

no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State Agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Thiophanate Methyl on Fruiting Vegetables and FFDCA Tolerances

Benomyl has historically been used to control the disease caused by *sclerotinia sclerotiorum*, more commonly known as white mold, timber rot, or sclerotinia stem rot, in fruiting vegetables, including tomatoes. The recent cancellation of benomyl has left fruiting vegetable producers in Florida, and tomato producers in New Jersey and Virginia without sufficient means to control this disease, and the applicants claim that there are no other registered fungicides or alternative control practices which are effective to control this disease. Thiophanate methyl is related to benomyl, and degrades to the same active compound as benomyl. Field trial data also shows thiophanate methyl to be significantly effective at controlling white mold. It is expected that a similar level of control would be achieved with thiophanate methyl as that achieved in the past with benomyl. Significant economic losses are expected without the requested use of thiophanate methyl. EPA has authorized under FIFRA section 18 the use of thiophanate methyl on fruiting vegetables in Florida, and tomatoes only in New Jersey and Virginia, for control of white mold, also known as timber rot, or sclerotinia stem rot (*sclerotinia sclerotiorum*). After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of thiophanate methyl in or on fruiting vegetables. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is

safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on December 31, 2005, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on fruiting vegetables after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether thiophanate methyl meets EPA's registration requirements for use on fruiting vegetables 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 States other than Florida, New Jersey, or Virginia 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 exemption 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 November 26, 1997 (62 FR 62961) (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 fruiting vegetables at 0.5 ppm.

The most recent estimated aggregate risks resulting from the use of thiophanate methyl, are discussed in the **Federal Register** of 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. In that prior action, risk was estimated assuming tolerance level residues in all commodities for established and proposed tolerances. Available residue data indicate that the use pattern for these emergency exemptions will not result in residues of thiophanate methyl in fruiting vegetables over 0.5 ppm. Therefore, a tolerance is being established for this crop group at this level. The risk assessment related to incremental addition of these items at this level to dietary exposure is discussed below. Refer also to the August 28, 2002 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies in part 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 published in the **Federal Register** of August 28, 2002 (67 FR 55137) (FRL-7192-1). 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, 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