

uses average field trial residue data with  $\frac{1}{2}$  LOQ substitutions for all non-detectable residues. In addition, a residue value of 0.011 ppm ( $\frac{1}{2}$  LOQ) and a percent crop treated value of 6.6% were used for all corn commodities. For the remaining registered and the proposed commodities listed above, the following residue data was used in the DEEM™: Cucurbit, leafy and brassica vegetables and tomatoes - average field trial residues from soil-only application residue studies; stone fruits, mint, succulent beans, sunflower seed, and coffee - average field trial residue data with  $\frac{1}{2}$  LOQ substitutions for non-detectable residues; and pecans - the proposed tolerance.

In regard to the cucurbit vegetables and tomatoes, the current tolerances are based upon soil and foliar uses; however, Syngenta is currently limiting the use of thiamethoxam in these crops to soil only applications - thus, the refinement in DEEM™ inputs described above. Likewise, the proposed tolerances on leafy vegetables, leafy brassica vegetables and head and stem brassica vegetables are based upon soil and foliar applications of thiamethoxam; however, Syngenta is currently pursuing only the soil application use - thus, the refinement of DEEM inputs described above. Syngenta will pursue foliar applications for these crops at a later date; therefore, the proposed and current tolerances on these crops remain based upon soil and foliar applications.

All consumption data for these assessments was taken from the USDA's Continuing Survey of Food Intake by Individuals (CSFII) with the 1994-96 consumption data base and the supplemental CSFII children's survey (1998) consumption data base. For the chronic assessments, the following percent of crop treated values were used for the proposed uses: Coffee, 16.7%; sunflower, 15%; mint, 10%; leaf lettuce, 24.6%; head lettuce, 32%; spinach and cress, 15.6%; all other leafy vegetables, 19.4%; broccoli, 26.2%, cabbage, 15.3%; all other brassica vegetables 17.2%; beans, 20%; stone fruits, 15%; and pecans, 100%. A percent crop treated value of 5% was used for apples and a value of 6.6% was used for all corn commodities. All other percent of crop treated values were taken from the August 28, 2000 EPA assessment.

i. *Food.* For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection has estimated aggregate exposure from all crops for which tolerances are established or proposed. The Tier I acute assessment utilized tolerance values and 100% of crop

treated values. The Tier III chronic assessments utilized the residue and percent of crop treated values described above.

a. *Acute exposure.* An acute reference dose of 0.10 mg/kg bwt/day for all population subgroups was based on a NOAEL of 100 mg/kg bwt/day from an acute neurotoxicity study in rats and an uncertainty factor of 100X (100X for combined interspecies and intraspecies variability). An additional Food Quality Protection Act (FQPA) safety factor of 10X was applied to all population subgroups due to the absence of a developmental neurotoxicity study. For the purpose of aggregate risk assessment, the exposure value was expressed in terms of margin of exposure (MOE). The MOE was calculated by dividing the NOAEL by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the acute reference dose (%aRfD). Acute exposure to the most exposed subpopulation (children 1-6 years old) resulted in a MOE of 6,452 (15.5% of the aRfD of 0.10 mg/kg/ bwt/day) at the 95<sup>th</sup> percentile of exposure. Since the benchmark MOE for this assessment was 1,000, and since EPA generally has no concern for exposures below 100% of the aRfD, Syngenta believes that there is a reasonable certainty that no harm will result from acute dietary (food) exposure to residues arising from the current and proposed uses for thiamethoxam chronic exposure.

b. *Chronic exposure.* The chronic reference dose (cRfD) for thiamethoxam is 0.0006 mg/kg/ bwt/day for all population subgroups and is based on a NOAEL of 0.6 mg/kg/bwt/day from a two generation rat reproduction study. An uncertainty factor of 100X (for combined interspecies and intraspecies variability) and an additional FQPA safety factor of 10X was applied due to evidence of increased susceptibility to young rats following prenatal/postnatal exposure. Exposure was expressed as MOE and percent of the reference dose (%RfD). Chronic exposure to the most exposed subpopulation (non-nursing infants) resulted in a MOE of 11,538 (8.6% of the cRfD of 0.0006 mg/kg/bw/day). Since the benchmark MOE for this assessment was 1,000 and since EPA generally has no concern for exposures below 100% of the RfD, Syngenta believes that there is a reasonable certainty that no harm will result from chronic dietary (food) exposure to residues arising from the current and proposed uses for thiamethoxam.

c. *Lifetime exposure.* The Q\* value for thiamethoxam is 0.0377 (mg/kg/day)<sup>-1</sup> and is based on benign and malignant

heptocellular tumors in mice in an 18-month carcinogenicity study. Lifetime exposure to the U.S. population resulted in a lifetime risk of  $8.17 \times 10^{-7}$  which represents 81.7% of EPA's lifetime risk limit of  $1.0 \times 10^{-6}$ .

ii. *Drinking water.* EPA used the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. 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. Based on the SCI-GROW and PRZM/EXAMS models, EPA calculated that estimated environmental concentrations of thiamethoxam at the highest use rate (0.125 lb a.i./acre) are 1.9 parts per billion (ppb) for acute and chronic exposure to ground water and 11.4 ppb and 0.77 ppb for acute and chronic exposure, respectively, to surface water. Based on field and laboratory data as well as on going prospective ground water monitoring studies, Syngenta believes that the potential exposure to ground water is much lower than that predicted by the conservative SCI-GROW model.

Preliminary results from the prospective ground water monitoring studies have indicated no detections of thiamethoxam in ground water. EPA determined estimated environmental concentrations (EECs) are used for comparison to Drinking Water Levels of Comparison (DWLOC).

a. *Acute drinking water risk.* Acute DWLOCs were calculated based on an acute populated adjusted dose (aPAD) of 0.1 mg/kg/day. For the acute assessment, the children (1-6 yrs) subpopulation generated the lowest acute DWLOC of approximately 845 ppb. EPA has determined that the surface water acute EEC is 11.4 ppb and the ground water EEC is 1.9 ppb. Since the surface water value is greater than the ground water value, the surface water value will be used for comparison purposes and will protect for any concerns for ground water concentrations. Since the acute DWLOC of 845 ppb is considerably higher than the acute EEC of 11.4 ppb, Syngenta believes that EPA should not have a concern for acute risk to either surface or ground water.