

US EPA ARCHIVE DOCUMENT



Profenofos Facts

EPA has assessed the risks of profenofos and reached an Interim Reregistration Eligibility Decision (IRED) for this organophosphate (OP) pesticide. With the risk mitigation measures required, profenofos fits into its own "risk cup"-- its individual, aggregate risks are within acceptable levels. Profenofos also is eligible for reregistration, pending a full reassessment of the cumulative risk from all OPs.

Used only on cotton crops, profenofos residues in food and drinking water do not pose risk concerns. Profenofos has no residential uses, and fits into its own "risk cup." With required mitigation measures, profenofos' worker and ecological risks are believed to be significantly reduced. Additional data have been required to confirm this expectation.

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 profenofos 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. OPs need decisions about their eligibility for reregistration under FIFRA.

Additional OPs with residues in food, drinking water, and other non-occupational exposures also must be reassessed to make sure they meet the new FQPA safety standard.

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

Uses

- An insecticide/miticide, profenofos is a restricted use pesticide used solely on cotton, to control the tobacco budworm, cotton bollworm, armyworm, cotton aphid, whiteflies, spider mites, plant bugs, and fleahoppers. An estimated 85% of all profenofos is used to control lepidopteran species (the worm complex) at varying rates. About 30% of this use is at the maximum label rate of one pound active ingredient per acre.
- Approximately 775,000 pounds of active ingredient are applied to cotton crops each year.
- There are no residential uses of profenofos.

Health Effects

- Profenofos 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 risks from food and drinking water are low for all segments of the population, including children.
- The current occupational risk assessment indicates risk concerns for aerial mixers/loaders and aerial applicators (with closed mixing/loading systems that are not now required, safety margins are estimated to be less than 50 – generally, margins less than 100 are of concern to the Agency).
- However, the Agency believes the results of a confirmatory worker exposure study will demonstrate that required mitigation has effectively reduced exposure and risk to a level that is not of concern to the Agency. For applicators and mixer/loaders using ground application equipment, safety margins are over 100 when the use of closed mixing/loading systems and enclosed tractor cabs are assumed. Risks to workers who enter fields shortly after treatment also are of concern if personal protective equipment is not used.
- Acute risks are of concern for fish. Large-scale fish kills can occur when profenofos is used in accordance with current labeling. Thirteen such fish kills occurred in Louisiana and Mississippi during 1994-1996.

Risk Mitigation

To mitigate risks to handlers and workers:

- Reduce the maximum application rate to 0.75 pounds of active ingredient per acre;
- Allow the higher rate (1 pound active ingredient per acre) only on lepidopteran pests up to twice per season;
- Require closed mixing/loading systems and enclosed cockpits and cabs;
- Prohibit pilots from mixing and loading on the same day as application;
- Reduce the seasonal application rate from 6 to 5 pounds active ingredient per acre per season.
- Require a notice on the label to inform certified crop advisors of the need to provide the proper level of protective clothing and equipment for workers reentering treated fields.

To mitigate ecological risks:

- Require a 300 foot buffer zone around bodies of water for aerial applications;
- Require a 100 foot buffer zone around bodies of water for groundboom applications.
- The reduced application rates discussed above should also reduce ecological risks.

Next Steps

- Numerous opportunities for public comment were offered as this decision was being developed. The profenofos IRED therefore is issued in final (see www.epa.gov/REDs/ or www.epa.gov/pesticides/op), 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.
- To effect risk mitigation as quickly as possible, time frames for making the changes required by the Profenofos IRED are shorter than those in a usual RED. The Agency is requiring that all labels must be amended to include the above mitigation and submitted to the Agency within 90 days after issuance of this IRED.
- The registrant has agreed to study the effectiveness of using the closed loading system required to reduce exposure to mixer/loaders and applicators. The results of the new exposure study is due by the year 2001.
- When the cumulative risk assessment for all organophosphate pesticides is completed, EPA will issue its final tolerance reassessment decision for profenofos and may require further risk mitigation measures. Similarly, the Agency may reconsider any part of this interim decision based on new information which may come to the Agency's attention. The Agency will revoke nine tolerances because there are no registered uses and amend one tolerance. For all OPs, raising and/or establishing tolerances will be considered once a cumulative assessment is completed.