

US EPA ARCHIVE DOCUMENT



# Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Methyl Eugenol



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

## **CERTIFIED MAIL**

Dear Registrant:

This letter and the attached risk assessment constitute the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision for Methyl Eugenol," which was approved on December 22, 2004. This document is also known as a Tolerance Reassessment Eligibility Decision, or TRED. A Notice of Availability of this TRED will be published shortly in the Federal Register.

### **Regulatory Determination**

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. Once a safety finding has been made, the tolerances are considered reassessed. Existing exemptions from tolerances associated with methyl eugenol must be reassessed in accordance with FFDCA, as amended by FQPA.

The Agency has evaluated the potential risks associated with methyl eugenol and has determined, that there is a reasonable certainty that no harm to any population subgroup will result from dietary and water exposure to methyl eugenol from uses specified in the existing exemption for the requirement for tolerance for methyl eugenol under 40 CFR 180.1067. Therefore, no mitigation measures are needed, and the exemption from the requirement of tolerances established in 40 CFR 180.1067 for residues of methyl eugenol on raw agricultural commodities are now considered reassessed under section 408(q) of the FFDCA.

The Agency has conducted a qualitative risk assessment for potential dietary and water exposures. A residential assessment was not conducted because there are no residential product labels for methyl eugenol. Because of its volatility and because of its use pattern, it is considered unlikely for methyl eugenol to contaminate food or drinking water. This was confirmed by a monitoring study which did not detect methyl eugenol from pesticide sources in fruit collected near sites of methyl

eugenol use. The attached risk assessment presents the Agency's conclusions regarding the potential for adverse effects resulting from methyl eugenol exposures, and forms the basis for this determination.

#### Cumulative Risk

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to methyl eugenol and any other substances, and methyl eugenol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that methyl eugenol has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

#### Tolerance Summary

Methyl eugenol is a bait attractant for non-indigenous, invasive fruit flies of the family Tephritidae in orchards. Methyl eugenol is an important part of the fruit fly control programs in states such as Hawaii, Florida, and California. For example, dibrom (contains naled as an active ingredient) in combination with methyl eugenol is commonly used in traps for both monitoring and eradication of the fruit fly population. Please contact Nathan Mottl with any questions regarding this decision. He may be reached by phone at (703)305-0208 or by e-mail at [mottl.nathan@epa.gov](mailto:mottl.nathan@epa.gov).

Sincerely,

Debra Edwards, Ph.D.  
Director  
Special Review and Reregistration Division

Enclosures

*Risk Assessment for Methyl Eugenol (Methyleugenol).* Memorandum from Kit Farwell to Nathan Mottl, December 16, 2004).