

vegetables, fruiting vegetables (except cucurbits), leafy vegetables, head lettuce, bulb and green onions, pecans, rice grain, rice hulls, rice straw, sorghum forage, sorghum grain, sorghum stover, soybean seed, succulent shelled peas and beans, sugarcane, wheat forage, wheat grain, wheat hay, wheat straw, meat, fat, and meat byproducts of cattle, goats, hogs, horses, and poultry, eggs, milk and milk fat. For the purposes of assessing the potential dietary exposure for these existing and the subject proposed tolerances, FMC Corporation has utilized available information on anticipated residues, monitoring data and percent crop treated as follows:

i. *Acute exposure and risk.* Acute dietary exposure 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. For the purposes of assessing acute dietary risk for zeta-cypermethrin, FMC Corporation has used the NOAEL of 10.0 mg/kg/day from the zeta-cypermethrin acute neurotoxicity study in rats with an UF of 100 (acute RfD = 0.10 mg/kg/day). The LEL of 50.0 mg/kg/day was based on clinical signs. This acute dietary endpoint is used to determine acute dietary risks to all population subgroups. Available information on anticipated residues, monitoring data and percent crop treated was incorporated into a Tier 3 analysis, using Monte Carlo modeling for commodities that may be consumed in a single serving. These assessments show that the percent acute PAD all fall below EPA's level of concern ($\geq 100\%$). The 95th percentile of exposure for the overall U.S. population was estimated to be 0.001177 mg/kg/day (percent acute RfD of 1.2); 99th percentile 0.003307 mg/kg/day (percent acute RfD of 3.3); and 99.9th percentile 0.012692 mg/kg/day (percent acute RfD of 12.7). The 95th percentile of exposure for all infants <1-year old was estimated to be 0.002441 mg/kg/day (percent acute RfD of 2.4); 99th percentile 0.011178 mg/kg/day (percent acute RfD of 11.2); and 99.9th percentile 0.029462 mg/kg/day (percent acute RfD of 29.5). The 95th percentile of exposure for nursing infants <1-year old was estimated to be 0.001247 mg/kg/day (percent acute RfD of 1.3); 99th percentile 0.004540 mg/kg/day (percent acute RfD of 4.5); and 99.9th percentile 0.011659 mg/kg/day (percent acute RfD of 11.7). The 95th percentile of exposure for non-nursing infants <1-year old (the most highly exposed population subgroup) was estimated to be 0.002786 mg/kg/day (percent acute RfD of 2.8);

99th percentile 0.012899 mg/kg/day (percent acute RfD of 12.9); and 99.9th percentile 0.033071 mg/kg/day (percent acute RfD of 33.1). The 95th percentile of exposure for children 1 to 6 years old and children 7 to 12 years old was estimated to be, respectively, 0.001942 mg/kg/day (percent acute RfD of 1.9) and 0.001244 mg/kg/day (percent acute RfD of 1.2); 99th percentile 0.005670 mg/kg/day (percent acute RfD of 5.7) and 0.003082 (percent acute RfD of 3.1); and 99.9th percentile 0.018280 mg/kg/day (percent acute RfD of 18.3) and 0.009335 (percent acute RfD of 9.3). The 95th percentile of exposure for females (13+/nursing) was estimated to be 0.001128 mg/kg/day (percent acute RfD of 1.1); 99th percentile 0.003112 mg/kg/day (percent acute RfD of 3.1); and 99.9th percentile 0.012903 mg/kg/day (percent acute RfD of 12.9). Therefore, FMC Corporation concludes that the acute dietary risk of zeta-cypermethrin, as estimated by the dietary risk assessment, does not appear to be of concern.

ii. *Chronic exposure and risk.* The chronic RfD of 0.06 mg/kg/day for zeta-cypermethrin is based on a NOAEL of 6.0 mg/kg/day from a cypermethrin chronic feeding study in dogs and an UF of 100. The endpoint effect of concern was based on clinical signs. A chronic dietary exposure/risk assessment has been performed for zeta-cypermethrin using the above chronic RfD. Available information on anticipated residues, monitoring data and percent crop treated was incorporated into the analysis to estimate the anticipated residue contribution (ARC). The ARC is generally considered a more realistic estimate than an estimate based on tolerance level residues. The ARC is estimated to be 0.000184 mg/kg body weight (bwt)/day and utilize 0.3% of the chronic RfD for the overall U.S. population. The ARC for non-nursing infants (<1-year) (subgroup most highly exposed) is estimated to be 0.000666 mg/kg bwt/day and utilizes 1.1% of the chronic RfD, respectively. The ARCs for children 1 to 6 years old and children 7 to 12 years old are estimated to be 0.000477 mg/kg bwt/day and 0.000254 mg/kg bwt/day and utilizes 0.8% and 0.4% of the chronic RfD, respectively. The ARC for females (13+/nursing) is estimated to be 0.000180 mg/kg bwt/day and utilizes 0.3% of the RfD. Generally speaking, EPA has no cause for concern if the total dietary exposure from residues for uses for which there are published and proposed tolerances is less than 100% of the chronic RfD. Therefore, FMC Corporation concludes that the chronic dietary risk of zeta-

cypermethrin, as estimated by the dietary risk assessment, does not appear to be of concern.

iii. *Drinking water.* Laboratory and field data have demonstrated that cypermethrin is immobile in soil and will not leach into ground water. Other data show that cypermethrin is virtually insoluble in water and extremely lipophilic. As a result, FMC Corporation concludes that residues reaching surface waters from field runoff will quickly adsorb to sediment particles and be partitioned from the water column. Drinking water estimated concentrations (DWECS) and the corresponding drinking water level of comparison (DWLOCs) values were calculated for chronic and acute exposures. The results show that all DWLOC values exceed the DWECS values. Thus, exposure to zeta-cypermethrin and cypermethrin residues in drinking water is not of concern.

EPA's draft Standard Operating Procedures (SOP) for incorporating estimates of drinking water exposure into aggregate risk assessments was used to perform a drinking water analysis. This SOP utilizes a variety of tools to conduct drinking water assessment. These tools include water models such as (Food Quality Protection Act (FQPA) FQPA Index Reservoir Screening Tool (FIRST)), EPA Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), Screening Concentration in Groundwater (SCI-GROW), and monitoring data. If monitoring data are not available then the models are used to predict potential residues in drinking water. The technique recommended in drinking water SOP compares a calculated DWLOC value to the DWECS value. The DWECS value results from either the monitoring data residues or modeled water residues. If the DWLOC value exceeds the DWECS value then there is reasonable certainty that no harm will result from the acute or chronic aggregate exposure.

In the case of cypermethrin and zeta-cypermethrin, monitoring data do not exist. Therefore, the FIRST model was used to estimate a surface water residue. The risk assessment for drinking water compares two values: The DWLOC and the DWECS. The DWLOC is the maximum allowable drinking water concentration (in part per billion (ppb)). The DWECS is derived either from monitoring studies or from modeling. If the DWLOC is greater than the DWECS, then the overall exposure from water, food, and residential is considered to be acceptable. The calculated DWLOC values for acute and chronic exposures for all adults, adult females, and