

EPA has not made any decisions about whether thiophanate methyl meets EPA's registration requirements for use on mushroom or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of thiophanate methyl by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Delaware, Maryland, and Pennsylvania to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for thiophanate methyl, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of thiophanate methyl and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of thiophanate methyl in or on mushroom at 0.01 ppm.

The most recent estimated aggregate risks resulting from the use of thiophanate methyl, are discussed in the **Federal Register** for August 28, 2002 (67 FR 55137) (FRL-7192-1), final rule establishing tolerances for residues of thiophanate methyl in/on grapes, pears, potatoes, canola, and pistachios. Available residue data did not indicate that this use pattern will result in residues of thiophanate methyl in mushrooms over the limit of quantitation (LOQ), 0.01 ppm. Therefore, a tolerance is being established for mushroom at this level. Incremental addition of mushrooms at this level to dietary exposure, from existing food/feed uses, is negligible. Additionally, the results for this section 18 use do not alter the current aggregate

exposure assessments with respect to drinking water or residential exposure. Refer to the August 28, 2002 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon that risk assessment and the findings made in the **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. A summary of the toxicological dose and endpoints for thiophanate methyl for use in human risk assessment is discussed in the final rule mentioned above, published in the **Federal Register** of August 28, 2002 (67 FR 55137).

For thiophanate methyl, the Agency recently modified the tolerance expression, so that the residues to be regulated in plant and animal commodities for purposes of tolerance enforcement will consist of the residues of thiophanate methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC)), expressed as thiophanate methyl.

Exposure from the use of benomyl, another pesticide which degrades under environmental conditions to MBC was not included in this assessment because the only basic registrant of benomyl requested voluntary cancellation of all benomyl-containing products in April 2001. Product cancellations were effective in early 2001 with sales and distribution of benomyl-containing products ending by December 31, 2001. However, the Agency conducted a dietary assessment using USDA Pesticide Data Program (PDP) monitoring data for benomyl, measured as MBC to estimate residues of thiophanate methyl because MBC is a common metabolite of both benomyl and thiophanate methyl. PDP data were available for apples, bananas, beans, cucurbits, peaches, and strawberries. The PDP analytical method employs a hydrolysis step that converts any benomyl present to MBC. MBC is then quantitated and corrected for molecular weight, and results are measured as the sum of benomyl and MBC. Therefore, using MBC data to estimate thiophanate methyl residues may be a conservative approach in that it may over estimate thiophanate methyl residues.

EPA assessed risk scenarios for thiophanate methyl under acute, chronic, and short- and intermediate-term exposures.

The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

For the acute exposure assessments, maximum percent crop treated estimates and anticipated residue estimates were used.

Using these exposure assumptions, EPA concluded that acute dietary exposure to thiophanate methyl uses 10% of the acute Population Adjusted Dose (aPAD) for the general U.S. population and 25% of the aPAD for the most highly exposed population subgroup of concern, infants (< 1 year). For MBC, the acute dietary risk estimate uses 4% of the aPAD for the general U.S. population and 89% of the aPAD for the population subgroup of concern, infants (< 1 year). The total thiophanate methyl plus MBC acute dietary risk estimate for the population subgroup of concern, females (13-50 years) uses 51% of the aPAD. The drinking water assessment, based on simultaneous dietary exposure to both MBC and thiophanate methyl (which was converted to MBC equivalents) resulted in the following Drinking Water Levels of Concern (DWLOCs): Infants (< 1 year) 18 ppb; children (1-6 years) 57 ppb; females (13-50 years) 150 - 170 ppb; and general U.S. population 5,700 ppb. The lowest DWLOC for the population subgroup, infants (< 1 year) does not exceed the Estimated Environmental Concentration (EEC) for ground water (0.033 ppb); however, the DWLOC does exceed the EEC for surface water (25 ppb). Although the EEC is exceeded, the DWLOC is greatly inflated because 50% of the aPAD percentage is consumed by citrus which is a 1-year emergency use only. When citrus is removed from the DWLOC estimation, the DWLOC becomes 94 ppb which is well above the EEC of 25 ppb. The DWLOC is significantly lowered by the addition of citrus because field trial data was used which results in an overly conservative estimation.

Another indication that the addition of citrus based on field trial data results in an over estimation is the fact that benomyl PDP data available for citrus indicated that there were zero hits out of 689 Florida samples of orange juice. These data were not used to refine the DWLOC estimation because the benomyl application rate is somewhat