

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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure in the available toxicity data.

3. *Conclusion.* There is a complete toxicity data base and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor for the protection of infants and children has been reduced to 1X because: (1) The toxicology data base is complete for the FQPA assessment. (2) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to metolachlor in the available toxicity data. (3) a developmental neurotoxicity study is not required for metolachlor. (4) the dietary (food and drinking water) and non-dietary exposure (residential) assessments will not under estimate the potential exposures for infants and children from the use of metolachlor.

E. 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 + residential 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 U.S. EPA 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 ground water are less than the calculated DWLOCs, EPA concludes

with reasonable certainty that exposures to the pesticide 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 residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* The acute aggregate risk assessment addresses potential exposure from combined residues of metolachlor/S-metolachlor on food and total residues of metolachlor/S-metolachlor plus ESA and OA degradates in drinking water (surface water and ground water). Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to metolachlor/S-metolachlor will occupy <1% of the aPAD for the U.S. population and all other population subgroups. In addition, there is potential for acute dietary exposure to metolachlor/S-metolachlor and the ESA and OA degradates in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO METOLACHLOR/S-METOLACHLOR

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	3.0	<1	200.9	103	104856.1
Infants <1 year	3.0	<1	200.9	103	29931.45
Children 1 to 2 years old	3.0	<1	200.9	103	29917.76
Females 13 to 49 years old	3.0	<1	200.9	103	89915.55

2. *Chronic risk.* The chronic aggregate risk assessment addresses potential exposure from combined residues of metolachlor/S-metolachlor on food and total residues of metolachlor/S-metolachlor plus ESA and OA degradates in drinking water (surface water and ground water). There are no residential uses that result in chronic

residential exposure to S-metolachlor. EPA has concluded that chronic exposure to metolachlor/S-metolachlor from food will utilize 2% of the cPAD for the U.S. population, 4% of the cPAD for children 1 to 2 years old, the subpopulations at greatest exposure and 1% of the cPAD for females 13 to 49 years old. In addition, there is potential

for chronic dietary exposure to metolachlor/S-metolachlor and ESA and OA degradates in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2: