

**Pesticide Registration (PR) Notice 2000-9  
September 29, 2000**

**Notice to Manufacturers, Producers, Formulators  
and  
Registrants of Pesticide Products**

**ATTENTION: Persons Responsible for the Registration and  
Reregistration of Pesticide Products**

**SUBJECT: Worker Risk Mitigation for Organophosphate Pesticides**

This Pesticide Registration (PR) notice announces EPA's approach for managing risk to workers who may be exposed to organophosphate (OP) pesticide products by mixing, loading, applying, flagging or otherwise handling OP pesticides, or are exposed to residues of these pesticides while performing tasks in recently treated areas. This approach generally provides for basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or personal protective equipment, as well as increased restricted-entry intervals for occupational situations where revised risk assessments indicate that they are necessary and where these measures are feasible. Further, this notice outlines the steps that EPA intends to take to address situations where baseline mitigation measures are not feasible, or situations where maximum feasible mitigation is still inadequate to protect

workers.

The approach set out in this document is not final Agency action, but is intended solely as guidance for manufacturers, producers, formulators, users and registrants. The notice itself does not impose binding obligations on either the registrants or EPA. The measures described in this notice will be implemented, as appropriate, through reregistration and other ongoing processes. No registrant is required to respond to this notice, or to modify product labels at this time.

## **I. Background**

This PR Notice is being issued in anticipation of the Agency's completion of comprehensive risk assessments for the OP pesticides, as part of the larger process of implementing the Food Quality Protection Act of 1996 (FQPA) amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), and the ongoing process of reregistration established by FIFRA. The management of risks identified in the OP assessments is governed by both FIFRA and the FFDCA. The "reasonable certainty of no harm" standard in section 408 of the FFDCA (which has been incorporated into FIFRA), applies to the establishment and reassessment of tolerances under FFDCA, as well as the assessment of dietary risk under FIFRA. The FIFRA "risk-benefit" standard includes consideration of the risks and benefits of all pesticide uses including occupational and ecological risks under the risk-benefit standard. In managing these latter risks, EPA must take into account the economic, social, and environmental costs and benefits of the pesticide's use.

The implementation of the FQPA amendments has been the subject of a joint effort by EPA, USDA, and interested stakeholders known as the Tolerance Reassessment Advisory Committee (TRAC; recently replaced by the Committee to Advise on Reassessment and Transition, CARAT). Among other initiatives, the TRAC has established a process for public participation in the review and refinement of risk assessments for the OPs and for developing risk management options. The public participation process consists of 6 phases. Phases 1 through 4 address the development and refinement of the risk assessments. Phases 5 and 6 are concerned with the development and implementation of risk management plans. Phase 5 of the public participation process is an opportunity for the registrants, user community, and the general public to propose risk mitigation based on the revised risk assessments. During phase 6 of the TRAC process, the Agency prepares an interim Reregistration Eligibility Decision (RED) Document or a Report on FQPA Tolerance Reassessment and Interim Risk Management Decision Document, from which interim risk management will be implemented. Throughout this process, USDA, stakeholders, and the public have the opportunity to participate by submitting comments on the risk assessment and also by providing risk management proposals. Prior to finalizing a risk management decision, the Agency typically receives input from USDA, growers and registrants to assess the feasibility of mitigation measures.

It is important to note that worker risk mitigation is only one part of the comprehensive

mitigation strategy being developed during Phases 5 and 6 of the TRAC process. Much of the work of the TRAC has focused on dietary risk and tolerance reassessment. EPA will develop mitigation plans for all risks of concern identified for each OP pesticide, including risks from food, drinking water, residential and other non-occupational risks, and ecological impacts as well as occupational risk. The risks associated with residential and other non-occupational exposures are evaluated and addressed as part of tolerance reassessment under FFDCA sec. 408 (q). This notice is intended to present EPA's policy for management of the occupational risk associated with the use of OPs. Specific proposed measures for individual chemicals will be announced through EPA's interim risk management decision documents, and will be implemented shortly thereafter.

In a number of cases the OP risk assessments show that, even with maximum feasible personal protective equipment (PPE) and engineering controls, including all provisions currently required by the Worker Protection Standard, risks to workers still exceed the Agency's levels of concern. Although each OP risk management decision and any associated mitigation measures will be implemented on a case-by-case basis, the Agency is outlining its decision process in this notice, because early notification to registrants will help to ensure that occupational risk management decisions for the OPs will be approached consistently and implemented quickly and equitably. The Agency also encourages registrants to demonstrate stewardship of their chemicals by adopting the protective measures described in this notice prior to the issuance of the interim RED, and to develop new packaging and application technologies that reduce worker exposures to pesticides. EPA is in the process of developing and implementing chemical specific mitigation strategies for the OPs.

The FQPA amendments to FFDCA direct the Agency to evaluate food tolerances on the basis of cumulative risk from pesticides sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the enzyme, cholinesterase. The Agency will evaluate the cumulative dietary risk posed by the entire OP class of chemicals after certain policy and scientific issues for conducting cumulative assessments are resolved. While these policies and methodologies are being developed, the Agency has decided to move forward with individual assessments and identify mitigation measures that the Agency believes are necessary to address the human health risks and ecological risks associated with the current use of the individual OP chemicals. The Agency will issue its final decision on the OP class of chemicals following completion of the methodology for cumulative assessments. The cumulative assessment may result in further dietary risk mitigation measures for OP chemicals, such as lower application rates, longer pre-harvest intervals, fewer applications, elimination of uses etc., which may also further reduce worker and ecological exposure and risk.

This interim evaluation of OPs does not limit the Agency from making further FFDCA determinations and tolerance-related rulemakings that may be required on these pesticides or any others in the future. If the Agency determines, as a result of this later implementation process, that any of the determinations described in the interim REDs or Interim Tolerance Reassessment Evaluation and Risk Management Document, are no longer appropriate, the Agency will pursue appropriate action.

While this notice focuses on workers exposed to organophosphate pesticides, EPA envisions that risks to workers exposed to other classes of pesticides with similar risks, e.g., carbamate pesticides, would be managed in a similar manner.

## **II. EPA's Approach to Occupational Risk Mitigation for OPs**

### **A. Scope**

The approach described in this notice applies to both workers and handlers as defined by the Worker Protection Standard (WPS), and other persons not specifically covered by WPS (such as people who handle pesticides or are exposed following applications to rangeland, rights-of-way, structures, livestock, golf courses, parks, public spaces, etc.), who nonetheless perform similar activities and are exposed to pesticides in a similar manner to agricultural workers. EPA is particularly concerned for workers and handlers because of the relatively high risks indicated by current assessments, the acute toxicity of these compounds coupled with the large volume of chemicals handled, and the potential for accidental exposure to concentrated products frequently used in commercial applications.

### **B. Worker Protection Standard**

EPA's Worker Protection Standard for Agricultural Pesticides, 40 CFR Parts 156 and 170, is intended to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers who are occupationally exposed to pesticides. WPS affects all pesticide products whose labeling reasonably permits use in the commercial or research production of agricultural plants on any farm, forest, nursery, or greenhouse. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification may be reviewed and revised as appropriate, on a case-by-case basis, during reregistration and other Agency review processes.

### **C. Level of Concern**

EPA estimates worker risk by evaluating occupational exposure levels, including both dermal and inhalation exposures, against the No Observed Adverse Effect Level (NOAEL) demonstrated in toxicity studies. The ratio of the estimated exposure to the NOAEL is referred to as the Margin of Exposure (MOE). Generally, MOEs that are less than 100 exceed the Agency's level of concern for worker risk. An MOE of 100 represents uncertainty factors (UFs) of 10X to account for differences in species sensitivity between animals and humans and another factor of 10X to account for differences in sensitivity to toxic effects within the human population. Additional UFs may be added to account for the use of a Lowest Observed Adverse Effect Level (LOAEL), the severity of the effect observed, the lack of certain data, or other such concerns.

The occupational risk assessments completed thus far for the OPs have shown that, with only a few exceptions, worker and handler MOEs for these pesticides exceed the Agency's level of concern (i.e., have MOEs < 100). In a number of cases, even with maximum personal protective equipment (PPE), such as double-layer clothing, chemical resistant gloves, and appropriate respirator, or with engineering controls, such as closed mixing/loading systems and enclosed cabs/cockpits, calculated MOEs are still lower than 100.

For workers entering a treated site, restricted entry intervals (REIs) are calculated using a similar MOE approach to determine the minimum length of time required after application before workers or others are allowed to enter to perform routine hand labor activities.

In addition, the Agency closely examines occupational cancer risks and seeks ways to reduce cancer risks to the extent required to protect worker health, taking into account both the estimated risks and the benefits of the pesticide.

#### **D. Types of Worker Risk Mitigation Measures**

Mitigation measures that will be considered to reduce risk to workers may include additional PPE (e.g., 2 layers of clothing, chemical resistant gloves, footwear, headgear, apron, and/or appropriate respirator), closed mixing and loading systems, enclosed cabs, enclosed cockpits, reduced application rates, reduced frequency of applications, mechanical harvesting and longer REIs. In addition, depending on toxicity and potential exposure, EPA may reclassify some pesticides as Restricted Use Pesticides (RUPs).

Technologies have been developed and are available to greatly reduce exposure to both handlers and workers. Many registrants are already providing their products in bulk and mini-bulk recyclable containers, water soluble packages, gel packs, less "dusty" granular formulations and systems which are engineered to greatly reduce workers' contact with the particular pesticide. In some cases, selection of the most appropriate system is chemical or use specific and will depend on formulation type, application method and cost considerations. The Agency recognizes and welcomes innovative approaches that may be developed to suit specific needs and encourages registrants to consult with EPA on specific mitigation approaches.

Additionally, under EPA funding, Cornell University is working to put together a catalog of engineering controls including information on the following: closed transfer systems, returnable/refillable containers, carbon cab filters, chemical induction bowls, diaphragm check valves, hydraulic boom folding, nozzles/holders, injection devices, and tank rinsing devices. This study is currently targeted for completion in late 2001.

For the purposes of occupational risk mitigation described in this notice, EPA anticipates that many occupational scenarios will require the use of some type of engineering control. Depending on the

magnitude of the risk and the severity of the potential effects associated with exposure to a pesticide, different levels of mitigation may be necessary. In some cases, where the risk warrants, specific technologies or methods may be required. Examples of possible technologies that may be required in a given case are: dry coupling systems for loading operations, enclosed cabs that meet specific performance standards (such as the American Society of Agricultural Engineers (ASAE) standard) to protect persons applying the pesticide, and specific chemigation methods such as drip irrigation, or subsurface placement equipment. The Agency is aware of standards that have been developed and are being developed by the ASAE, such as an enclosed cab standard, and an closed system standard (still in development). Enclosed cabs, certified by the manufacturer as meeting the ASAE standard S-525, would generally meet EPA's request that use be restricted to enclosed cab applications. However, other types of engineering controls may also be adequate to address risk.

In order to illustrate what the Agency envisions by the term "engineering controls", several examples of varying degrees of protection are given below. These items are not intended to suggest that a registrant will be required to incorporate all types of engineering controls simultaneously, but rather that these systems are currently known to the Agency as options for risk mitigation.

## **1. Contained/Closed Mixing and Loading Systems**

One engineering control available for mixing and loading pesticides is a closed system. By closed system EPA means a system designed by the manufacturer to enclose the pesticide to prevent it from contacting individuals while it is being handled. Under the WPS, when a closed mixing and loading system is used correctly and maintained according to the manufacturers operating instructions, handlers may reduce some of the personal protective equipment listed on the pesticide labeling for mixing and loading activities.

**a. Mechanical Transfer System.** One type of closed system for liquid formulations is a mechanical transfer system that consists of a probe that is inserted into the pesticide container and seals tightly to the pesticide container to prevent liquid (but not necessarily any vapor) from contacting handlers or other people. The pesticide is either transferred directly from its container to a spray tank, or the container is connected directly to the spray system. Mixers and loaders using this closed system are permitted to wear reduced PPE. A mechanical transfer system usually does not meet the definition of a closed system under the WPS unless inhalation exposure is not a concern; however it is considered an engineering control which greatly reduces dermal exposure.

**b. Dry Disconnect System.** A dry-disconnect system does not meet the definition of a closed system under WPS unless it is part of a mechanical closed system. Dry disconnect systems are considered to be an engineering control that reduces potential worker exposure by reducing leakage of liquid when pipes or hoses are uncoupled from equipment or from other pipes or hoses. Dry-disconnect systems involve fittings designed by the manufacturer to minimize pesticide leakage at each hose disconnect point. These systems are often used in conjunction with mechanical transfer systems.

**c. Water-soluble Packaging.** Water-soluble packaging is considered to be an engineering control that reduces exposure during the handling of a pesticide. Under the WPS, individuals handling a product while it is enclosed in intact water-soluble packets are permitted to wear reduced PPE.

Water-soluble packaging is the only currently available type of engineering control for use with wettable powder formulations. Some liquid pesticide formulations may also be converted into gels and packaged into water-soluble packets (gel packs).

**d. Prepackaged Granular Containers.** Some technologies are available for granular formulations, where the granules are packaged in a container that fastens directly onto specially made application equipment. Once attached, the equipment opens the container and meters out the granules. Under the WPS, such systems meet the definition of a closed loading system and a closed application system, if the granules are soil incorporated, in which case reduced PPE is permitted under that regulation.

## **2. Enclosed Cabs**

**a. Enclosed Cabs for Application and Flagging.** The engineering control available for handlers applying pesticides using motorized ground equipment or flagging to support aerial applications is an enclosed cab. By enclosed cab, EPA means a cab having a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside of the cab. By definition, all enclosed cabs protect against dermal exposure. Some enclosed cabs also provide respiratory protection -- they can be equipped with a ventilation system that provides particulate filtration equivalent to a NIOSH-approved dust/mist respirator or that provides organic-vapor-removing and particulate filtration equivalent to a NIOSH-approved organic-vapor-removing respirator with a dust/mist prefilter. The performance criteria for enclosed cabs are found in the WPS at 40 CFR Part 170.240(d)(5).

If the occupational risk assessment for such handlers indicates that dermal exposure is the only exposure route of concern (i.e., inhalation risks are not a concern even when no respirator is worn), then an enclosed cab providing only dermal protection is sufficiently protective and will be required on the pesticide labeling. However, if the risk assessment indicates that inhalation risks are a concern unless an appropriate respirator is worn, then the pesticide labeling will indicate that the enclosed cab must provide respiratory protection equivalent to the type of respirator required for the pesticide *or* that the handler must wear the appropriate respirator while inside the enclosed cab. As noted in section D above, depending on the severity of inhalation risks, EPA may require that enclosed cabs meet performance criteria beyond those specified in the WPS.

Under the WPS, handlers in any enclosed cab need not wear all of the label-required PPE designed for dermal protection (e.g., double layer body protection, or chemical-resistant gloves,

footwear, or headgear), provided such PPE is immediately available for use if the handler exits the enclosed cab in the treated area and contacts treated surfaces. If the manufacturer or a government agency declares that the enclosed cab provides respiratory protection equivalent to the label-required respirator (and certain use and maintenance conditions are met), handlers need not wear the respirator while in the enclosed cab. However, the appropriate respirator must be immediately available for use if the handler exits the cab within the treated area.

**b. Enclosed Cockpits for Aerial Application.** The engineering control available for applying pesticides in aerial equipment is an enclosed cockpit. Under the WPS, applicators in an enclosed cockpit may substitute long sleeve shirt, pants, shoes and socks for label specified PPE.

### **3. Reentry**

For individuals entering treated fields, depending on the magnitude of the risk and the severity of the effect, the Agency would consider several different mitigation measures. REIs longer than those currently specified on labels, as well as mechanical harvesting, where possible, would be evaluated to reduce exposure to reentry workers. The Agency is aware of many different efforts to mechanize harvesting and other tasks, and encourages continued research in this area. Finally, the Agency may consider allowing exceptions to the REIs, depending on the potential level of risk for time-critical reentry activities, and the data available regarding the extent of these various activities.

#### **E. Occupational Risk Management Approach for OPs**

The following approach will generally be used by the Agency in making risk management decisions for workers:

1. Based on the occupational assessments that have been conducted, EPA will first determine whether or not existing uses have adequate MOEs based on available data and current labeling. Worker risks for which the MOE is greater than the target MOE (typically 100) are not considered to be of concern. In such cases, the Agency generally will not pursue additional risk reduction measures.

2. For uses with MOEs of concern (generally < 100) based on current labeling, EPA will seek to reduce risks to workers to the greatest extent feasible with PPE and engineering controls, as well as application modifications such as decreased application rates. Based on the Agency's experience with the OP occupational risk assessments completed thus far, this approach will likely include, at the minimum, the use of closed mixing and loading systems and enclosed cab/cockpit equipment for pesticide applications for many outdoor agricultural uses.

3. Where engineering controls are not feasible due to logistical constraints, for example, greenhouse applications, EPA intends to seek maximum feasible PPE which may include 2 layers of



clothing, chemical resistant gloves, footwear, headgear, apron, and respirators, where appropriate. EPA may also seek modifications to use patterns, and modifications in application equipment or formulation systems.

4. Due to the availability of mechanical flaggers and Global Positioning Systems, the industry is moving away from the use of human flaggers. The Agency may seek to prohibit the use of human flaggers or restrict the use of human flaggers to enclosed cabs where the risk assessment warrants mitigation for these workers.

5. For harvesters and other workers reentering treated fields, if MOEs based on existing REIs are inadequate, EPA will likely seek to extend REIs in order to provide greater protection to these reentry personnel, or require changes in use patterns to reduce residues following applications.

6. In situations where the MOEs are inadequate and risks continue to exceed benefits even after consideration of maximum PPE, engineering controls and modifications to the use pattern, the Agency will consider cancellation of the use. For example, certain application methods such as hand-held equipment (backpack sprayers, handwands and knapsacks), may have risks that exceed benefits even after consideration of PPE, engineering controls or modified use patterns.

In managing risk, EPA must take into account the economic, social, and environmental costs and benefits of the pesticide's use. The approach outlined in this notice allows for consideration of a wide range of factors in making risk management decisions for worker risks. These factors may include, in addition to calculated MOEs, consideration of pesticide exposure incident data, the nature and severity of adverse effects, uncertainties in the risk assessment, the cost, availability and relative risk of alternatives, and the importance of the chemical in IPM or public health programs.

EPA employs a wide range of data in assessing the risks and benefits of pesticides and in making regulatory decisions. Among these data are a variety of use-related information, such as how each pesticide is applied, where and when it is used, how much is actually used, and what it controls. Use-related data cover the extent of pesticide use across different sites and geographic regions, typical use patterns, use profiles for specific pesticides, and the role of pesticides in pest management systems. The Agency considers this use-related data in developing appropriate risk mitigation and risk management decisions.

## **F. Label Amendments**

Changes to OP pesticide labels resulting from worker risk mitigation measures will be accomplished as part of reregistration. Registrants may choose to amend their registrations to incorporate worker risk mitigation measures prior to the issuance of the interim RED or tolerance decision. Before submitting label changes, registrants are strongly encouraged to consult with the EPA Chemical Review Manager responsible for the review of the specific chemical. Registrants may submit EPA Form No. 8570-1 Application for Pesticide Registration/Amendment and five copies of the

revised label for EPA approval. Send this application to:

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave.  
Washington, DC 20460-0001

### **G. Implementation and Timing**

As of September 28, 2000, 36 OPs have entered the risk management phase (Phase 5) of the Public Participation Process (developed as part of TRAC). It is during Phase 5 that the Agency will develop, in consultation with registrants and other stakeholders, integrated risk management strategies for each chemical to address all the risks identified in the revised assessments.

It is the Agency's expectation that risk mitigation established during Phase 5 of the TRAC process would be implemented as soon as possible, generally for the growing season following the publication of the interim RED document. Sale under previously approved labeling and existing stocks will be developed on a case-by-case basis and will be articulated once the individual chemical specific assessment is completed.

## **III. For Further Information**

### **A. Related Documents and How to Access Them**

Preliminary and revised risk assessment for the OPs are available on EPA's web page (<http://www.epa.gov/pesticides/op>) and from the Office of Pesticide Program's (OPP) Public Docket. The OPP Docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Other documents related to the TRAC process and the schedule for completing the public participation process for the OPs are also available on EPA's web page.

EPA encourages registrants and other interested parties to review the OP risk assessments currently available at the EPA web site or through the OPP Public Docket to determine which worker situations are likely to require mitigation and which products may be affected.

### **B. Contact**

Any questions regarding this notice or the Agency's approach for managing worker risks for the OPs should be directed to: Kathleen Meier, Reregistration Branch II, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, US EPA, Ariel Rios Building, 1200 Pennsylvania Ave NW, Washington DC 20460; phone: (703) 308-8017; Fax: (703) 308-8041; e-

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