

US EPA ARCHIVE DOCUMENT

Progress in Completing Individual Organophosphate Assessments

FQPA and the Organophosphate Pesticides

The Food Quality Protection Act (FQPA) requires EPA to reassess all existing tolerances and tolerance exemptions (established as of August 3, 1996) within 10 years, to ensure that they meet the safety standard of the new law. EPA was directed to give priority to the review of those pesticides that appear to pose the greatest risk to public health, and to evaluate each pesticide's risks considering:

- aggregate exposure from food, drinking water, and residential uses;
- cumulative effects from all pesticides sharing a common mechanism of toxicity;
- possible increased susceptibility of infants and children; and
- possible endocrine or estrogenic effects.

FQPA requires the Agency to reassess 33% of the 9,721 existing tolerances and tolerance exemptions within three years (by August 3, 1999), 66% within six years (by August 3, 2002), and 100% in 10 years (by August 3, 2006).

Previously, FIFRA as amended in 1988 authorized the Agency to conduct a comprehensive reregistration program – a complete review of the human health and environmental effects of all pesticide active ingredients initially registered before November 1, 1984. Those pesticides meeting today's scientific and regulatory standards may be declared "eligible" for reregistration. To be "eligible," a pesticide must have a substantially complete data base, and must be found not to cause unreasonable risks to human health or the environment.

To maximize efficiency, EPA has combined tolerance reassessment and reregistration, and expects to complete both programs by August 2006. The Agency is focusing attention particularly on priority Group 1 pesticides (as described in the August 4, 1997, Federal Register notice, Raw and Processed Food Schedule for Pesticide Tolerance Reassessment), starting with the organophosphate pesticides (OPs).

Because the OPs share a common mechanism of toxicity (cholinesterase inhibition), EPA must evaluate both their individual and cumulative effects. This paper primarily describes the Agency's progress in completing risk assessments, tolerance reassessments, and risk management decisions for the 39 individual OP pesticides. These assessments and decisions were made with considerable input from stakeholders and the public, through the 6-phased OP pilot public participation process. As EPA completes individual assessments and decisions for the remaining 20 OP pesticides, we are simultaneously developing a cumulative OP preliminary risk assessment, to be issued for public comment by December 1, 2001.

Types of Individual OP Decisions and When They Become Final

Through the reregistration and tolerance reassessment programs, EPA has made individual risk management decisions for about half of the OP pesticides, and plans to complete individual decisions for the remaining OPs this year. These decisions may take the form of REDs, IREDs, or TREDs.

- **REDs (Reregistration Eligibility Decisions)...** When EPA completes the review and risk management decision for a pesticide that is subject to reregistration (that is, one initially registered before November 1984), the Agency generally issues a Reregistration Eligibility Decision or RED document. The RED summarizes the risk assessment conclusions and outlines any risk reduction measures necessary for the pesticide to continue to be registered in the U.S. Voluntary cancellations late in the reregistration process are counted as REDs. For the individual OPs, only voluntary cancellations (with tolerance revocations for any food uses) or decisions for pesticides with no food, drinking water, or residential exposures may be counted as REDs.
- **IREDs (Interim Reregistration Eligibility Decisions)...** EPA issues an IRED for a pesticide that is undergoing reregistration, requires a reregistration eligibility decision, and also must be included in a cumulative assessment under FQPA. The IRED, issued after completing the individual pesticide's risk assessment, may include risk reduction measures— for example, reducing risks to workers or eliminating uses that the registrant no longer wishes to maintain— to gain the benefits of these changes before the final RED can be issued following the cumulative assessment. OP IREDs are not considered final REDs until after the OP cumulative risks have been considered.
- **TREDs (Reports on FQPA Tolerance Reassessment Progress and Interim Risk Management Decisions)...** EPA issues a TRED for a pesticide that requires tolerance reassessment decisions but is not subject to reregistration at present because:
 - the pesticide was initially registered after November 1, 1984, so it is considered a “new” active ingredient, not within the scope of the reregistration program;
 - EPA completed a RED for the pesticide before FQPA was enacted on August 3, 1996; or
 - the pesticide is not registered for use in the U.S. but tolerances are established that allow crops treated with the pesticide to be imported from other countries.Like OP IREDs, OP TREDs are not considered final until after the OP cumulative risks have been considered.

Tolerance Reassessment for Individual OPs

In completing risk assessments and risk management decisions for individual OP pesticides, EPA also is reassessing the pesticides' tolerances and tolerance exemptions. OP tolerance revocations may be considered final decisions and counted as completed tolerance reassessments.

Agreements Not "Counted" as Individual OP Decisions

At any time during the review process, if the Agency identifies risks of concern that warrant mitigation beginning in the short term, EPA will initiate activities with pesticide registrants and other stakeholders to mitigate those risks. For example, EPA and the manufacturers of azinphos-methyl, methyl parathion, chlorpyrifos, and diazinon reached agreements during the past several years to phase out and cancel various indoor, residential, and/or food crop uses of these OP pesticides, to reduce risks or increase safety for children, families, workers, wildlife, and/or the environment. While the agreements addressed major elements of risk, these agreements did not address all the risks potentially associated with these OPs. Individual IREDs are being prepared for azinphos-methyl, methyl parathion, chlorpyrifos, and diazinon to complete the OP review process and to fully address all potential risks of concern.

Status of the Universe of OPs

49 OP pesticides = the universe /grand total

- ▶ 7 were canceled or had no active U.S. registrations when FQPA was enacted in August 1996, including chlorfenvinphos, chlorthiophos, dialifor, dioxathion, monocrotophos, phosphamidon, and sulprofos

42 OP pesticides were subject to reregistration and/or tolerance reassessment in August 1996 and began the OP pilot public participation process

- ▶ 3 were canceled before their revised risk assessments were completed – fonofos, isazophos, and isofenphos. (EPA completed a preliminary risk assessment for isofenphos. However, both fonofos and isazophos were canceled before preliminary risk assessments were completed.)

39 OP pesticides have (or soon will have) revised risk assessments, and have completed or are expected to complete the pilot public participation process

- ▶ 4 have completed REDs – *ethion, *ethyl parathion, *sulfotepp, and temephos
- ▶ 7 have completed IREDs – bensuide, fenthion, phorate, pirimiphos methyl, profenofos, propetamphos, and tribufos
- ▶ 8 have completed TREDs – cadusafos, chlorethoxyfos, *chlorpyrifos methyl, ✓✓coumaphos, fenitrothion, ✓*mevinphos, phosalone, and phostebupirim
- ▶ 19 are in Phase 6, awaiting individual decisions (see list below)
- ▶ 1 is in Phase 4, awaiting completion of its revised risk assessments: dichlorvos (DDVP)

Cancellations – OP pesticide decisions asterisked () above are also voluntary cancellations
 ✓RED – Mevinphos was also counted as a RED in 1994
 ✓✓RED Addendum – Coumaphos TRED is also an addendum to the 1996 Coumaphos RED

20 Individual OP Decisions to Complete

- ▶ EPA must complete revised risk assessments for dichlorvos (DDVP), and
- ▶ EPA must complete individual decisions – REDs, IREDs or TREDs – for 20 OPs:

Acephate	Disulfoton	Naled
Azinphos methyl	Ethoprop	Oxydemeton methyl
Chlorpyrifos	Fenamiphos	Phosmet
Diazinon	Malathion	Tetrachlorvinphos
Dichlorvos (DDVP)	Methamidophos	Terbufos
Dicrotophos	Methidathion	Trichlorfon
Dimethoate	Methyl Parathion	

19 Individual OP Decisions Completed

- ▶ As described above, EPA has completed individual decisions for 19 OPs through the pilot public participation process:

Bensulide IRED	Fenitrothion TRED	Pirimiphos methyl IRED
Cadusafos TRED	Fenthion IRED	Profenofos IRED
Chlorethoxyfos TRED	Mevinphos TRED	Propetamphos IRED
Chlorpyrifos methyl TRED	Phorate IRED	Sulfotepp RED
Coumaphos TRED	Phosalone TRED	Temephos RED
Ethion RED	Phostebupirim TRED	Tribufos IRED
Ethyl Parathion RED		