

current and previously submitted field trial data as well as EPA percent crop treated (PCT) estimates for a number of commodities. PCT estimates used were 1% for cotton commodities; 52% for head lettuce; 2.5% for the subgroup 4A (leafy greens); 20% for the subgroup 4B (leaf petioles), the group 5 (*Brassica* leafy vegetables), and peppers; and 11% for tomatoes and its processing commodities. Anticipated residues were used for group 5 (*Brassica* leafy vegetables), group 4 (leafy vegetables (except *Brassica*)), and group 8 (fruiting vegetables). The calculation of anticipated residues for tomatoes (a representative commodity in group 8) used the following approach: For residues of MAB<sub>1a</sub> and MAB<sub>1b</sub> which were below the limit of detection (< LOD), calculation was based on the MAB<sub>1a</sub> and MAB<sub>1b</sub> ratio of 9:1; a residue value of 0.0005 ppm ( $\frac{1}{2}$  LOD) for MAB<sub>1a</sub> and a residue value of 0.000055 ppm ( $\frac{1}{9}$  of the  $\frac{1}{2}$  LOD or  $\frac{1}{18}$  LOD) for MAB<sub>1b</sub> was reported in the assessment. For residues of L'649 and (L'599 + L'831), a residue value of 0.0005 ppm (the  $\frac{1}{2}$  LOD) was reported if residues were below the limit of detection (<LOD). Anticipated residue levels of 0.0003 ppm for milk and skim milk, and 0.0009 ppm for cream were used. The recommended tolerance level residues were used for all other crops and meat products. Additionally, default DEEM® (version 7.76) concentration factors were used when necessary.

The acute dietary exposure estimates are below EPA's level of concern (< 100% aPAD) at the 99.9<sup>th</sup> exposure percentile for the general U.S. population (29% of the aPAD) and all other population subgroups. The most highly exposed population subgroup is children 3–5 years old, at 58% of the aPAD. The acute assessment was highly refined, however, inclusion of additional PCT data and modified concentration/processing factors could aid in further refining the acute dietary assessment.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue

consumption estimate for each food/food-form is summed with the residue consumption estimates for all other food/food-forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup. A somewhat refined Tier 2 chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. The assumptions of the assessment were tolerance level residues for all commodities except milk (for which anticipated residue estimates were used), and PCT estimates for a number of commodities. PCT estimates used were 0.4% for cotton commodities; 26% for head lettuce; 1.5% for the subgroup 4A (leafy greens); 10% for the subgroup 4B (leaf petioles), the group 5 (*Brassica* leafy vegetables), and peppers; and 6% for tomatoes and its processing commodities. Anticipated residue levels of 0.0003 ppm for milk and skim milk, and 0.0009 ppm for cream were used. The recommended tolerance level residues were used for all other crops and meat products. Additionally, default DEEM® (version 7.76) concentration factors were used when necessary.

The chronic dietary exposure estimates are below HED's level of concern (<100% cPAD) for the general U.S. population (19% of the cPAD) and all population subgroups. The most highly exposed population subgroup is children 1–2 years old, at 34% of the cPAD. The chronic assessment was somewhat refined; inclusion of ARs, additional PCT information, and modified concentration/processing factors would further refine the chronic dietary assessment.

iii. *Cancer.* Emamectin is classified as a "not likely" human carcinogen based on the lack of evidence of carcinogenicity in male and female rats or male and female mice at doses that were judged to be adequate to assess the carcinogenic potential of the chemical.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to

require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as detailed above under Unit III.C.1.i and III.C.1.ii. Different PCTs and anticipated residues were used for the acute versus the chronic dietary risk from food and feed uses as explained in these units.

The Agency believes that the three conditions listed in Unit III.C.1.iv have been met. With respect to Condition 1, PCT estimates for existing registrations are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. For new uses, PCT