

used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by the appropriate UF ($RfD = NOAEL/UF$). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Percent Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL/exposure$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure}/\text{exposures}$) is calculated. A summary of the toxicological endpoints for S-metolachlor used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 2, 2003 (68 FR 15945) (FRL-7299-8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances established for metolachlor (40 CFR 180.368(a)(1) and (c)) currently cover residues of S-metolachlor on the same commodities for the same use pattern when the maximum labeled use rate of S-metolachlor is approximately 35% less than the historical use rate of metolachlor. Tolerances have also been established (40 CFR 180.368(a)(2)) for the combined residues of S-metolachlor, in or on a variety of raw agricultural commodities. Time-limited tolerances are established for metolachlor and S-metolachlor (40 CFR 180.368(b)) in support of section 18 emergency exemptions. Risk assessments were conducted by EPA to assess combined 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 1 day or single exposure. In conducting this acute dietary risk assessment, EPA used the Dietary Exposure Evaluation Model (DEEM) software with the Food Commodity Intake Database (FCID) which incorporates food consumption data as reported by respondents in the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. A conservative Tier 1 acute dietary exposure assessment was conducted for all labeled metolachlor and all labeled and proposed S-metolachlor food uses using 100% crop treated (CT) and tolerance level residues.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, EPA used the DEEM software with the FCID which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. A conservative Tier 1 combined, chronic dietary exposure assessment was conducted for all labeled metolachlor and all labeled and proposed S-metolachlor food uses using 100% CT and tolerance level residues.

2. *Dietary exposure from drinking water.* The environmental fate data base is complete for S-metolachlor. Parent metolachlor/S-metolachlor appear to be moderately persistent to persistent, and range from mobile to highly mobile in different soils. Metolachlor and S-

metolachlor are expected to have similar degradation pathways and rates in soil and water environments. This assessment includes concentrations of parent metolachlor/S-metolachlor and the degradates metolachlor ethane sulfonic acid (ESA) and metolachlor oxanilic acid (OA). Although it was determined that the ESA and OA metabolites appear to be less toxic than parent metolachlor/S-metolachlor, they are included in this risk assessment since they were found in greater abundance than the parent in water monitoring studies. No surface or ground water monitoring studies that specifically target metolachlor/S-metolachlor were available for the drinking water assessment. As a result, the drinking water assessment for parent metolachlor/S-metolachlor is based primarily on monitoring data from the following sources: The U.S. Geological Survey (USGS) National Water Quality Assessment (NAWQA) data base, the U.S. EPA STORET data base, the Acetochlor Registration Partnership (ARP) data base, and two USGS reservoir monitoring studies.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will 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. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and include a PC area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

The acute estimated environmental concentration (EEC) of 77.6 parts per billion (ppb) was selected from the NAWQA data base, and the chronic EEC of 4.3 ppb was selected from the maximum annual time weighted mean from the NAWQA data. These values represent the estimated concentration of parent metolachlor/S-metolachlor in surface water, and are supported by the metolachlor concentrations from the National Contaminant Occurrence Data base representing analysis of treated drinking water, as well as from model predictions using PRZM/EXAMS. When the monitoring data and modeling data are considered together, there is a general agreement between the various