and the developmental LOAEL was >15 mg/kg/day.

In a developmental toxicity study in rabbits, the maternal NOAEL was 10 mg/kg/day and the LOAEL was 30 mg/kg/day based on reduced body weight gain and food consumption. The developmental NOAEL was 30 mg/kg/day, HDT and the developmental LOAEL was >30 mg/kg/day.

3. *Reproductive toxicity study.* In a 3-generation reproduction study in rats, the parental/offspring NOAEL was 1.5 mg/kg/day and the LOAEL was 5.0 mg/kg/day based on decreased parental body weight and body weight gain during pre-mating and gestation periods and reduced pup weight and weight gain during lactation. The reproductive NOAEL was 5.0 mg/kg/day (HDT).

4. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with cyhalothrin and there is no evidence of increased susceptibility of young rats in the reproduction study with cyhalothrin.

5. *Conclusion.* Through the use of bridging data, the toxicology database for lambda-cyhalothrin is complete. The Agency has determined that the special FQPA safety factor should be reduced to 1x because as noted above, there is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with cyhalothrin and there is no evidence of increased susceptibility of young rats in the reproduction study