United States Environmental Protection Agency Prevention, Pesticides and Toxic Substances (7508C) EPA 738-F-00-010 October 2000

SEPA Fenitrothion Facts

EPA has assessed the risks of fenitrothion and completed a "Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision for Fenitrothion" for this organophosphate (OP) pesticide. Without risk mitigation, fenitrothion fits into its own "risk cup"-- its individual, aggregate risks are within acceptable levels. Fenitrothion also is eligible for reregistration, pending a full reassessment of the cumulative risk from all OPs.

In July 1995 a RED was issued for fenitrothion. Most uses were canceled during the RED process or subsequent to the issuance of the RED. Currently used in Australia on stored wheat and in the U.S. in containerized ant and roach baits in child resistant packaging, fenitrothion residues in food do not pose risk concerns and exposure resulting from use of the containerized ant and roach baits is expected to be insignificant. Without mitigation fenitrothion fits into its own "risk cup."

EPA's next step under the Food Quality Protection Act (FQPA) is to complete a cumulative risk assessment and risk management decision encompassing all the OP pesticides, which share a common mechanism of toxicity. The interim decision on fenitrothion cannot be considered final until this cumulative assessment is complete. Further risk mitigation may be required at that time.

EPA is reviewing the OP pesticides to determine whether they meet current health and safety standards. Older OPs need decisions about their eligibility for reregistration under FIFRA. OPs with residues in food, drinking water, and other nonoccupational exposures also must be reassessed to make sure they meet the new FQPA safety standard.

The OP Pilot Public Participation Process

The organophosphates are a group of related pesticides that affect the functioning of the nervous system. They are among EPA's highest priority for review under the Food Quality Protection Act.

EPA is encouraging the public to participate in the review of the OP pesticides. Through a six-phased pilot public participation process, the Agency is releasing for review and comment its preliminary and revised scientific risk assessments for individual OPs. (Please contact the OP Docket, telephone 703-305-5805, or see EPA's web site, www.epa.gov/pesticides/op .)

EPA is exchanging information with stakeholders and the public about the OPs, their uses, and risks through Technical Briefings, stakeholder meetings, and other fora. USDA is coordinating input from growers and other OP pesticide users.

Based on current information from interested stakeholders and the public, EPA is making interim risk management decisions for individual OP pesticides, and will make final decisions through a cumulative OP assessment.

The fenitrothion interim decision was made through the OP pilot public participation process, which increases transparency and maximizes stakeholder involvement in EPA's development of risk assessments and risk management decisions. EPA worked extensively with affected parties to reach

the decisions presented in this interim decision document, which concludes the OP pilot process for fenitrothion.

Uses

- An insecticide/acaricide, fenitrothion is used in Australia on stored wheat and there is a U.S. tolerance for imported wheat gluten. The only registered use in the U.S. is for containerized ant and roach baits in child resistant packaging.
- Annual domestic use is low. Annual U.S. consumption of wheat gluten by the food industry is about 250 million pounds; currently approximately 26% (65 million pounds) is imported from Australia. No data are available on percent crop treated in Australia.

Health Effects

• Fenitrothion can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death.

Risks

- Dietary exposures from consuming wheat gluten treated with fenitrothion are below the level of concern for the entire U.S. population, including infants and children. Drinking water is not a source of exposure.
- Risks are not of concern for the use of fenitrothion in containerized ant and roach baits in child resistant packaging. Exposure is expected to be insignificant because the material is not available through the dermal and oral routes; and, due to the small amount of material which would be available through volatilization, inhalation exposure is expected to be minimal.

Risk Mitigation

• No risk mitigation is necessary at this time.

Next Steps

 Numerous opportunities for public comment were offered as this decision was being developed. The fenitrothion IRED therefore is issued as final (see <u>www.epa.gov/pesticides/op</u>), without a formal public comment period. The docket remains open, however, and any comments submitted in the future will be placed in this public docket. • When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for fenitrothion and may require further risk mitigation measures. The Agency will amend the only tolerance for fenitrothion now. The tolerance for wheat gluten imported from Australia will be lowered to 3 ppm and the tolerance expression will be modified to include only the parent compound. For all OPs, raising and/or establishing tolerances will be considered once a cumulative assessment is completed.