

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR S-METOLACHLOR FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-Term Inhalation (several months to lifetime) (Residential)	Inhalation (or oral) study NOAEL= 9.7 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Chronic toxicity study in dogs LOAEL = 33.0 mg/kg/day based on decreased body weight gain in females
Cancer (oral, dermal, inhalation)	Metolachlor has been classified as a Group C, possible human carcinogen. This classification was based on the occurrence of liver tumors in rats at the highest dose level tested (150 mg/kg/day). The carcinogenic risks for metolachlor have been quantitated using a non-linear approach, with a NOAEL of 15 mg/kg/day. However, the NOAEL of 15 mg/kg/day that was established based on liver tumors in rats is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the chronic reference dose for metolachlor. It is assumed that the chronic dietary endpoint is protective for cancer dietary exposure. Therefore, a separate cancer aggregate risk assessment was not conducted, and cancer DWLOC values were not calculated.		

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* S-metolachlor, [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide], is a member of the chloroacetanilide class of herbicides. In this risk assessment the term s-metolachlor will refer to a metolachlor product which is enriched in the S-isomer. The term metolachlor will refer to a racemic mixture of the R and S isomers. Currently, there are permanent tolerances for metolachlor (40 CFR 180.368) on a variety of crops and animal commodities. These tolerances range from 0.02 ppm to 30 ppm. There are also time-limited tolerances (in conjunction with section 18 uses) on grass, spinach, and tomatoes. Risk assessments were conducted by EPA to assess dietary exposures from metolachlor and s-metolachlor 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The analyses assumed tolerance-level residues (with the exception of those with DEEM default processing factors) and 100% crop treated for all commodities.

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 USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The analyses assumed tolerance-level residues (with the exception of those with DEEM default processing factors) and 100% crop treated for all commodities.

iii. *Cancer.* Metolachlor has been classified as a Group C, possible human carcinogen. This classification was based on the occurrence of liver tumors in rats at the highest dose level tested (150 mg/kg/day). The carcinogenic risks for metolachlor have been quantitated using a non-linear approach, with a NOAEL of 15 mg/kg/day. However, the NOAEL of 15 mg/kg/day that was established based on liver tumors in rats is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the chronic reference dose for metolachlor. It is assumed that the chronic dietary endpoint is protective for cancer dietary exposure. Therefore, a separate cancer aggregate risk assessment was not conducted, and cancer DWLOC values were not calculated.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for s-metolachlor in drinking water. Because the Agency does not have comprehensive monitoring data for both parent and the degradates of concern in drinking water, exposure from drinking water is being addressed through modeled estimated environmental concentrations (EECs) and the use of drinking water levels of comparison

(DWLOCs). This assessment includes concentrations of parent metolachlor and the degradates metolachlor ethanesulfonic acid (ESA) and metolachlor oxanilic acid (OA). Although it was determined by the Agency that the ESA and OA metabolites appear to be less toxic than parent metolachlor, they are included in this risk assessment because they were found in greater abundance than the parent in water monitoring studies.

The surface water EECs were derived from the National Water Quality Assessment Database (parent) and the FIRST Model (ESA and OA metabolites). The SCI-GROW Model was used to generate all ground-water EECs. 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