

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 metolachlor and s-metolachlor they are further discussed in the aggregate risk sections below.

Based on the National Water Quality Assessment Database (parent) and the FIRST Model (ESA and OA metabolites) and SCI-GROW models the estimated environmental concentrations (EECs) of parent metolachlor and its degradates for acute exposures are estimated to be 201 parts per billion (ppb) (parent: 77.6 ppb, ESA: 31.9 ppb, and OA: 91.4 ppb) for surface water and 103 ppb (parent: 5.5 ppb, ESA: 65.8 ppb, and OA: 31.7 ppb) for ground water. The EECs for chronic exposures are estimated to be 92 ppb (parent: 4.3 ppb, ESA: 22.8 ppb, and OA: 65.1 ppb) for surface water and 103 ppb (parent: 5.5 ppb, ESA: 65.8 ppb, and OA: 31.7 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).

i. *Handlers.* Metolachlor and s-metolachlor are registered (as an emulsifiable concentrate formulation) for use on lawn, turf (including sod farms), golf courses, sports fields, and ornamental gardens. Although metolachlor is not labeled as a restricted-use pesticide, it is not intended for homeowner purchase or use. On this basis, a residential handler is not expected to be exposed to residues of metolachlor and s-metolachlor. Therefore, a residential handler assessment was not conducted.

ii. *Postapplication.* There is potential for postapplication exposure to adults and children resulting from the use of metolachlor/s-metolachlor on residential lawns. Although the use sites for metolachlor and s-metolachlor vary from golf courses to ornamental gardens, the residential lawn scenario represents what the Agency considers to be the likely upper-end of possible exposure. Postapplication exposures from various activities following lawn treatment are

considered to be the most common and significant in residential settings.

Postapplication exposure is considered to be short-term (one to 30 days of exposure) only, based on a label specification of a six week interval before the re-application of metolachlor/s-metolachlor. The registrant has also indicated a label revision to limit application to one time per season.

A short-term dermal endpoint was not selected because no systemic toxicity was seen at the limit dose of 1,000 mg/kg/day. As a result, a dermal risk assessment was not conducted and dermal risks are assumed to be minimal. Postapplication inhalation exposure is expected to be minimal since metolachlor and s-metolachlor are only applied in an outdoor setting, the vapor pressure is low (2.8×10^{-5} mm Hg at 25°C), and the label specifies that residents should not re-enter treated areas until after sprays have dried.

The following postapplication incidental oral scenarios which result from application to lawns and turf have been identified:

a. Short-term oral exposure to toddlers and children following hand-to-mouth exposure;

b. Short-term oral exposure to toddlers and children following object-to-mouth exposure; and

c. Short-term oral exposure to toddlers and children following soil ingestion. The term "incidental" is used to distinguish the inadvertent oral exposure of small children from exposure that may be expected from treated foods or residues in drinking water.

As the FQPA safety factor for the protection of children and infants was reduced to 1x, a target MOE value of 100 has been identified for residential assessments. MOE values greater than 100 are not considered to be of concern to the Agency. MOE estimates are based on the dose level of 50 mg/kg/day established for short-term oral risk assessment.

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 s-metolachlor 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, s-metolachlor 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 s-metolachlor 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—i. Prenatal developmental toxicity study—Metolachlor—Rat.* The maternal toxicity LOAEL was 1,000 mg/kg/day based on an increased incidence of death, clinical signs of toxicity (clonic and/or toxic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive lacrimation) and decreased body weight gain. The NOAEL was 300 mg/kg/day.

The developmental toxicity LOAEL was conservatively established at 1,000 mg/kg/day based on slightly decreased number of implantations per dam, decreased number of live fetuses/dam, increased number of resorptions/dam and significant decrease in mean fetal body weight. The NOAEL was 300 mg/kg/day.

ii. *Prenatal developmental toxicity study—S-metolachlor—Rat.* The maternal toxicity NOAEL was 50 mg/kg/day with a LOAEL of 500 mg/kg/day based on increased clinical signs of toxicity, decreased body weights and body weight gains and reduced food consumption and reduced food efficiency.

No significant treatment related developmental toxicity was noted at the dose levels tested. The developmental toxicity NOAEL was equal to or greater