

completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects and no such effects were noted in any of the studies with mesosulfuron-methyl.

C. Aggregate Exposure

1. *Dietary exposure.* Mesosulfuron-methyl is proposed for use as an herbicide on cereals. No non-agricultural uses are anticipated. The potential sources of exposure would consist of any potential residues in food and drinking water.

i. *Food.* Chronic dietary analysis was conducted to estimate exposure to potential mesosulfuron-methyl residues in/on wheat. A Tier I analysis was conducted using the DEEM™ software and the 1994–1996 Continuing Survey of Food Intake by Individuals (CSFII) food consumption data. It was assumed that residues were at tolerance levels of 0.03 ppm in grain and that 100% of crop was treated. Additionally, based on the results from appropriate studies, it was assumed that there was no concentration into processed commodities and that contributions from residues in meat, milk or eggs are not required. A chronic RfD of 1 mg/kg/day is derived from the 18-month mouse NOAEL of 103 mg/kg bwt/day, applying an uncertainty factor of 100 to account for intra-species variation and inter-species extrapolation. Using these input parameters, chronic exposure estimates for the U.S. population and all 25 population subgroups utilized less than 0.01% of the chronic reference dose. The most highly exposed population subgroup was non-nursing infants (<0.01% cRfD). These values are highly conservative, having been based on worst case assumptions of tolerance level residues and 100% of the crop treated.

ii. *Drinking water.* EPA's standard operating procedure (SOP) for drinking water exposure and risk assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct a screening level drinking water assessment. These tools include water models such as Screening Concentration in Groundwater (SCI-GROW), Generic Expected Environmental Concentration (GENEEC), EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZMS/EXAMS), the Food Quality Act (FQPA) Index Reservoir Screening Tool, and monitoring data. If monitoring data are not available, then

models are used to predict potential residues in surface water and ground water and the highest value is assumed to be the potential drinking water residue. In the case of mesosulfuron-methyl, monitoring data do not exist; therefore, a Tier 1 model calculation was conducted to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for chronic exposures for adults is 35,000 ppb (35 ppm). The chronic DWLOC for children/toddlers is 15,000 ppb (15 ppm). The worst case chronic drinking water estimated concentration (DWECC) is 0.105 ppb based on the FQPA Index Reservoir Screening Tool simulation of runoff into surface water in a standard EPA exposure assessment scenario. The calculated DWLOCs for chronic exposures for all adults and children, therefore, greatly exceed the DWECCs from the models.

2. *Non-dietary exposure.* Exposure to mesosulfuron-methyl for the mixer/loader/ground boom/aerial applicator was calculated using the Pesticide Handlers Exposure Database (PHED). It was assumed that the product would be applied to a maximum of 32 hectares per day (80 A/day) by ground boom applicator and 140 hectares per day (350 A/day) by aerial applicator at a maximum use rate of 15 grams active ingredient/hectares (a.i./ha.) Normal work attire consisting of long-sleeved shirt, long pants, and protective gloves was assumed in the PHED assessment. Margin of exposures (MOEs) for a 70 kg operator were calculated utilizing the NOAEL of 648 mg/kg body weight/day from the 90-day dog dietary study, which is adjusted for a 15% dermal absorption as revealed in an *in vivo* dermal absorption study, and 100% inhalation absorption to obtain the absorbed dermal and inhalation dose, respectively. The combined MOE (inhalation plus dermal) for mesosulfuron-methyl was 3,240,000 for a ground operator undertaking mixing, loading and spraying. For aerial application where the mixer/loader was assumed to be a different operator from the pilot, combined MOEs were 926,000 for the mixer/loader and 12,000,000 for the pilot. The results indicate that large margins of safety exist for the proposed use of mesosulfuron-methyl.

D. Cumulative Effects

There is no available data at this time to determine whether mesosulfuron-methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Therefore, a cumulative assessment was not done for this chemical.

E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure, in this case food only, to the proposed uses of mesosulfuron-methyl will utilize <0.01% of the reference dose for the U.S. population. The actual exposure is likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. Drinking water levels of comparison based on the dietary exposure are much greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to mesosulfuron-methyl.

2. *Infants and children.* No evidence of increased sensitivity to fetuses was noted in developmental toxicity studies in rats or rabbits. There has been no indication of reproductive effects or indication of increased sensitivity to the offspring in the 2-generation rat reproduction study. No additional safety factor to protect infants and children is necessary as there is no evidence of increased sensitivity in infants and children.

Using the conservative assumptions described in the exposure section above, the percent of the reference dose that will be used for exposure to residues of mesosulfuron-methyl in food for non-nursing infants (the most highly exposed sub group) is <0.01%. The children (1–6) exposure uses are also <0.01% of the reference dose. As in the adult situation, drinking water levels of comparison are much higher than the worst case drinking water estimated concentrations and are expected to use well below 100% of the reference dose, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of mesosulfuron-methyl.

F. International Tolerances

There are no Codex Alimentarius Commission maximum residue levels established for residues of mesosulfuron-methyl.

[FR Doc. 03-26670 Filed 10-21-03; 8:45 am]

BILLING CODE 6560-50-S