

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 (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 data base 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 with cyhalothrin. The Agency concluded there are no residual uncertainties for pre- and/or postnatal exposure. The RfDs and other endpoints established for risk assessment are protective of pre-/postnatal toxicity following exposure to cyhalothrin.

### D. 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 estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking 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 residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to lambda-cyhalothrin in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of lambda-cyhalothrin on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to lambda-cyhalothrin will occupy 41% of the aPAD for the U.S. population, 24% of the aPAD for females 13 years and older, 71% of the aPAD for all infants <1 year old and 82% of the aPAD for children 1–6 years old. In addition, despite the potential for acute dietary exposure to lambda-cyhalothrin in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of lambda-cyhalothrin in surface and