

chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that 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 Exemption for Thymol and Eucalyptus Oil on Honey and Honeycomb and FFDCA Tolerances

The varroa mite is an ectoparasite of honey bees. It was first detected in the continental United States in Maryland in 1979, and found in Florida and Wisconsin by 1987. Currently, it is the most important pest of honey bee colonies. The mites feed on the hemolymph of the developing bee larva, pupa, and adult bees. Dead or dying newly emerged bees have malformed wings, legs, abdomens, and thoraces. Recent anecdotal evidence suggests that bee viruses and varroa mites are closely linked. The mites have been shown to activate some of these viruses; causing virus outbreaks that ultimately lead to colony mortality.

Fluvalinate is currently registered for the control of varroa mites; however, populations of varroa mites have developed resistance to fluvalinate. Varroa mite resistance to fluvalinate has been well documented by the United States Department of Agriculture (USDA), Agricultural Research Service (ARS). According to USDA, ARS many hives treated with fluvalinate have resulted in wholesale colony losses. Due to the destructive nature of this pest coupled with the importance of honey bees (for honey production and pollination of numerous agricultural crops) to the U.S. economy, it is imperative that alternative means of controlling the varroa mite be developed.

The Agency has authorized the use of coumaphos in beehives to control varroa

mites under section 18 of FIFRA since 1999 in up to 46 states. During the 2001 use season there were limited reports of mites resistant to coumaphos in Maine and Florida. Resistance to coumaphos in Florida was confirmed by the USDA's Texas Bee Lab in December of 2001. In Maine, bees are primarily imported during the growing season from Florida. South Carolina has indicated that the beekeeping industry is migratory in nature, especially in the coastal region of the state and subject to the introduction of coumaphos resistant mites from Florida. Therefore, the states have requested use of the unregistered product ApiLife VAR, containing thymol and eucalyptus oil to control mites resistant to coumaphos. EPA has authorized under FIFRA section 18 the use of thymol and eucalyptus oil in beehives for control of varroa mites in Maine, Minnesota, Mississippi, Utah, Indiana, and South Carolina. After having reviewed the submission, 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 thymol and eucalyptus oil in or on honey and honeycomb. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary exemptions from the requirement of a 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 these exemptions without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these exemptions from the requirement of a tolerance will expire and are revoked on June 30, 2005, under section 408(l)(5) of the FFDCA, residues of the pesticide in the tolerance remaining in or on honey and honeycomb after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these exemptions earlier if any experience with, scientific data on, or other relevant information on these pesticides indicate that the residues are not safe.

Because these exemptions from the requirement of a tolerance are being approved under emergency conditions, EPA has not made any decisions about whether thymol and eucalyptus oil meets EPA's registration requirements for use on honey and honeycomb or

whether permanent exemptions for this use would be appropriate. Under these circumstances, EPA does not believe that these exemptions from the requirement of a tolerance serve as a basis for registrations of thymol and eucalyptus oil by a State for special local needs under FIFRA section 24(c). Nor do these exemptions serve as the basis for any State other than Maine and South Carolina to use these pesticides in beehives 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 thymol and eucalyptus oil, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety for Thymol

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 thymol and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for exemptions from the requirement of a tolerance for residues of thymol in or on honey and honeycomb. EPA's assessment of the dietary exposures and risks associated with establishing these exemptions from the requirement of a tolerance follows.

A. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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. The nature of the toxic effects caused by thymol is discussed in this unit.

The EPA has not received nor does it have available any guideline studies on the mammalian toxicity of thymol. Thymol is found naturally occurring in