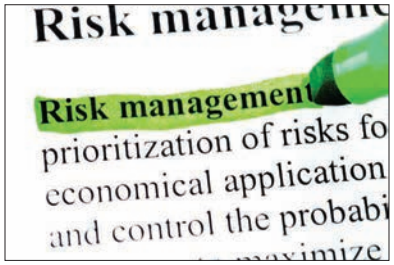
Risk Management



Closely related to risk assessment is risk management, the process by which the results of risk assessment are integrated with other information—such as political, social, economic, and engineering considerations—to arrive at decisions about the need and methods for risk reduction.

***— Science and Judgment in Risk Assessment,* National Academy of Sciences**

Risk management reduces adverse risks by reducing the likelihood of the risk or its effects.

The risk-based approach to safety is applied in such diverse areas as marine operations, building construction and financing, and environmental regulation. Successful risk management applies practical, useful solutions to deal with the uncertainty that characterizes risk.

Because of the properties and characteristics that make them effective for their intended purposes, pesticides may also pose risks to people and the environment. Most pesticides require use controls to keep exposures below unsafe levels. In each case, the selected risk-reduction strategy provides the basis for specific use controls. These may include label restrictions, permit limits, application controls, buffer zones, and reentry and preharvest intervals. All registered pesticides are thus restricted in that they can be used only for specified purposes and in a manner specified on the label.

ABOUT RISK MANAGEMENT

For Department of Pesticide Regulation (DPR) risk managers to develop limits that are appropriate and effective, the department's risk assessors must first identify the types of risks to be controlled, the activities from which those risks may arise, and the means available to assess the extent of the risks.

Risk managers also identify the means available to mitigate and minimize the risks. That is, while risk assessment provides information on potential health risks, risk management is the action taken based on consideration of that information and other data. Risk managers evaluate and select mitigation options, and develop effective measures to reduce potential unsafe pesticide levels in air, water, food or the workplace. (*See Chapter 5 for more information on risk assessment.*)

Risk management is defined by the U.S. Environmental Protection Agency (U.S. EPA) as the process of identifying, evaluating, selecting and carrying out actions to reduce risk to human health and the environment. Although risk management is presented here as a series of sequential steps, the underlying process is interactive and dynamic. If a pesticide's use is associated with an unacceptable level of risk, DPR risk managers will consider controls on use or other regulatory options to reduce the risk to acceptable levels. The process usually produces many possible approaches to risk reduction. Regulators must develop each alternative and combination of alternatives in enough detail to find out if they reduce risk to acceptable levels. The goal is to select a risk-reduction strategy of integrated measures that are scientifically sound and cost-effective, and that reduce or prevent risks while taking into account social, cultural, ethical, political and legal considerations.

Risk assessment is conducted largely by staff from the Human Health Assessment Branch, while risk managers are comprised by a team of executive and program managers.

Discussions between risk assessors and risk managers early in risk assessment can help focus the overall purpose, identify information gaps and establish expected risk management needs. The risk assessment is designed and presented in a way that addresses the needs of decision makers who must decide if a pesticide can be used safely and, if so, what the use limits should be. Risk assessors should pro-

vide risk managers with reasonable conclusions about risk based on the available information, with evaluations of the scientific weight of evidence supporting those conclusions and descriptions of major sources of uncertainty and alternative views.

The basic steps in risk management include:

- Deciding whether the proposed or current use of a pesticide results in an unacceptable risk—that is, exposures likely to cause harm to workers, the public or the environment.
- Identifying options to minimize those risks.
- Evaluating those options according to a value system that includes scientific, social, legal and economic factors, as well as practicality and enforceability. Regulators may also review what other states and nations have done to evaluate similar measures.
- Selecting an effective course of action to reduce or eliminate unacceptable health or environmental risks.
- Monitoring the mitigation measures after they are in place to ensure they are effective and adjusting them if necessary.

IDENTIFICATION AND ANALYSIS OF RISK MANAGEMENT OPTIONS

The goal of risk management is to identify a range of options that can reduce exposure and to analyze them to determine if they achieve acceptable risk standards for human health and the environment. The identification and analysis must focus on and be responsive to the nature and extent of risk, its source or sources, and the affected human population identified in the risk assessment or evaluation of potential effects to the environment.

Often the choice is not between individual risk management options, but from various combinations of options. There may be competing risks within the range of possible risk mitigation alternatives. What may be a reasonable strategy to reduce risk to applicators, for example, may pose unacceptable risks to the environment. Thus, development of options must provide a clear basis to ensure that all risk elements are considered and are acceptable.

The range of risk management options is constrained by legal and practical considerations. The options must be consistent with federal and state law and be legally enforceable. The available alternatives under these legal constraints can include denial or cancellation of registration, or imposition of conditions and controls on use.

The practicality of risk management options is guided by the regulators' thorough understanding of the use situations, use practices, application technology, extent of use, and California use conditions. This level of understanding is necessary for regulators to focus their development of options on those that are appropriate and can be achieved. For example, because application rates, frequency, equipment and other practices influence the effective use of a pesticide, management options are necessarily limited to those that do not make the pesticide ineffective for its intended use. Practicality in use is also considered.

DPR does not conduct economic analyses as part of risk management and does not consider economic benefits in making registration decisions. Economic considerations, however, can inform an evaluation of alternative risk mitigation options. In discussing risk management at the federal level, the Presidential/Congressional Commission on Risk Assessment and Risk Management said in a 1997 report, "Considering incremental costs and benefits in regulatory decision-making can help to clarify the tradeoffs and implications associated with alternative regulatory policies and help regulatory agencies to set priorities."

Risk management is the control of risk by eliminating or modifying the conditions that produce the risk. People practice risk management in all aspects of daily life, often without realizing it. The parent who stores medicines and household chemicals out of a child's reach…The driver who fastens his seat belt… The gardener who puts on protective clothing before spraying pesticides is practicing risk management. ...
(Continues on next page)

Government practices risk management by passing rules and regulations that specify procedures for controlling risks and penalties for disregard of the procedures. The risks that governments manage are those that affect the public in general or specific groups of people.

***— The Dose Makes the Poison: A Plain Language Guide to Toxicology,* by M. Alice Ottoboni**

Cost-effectiveness analysis can, as the Framework for Environmental Health Risk Management states, "be used to help to choose among options that are expected to attain [the specified health or environmental goal] but use different approaches, generate different costs, and may have different probabilities of success."

Regulators must also consider if an alternative mitigation option may cause any adverse effects and decide what the trade-offs among the different risks may be. For example, requiring a pesticide be worked into the soil reduces the risk of airborne drift but may affect drinking water. If the pesticide is chemically unlikely to reach ground water, this trade-off may be worthwhile.

Similarly, banning a pesticide because it might cause one health risk may increase the use of another pesticide or substance known to cause another health risk or other effects not well understood.

To ensure that the various factors are considered, DPR management may also consult with outside stakeholders, including farmworker representatives, environmental advocacy groups and the regulated industries (registrants, licensees and agricultural interests). If needed, DPR may schedule workshops to get public comment on the most feasible and effective approaches to mitigation.

SELECTION OF A RISK MANAGEMENT STRATEGY

Regulators must base their decisions on the best available scientific, practical and other technical information. Since available information is usually incomplete, decision makers often must rely on:

- Predictions about human hazards based on experiments in laboratory animals.
- Predictions about how much exposure occurs in a lifetime based on few or no measurements of the actual levels of exposure in people (because most studies are done on laboratory animals).
- Assumptions and models of exposure, exposure-response relationships, and estimates of the feasibility and effectiveness of different options.

Because regulators must make judgments based on limited information, it is critical they consider all reliable information. Risk assessors must provide decision makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions, uncertainties and conclusions. Risk managers are constrained by the scientific, legal, social, technological and behavioral factors they must consider. The process is necessarily subjective in that it requires value judgments on safety margins and the reasonableness of control measures.

Selecting a risk management strategy requires an understanding of the risk assessment, mitigation approaches, California agriculture and the practical aspects of pesticide application. The selection is based largely on data suggesting the expected risks will be sufficiently reduced and the pesticide will remain effective. Risk managers must also be able to decide if the selected strategy is practicable from both a use pattern and a compliance and enforcement perspective.

Selecting management options, therefore, is case-specific. It is a search for the best combination of choices that reduce exposure below unsafe levels, are enforceable in the field, preserve acceptable product efficacy, and do not result in other, unacceptable health or environmental risks.

IMPLEMENTATION OF THE STRATEGY

The selected risk management strategy is at the core of a regulatory decision. It is carried out as part of a decision to approve or deny a proposed registration, or to put into place greater controls on an already registered pesticide.

DPR risk managers consider a range of decision options.

Revised label language

If the product is not yet registered, DPR may work with a registrant and U.S. EPA on amended label language to ensure that it meets California's requirements. Under federal law, U.S. EPA has sole authority over label language and no state can require changes on pesticide labels. DPR can deny registration to a product unless the manufacturer obtains a U.S. EPA-approved label incorporating needed protections. Any use in conflict with the label is illegal under state and federal law.

If the product or products are already registered, DPR may request that registrants work voluntarily with U.S. EPA to revise label language.

California-restricted material

DPR can also adopt regulations making the pesticide a California-restricted material. This limits the purchase and use of these pesticides to trained individuals and only under time- and place-specific permits issued by county agricultural commissioners (CACs). DPR typically develops extra controls for restricted materials in the form of suggested permit conditions designed to be part of the permit. CACs use this information and their knowledge of local conditions to develop controls suitable for each site at the time of application.

Additional regulatory controls

Another alternative is for DPR to adopt regulations placing specific controls on a pesticide that are more restrictive than those on the federal product label. Examples include longer preharvest and reentry intervals, reduced application rates and acreage, controls on timing and frequency of application, and limits on crops and other sites to be treated. Other controls include personal protective equipment, special licensing for applicators, and buffer zones to protect people or wildlife near treated fields.

If occupational exposures will lead to worker safety regulations, state law requires that DPR and the state Office of Environmental Health Hazard Assessment (OEHHA) work together to develop the regulations. DPR must base its regulations related to health effects on OEHHA's recommendations; the risk management decision and strategies are the responsibility of DPR management. When the risk management decision is not related to occupational exposures, OEHHA is provided with the opportunity to provide input before the regulations are adopted. (This is separate from OEHHA's peer reviews of DPR risk assessments.)

Depending on the issue, DPR may also consult CACs, the Department of Industrial Relations, Department of Food and Agriculture, Air Resources Board, State Water Resources Control Board and the University of California.

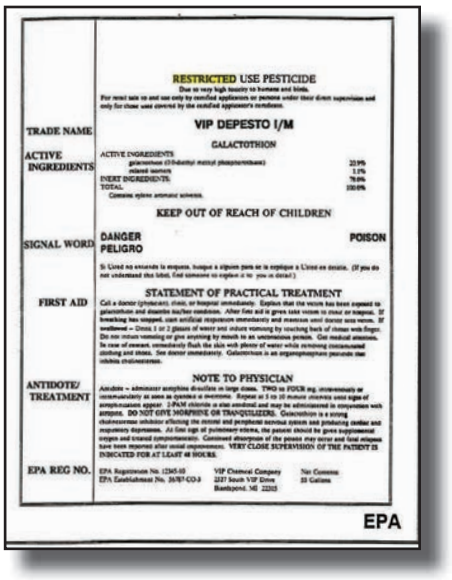
Denial of registration or cancellation

If mitigation measures cannot reduce the risk sufficiently, DPR can deny or cancel the registration of the pesticide product or products of concern.

MONITORING AND EVALUATION OF RESULTS

Decisions to register pesticides or to allow continued use after registration reflect the state of knowledge and regulatory practices at the time the decision is made. Continuous evaluation by DPR plays an essential role in ensuring the continued safety of registered pesticides. (*See Chapter 4 for more information on DPR's mandate to conduct continuous evaluation.*)

Post-registration developments in scientific knowledge and in experience may point to a need for information in addition to the data on which DPR based its risk


RESTRICTED USE PESTICIDE

TRADE NAME

VIP DEPESTO I/M

GALACTOTHION

ACTIVE INGREDIENTS

KEEP OUT OF REACH OF CHILDREN

SIGNAL WORD

DANGER
PELIGRO

POISON

FIRST AID

STATEMENT OF PRACTICAL TREATMENT

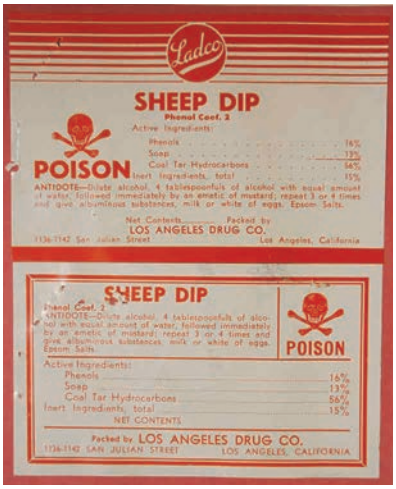
ANTIDOTE/ TREATMENT

NOTE TO PHYSICIAN

EPA REG NO.

EPA

A sample pesticide label frequently used in training manuals.



Historical pesticide label.

Several factors are weighed in DPR's risk-management process.

assessment, mitigation and registration decisions. Situations that may signal the need for a reassessment include:

- New scientific knowledge of toxicological endpoints of concern, often combined with new investigative methods.
- Adverse effects reporting, illness reporting and results from epidemiological, exposure monitoring or environmental studies.
- Age of the supporting database. Over time, data requirements may have expanded, quality and scientific rigor increased and a wider range of risks must be considered. DPR may place an active ingredient into formal reevaluation to require registrants to develop needed data.

Post-registration monitoring may include:

- Evaluation of compliance with regulations and other control measures put into place to reduce exposure.
- Routine inspections and special studies (for example, monitoring environmental levels and effects), food residue surveys and illness surveillance.
- Discussions with stakeholders on observed effects and potential problems.

Monitoring can encompass several pesticides or can be focused on a single one. It can be limited to certain areas or be statewide. It can apply to one environmental medium (for example, air) or several. It can target certain types of pesticides (for example, fumigants) or certain commodities or activities.

Key questions to address when evaluating results include:

- Has the risk management strategy minimized risk enough to bring exposures below potentially harmful levels?
- Are the assumptions, including those made about the environment, technology and resources, still valid?
- Is the risk management strategy comparatively efficient and cost-effective?
- Can improvements be made and, if so, what might they be?