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EPA

EPA's Pesticide Programs

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Introduction

Few chemicals have had as much impact or been the subject of as much controversy in recent decades as pesticides. Introduced on a massive scale following the Second World War, pesticides have become an integral part of American agricultural production, making possible the most plentiful and safest food supply in human history. Over time, however, public concerns have mounted about the toxic effects of chemical pesticides. Pesticide residues in food, farmworker exposure to pesticides, and pesticide contamination of ground water have all contributed to a growing unease over the widespread use of pesticides.

Some of these concerns have had beneficial results. Consumers are using more caution in handling pesticides and in limiting their exposures to pesticides in food. In the agricultural community, many growers are using fewer chemical pesticides and adopting a more integrated approach to managing pests. And new pesticides coming on the market tend to be less toxic than the chemicals they replace. While all of these are encouraging signs, pesticides nevertheless remain a fact of our daily lives. Managing pesticides to minimize their risks and maximize their benefits is the task we face.

The U.S. Environmental Protection Agency (EPA) has been charged by Congress with the job of regulating the use of pesticides and balancing the risks and benefits posed by pesticide use.

To carry out this task, EPA has developed a variety of regulatory and educational programs to protect human health and the environment from the harmful effects of pesticides. These include registering pesticides for specific uses, setting tolerances for pesticide residues on food, setting standards to protect workers who are exposed to pesticides, certifying and training pesticide applicators, and educating consumers about pesticide use and exposure.

This booklet is intended to introduce readers to EPA's pesticide programs. Pesticide registration and food safety are discussed first, followed by descriptions of other pesticide programs. The appendices at the back of the booklet contain a glossary of technical terms, a list of materials for further reading and reference, and the addresses and telephone numbers of pesticide program contacts in EPA headquarters and 10 regional offices and in all 50 states.

Overview of EPA's Role

EPA regulates the use of pesticides in the United States under the authority of two laws — the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act. No pesticide may legally be sold or used in the United States unless it bears an EPA registration number. It is a violation of the law for any person to use a pesticide in a manner inconsistent with its label.

EPA's pesticide regulations cover:

- Some 30 major pesticide producers plus another 100 smaller producers
- 3,300 formulators
- 29,000 distributors and other establishments
- 40,000 commercial pest control firms
- About 1 million farms
- Several million industry and government users
- About 90 million households.

FIFRA gives EPA the authority and responsibility for registering pesticides for specified uses, provided that such uses do not pose an unreasonable risk to human health or to the environment. EPA also has the authority to suspend or cancel the registration of a pesticide if subsequent information indicates that use of the pesticide would pose unreasonable risks.

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Facts and Figures

Broadly defined, a pesticide is any agent used to kill or control undesired insects, weeds, rodents, fungi, bacteria, or other organisms. Thus, the term "pesticides" includes insecticides, herbicides, rodenticides, fungicides, nematicides, and acaracides, as well as disinfectants, fumigants, and plant growth regulators.

At present, approximately 25,000 formulated pesticide products are registered for marketing and use in the United States. EPA regulates these products primarily on the basis of their pesticidal active ingredients, the component of a pesticide product that acts on the pest. There are fewer than 750 active ingredients currently in production, with 200 leading active ingredients.

Total U.S. annual pesticide consumption is estimated at 2.7 billion pounds of active ingredients. Of this amount, 1.6 billion pounds represents wood preservatives, disinfectants, and sulfur (a fungicide). The remaining 1.1 billion pounds of "conventional pesticides" (herbicides, insecticides, and fungicides) were sold to users at a cost of $7.4 billion in 1988.

In the conventional pesticide market (see Figure 1), agriculture accounts for over two-thirds of pesticide user expenditures and about three-quarters of the volume used annually; the remainder of the market comprises industry, government, and home and garden uses. Herbicides are the leading type of conventional pesticide, with over 50 percent of both domestic sales and volume used. EPA estimates that total U.S. farm expenditures on pesticides, $5.1 billion in 1988, represents less than 4 percent of total farm production expenditures ($132 billion in 1989).

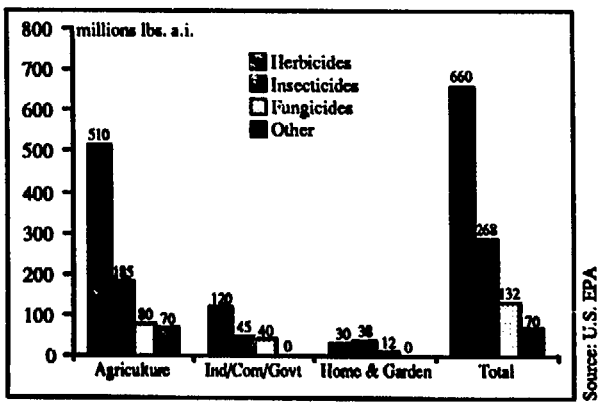


Fig. 1 - Volume of Conventional Pesticide Active Ingredients Used in U.S., 1988

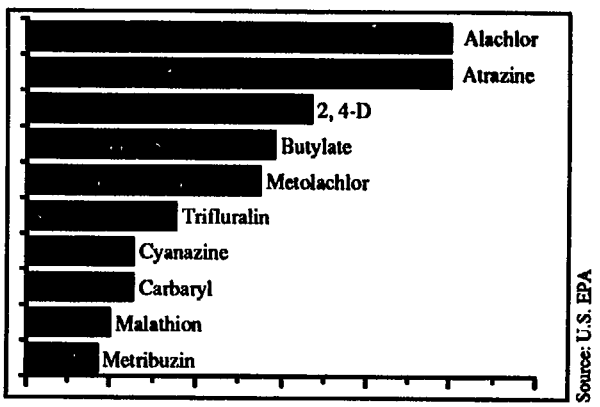


Fig. 2 - Annual Usage of the Largest Agricultural Pesticides in the U.S.

The 10 largest-use agricultural pesticides are shown in Figure 2, along with estimates of their annual usage for all agricultural and non-agricultural uses. Alachlor and atrazine are the two most widely used pesticides by volume. Eight of the 10 pesticides shown are herbicides (carbaryl and malathion are insecticides.)

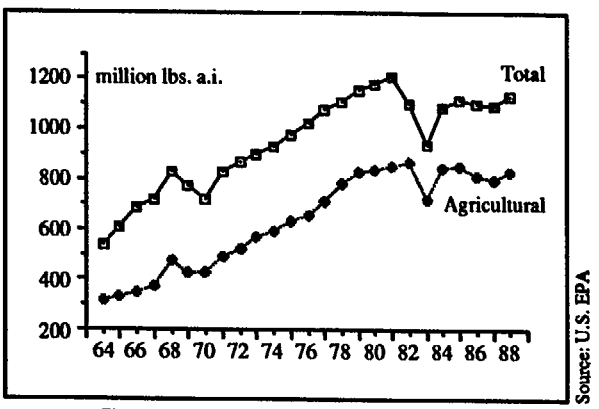


Fig. 3 - Trends in U.S. Pesticide Usage, 1964-1988

After increasing steadily throughout the 1960's and 1970's, pesticide usage reached its all-time high in the early 1980's; since then, it appears to be holding steady at just slightly lower levels (see Figure 3) and may decline in coming years. More efficient use of pesticides, the availability of even more effective pesticides, and an increased interest in sustainable agriculture contribute to this trend.

Pesticide Registration

How EPA Regulates New Pesticides

EPA is responsible under FIFRA for registering new pesticides to ensure that, when used according to label directions, they will not pose unreasonable risks to human health or the environment. FIFRA requires EPA to balance the risks of pesticide exposure to human health and the environment against the benefits of pesticide use to society and the economy.

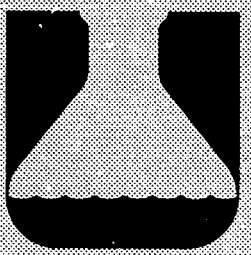
Pesticide registration decisions are based primarily on EPA's evaluation of the test data provided by applicants. Depending on the type of pesticide, EPA can require up to 70 different kinds of specific tests (see box). For a major food-use pesticide, testing can cost the manufacturer up to $10 million.

Testing is needed to determine whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish, and plants, including endangered species. Potential human risks, which are identified by using the results of laboratory tests, include acute toxic reactions, such as poisoning and skin and eye irritation, as well as possible long-term effects like cancer, birth defects, and reproductive system disorders. Data on "environmental fate" (how a pesticide

Basic Data Requirements for a New Food-Use Pesticide

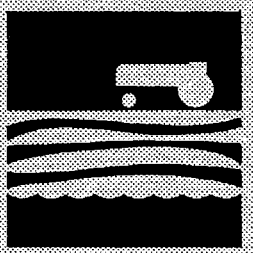
At the present time, data from the following tests must be submitted to EPA by a manufacturer prior to registration:

Chemistry:



- list of ingredients
- description of manufacturing process
- discussion of formation of impurities
- physico-chemical properties
- residue studies
- metabolic studies
- analytical methods
- results of analytical procedures

Environmental Fate:

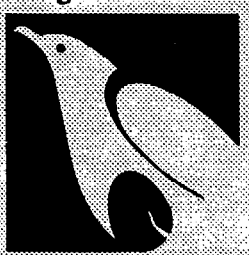


- hydrolysis
- leaching
- terrestrial dissipation
- photodegradation
- soil metabolism
- rotational crop study

Toxicology:

- acute oral
- acute dermal
- acute respiratory
- eye irritation
- chronic toxicity
- subchronic oral toxicity
- reproduction and fertility
- metabolism
- mutagenicity
- birth defects
- carcinogenicity

Ecological Effects:



- aquatic, acute toxicity
- avian, dietary & acute oral

behaves in the environment) also are required so that EPA can determine, among other things, whether a pesticide poses a threat to ground or surface water. The list of tests required is currently undergoing review; revisions are expected to be proposed in 1991. Certain additions to the list, such as neurotoxicity, applicator exposure, ground and surface water contamination, and residential exposure tests, will strengthen the data requirements.

EPA may classify a product for restricted use if it warrants special handling due to its toxicity. Restricted use pesticides may be used only by or under the supervision of certified applicators trained to handle toxic chemicals and this classification must be shown on product labels. During registration review, the Agency may also require changes in proposed labeling, use locations, and application methods. If the pesticide is being considered for use on a food or feed crop, the applicant must petition EPA for establishment of a tolerance (see the section on Food Safety below).

A brand-new active ingredient may need six to nine years to move from development in the laboratory, through full completion of EPA registration requirements, to retail shelves. This time-frame includes at least two or three years to obtain registration from EPA. A diagram of the process is shown in Figure 4 on the next page.

Since 1978, when EPA began requiring more extensive data on pesticides than in the past, over 130 brand-new chemical active ingredients have been registered; between 10 and 15 new pesticide active ingredients are registered each year.

Reregistration of Existing Pesticides

EPA is required by law to reregister existing pesticides that were originally registered before current scientific and regulatory standards were formally established. The reregistration process ensures that:

(1) Up-to-date data bases are developed for each of these chemicals (or their registrations will be suspended or cancelled)

(2) Modifications are made to registrations, labels, and tolerances as necessary to protect human health and the environment

(3) Special review or other regulatory actions are initiated to deal with any unreasonable risks.

Reregistration has proved to be a massive undertaking and has proceeded slowly. To date, EPA has issued 194 "registration standards." A registration standard includes a comprehensive review of all the available data on an existing chemical, a list of additional data needed for full reregistration, and the Agency's current regulatory position on the pesticide. The 194 registration standards already issued represent about 350 individual active ingredients that account for 85 to 90 percent of the total volume of pesticides used in the United States.

Under the 1988 FIFRA amendments, EPA has been directed to accelerate the progress of reregistration so that the entire process is completed by 1997. FIFRA '88 sets out a five-phase schedule to accomplish this task with deadlines applying to both pesticide registrants and EPA. It was originally estimated that EPA's reregistration activities would cost in excess of $250 million over a nine year period, with almost half the amount coming from EPA's current budget for reregistration and the remainder coming from reregistration fees assessed on the pesticide industry. These cost estimates are being revised upwards to reflect actual costs incurred in the accelerated program.

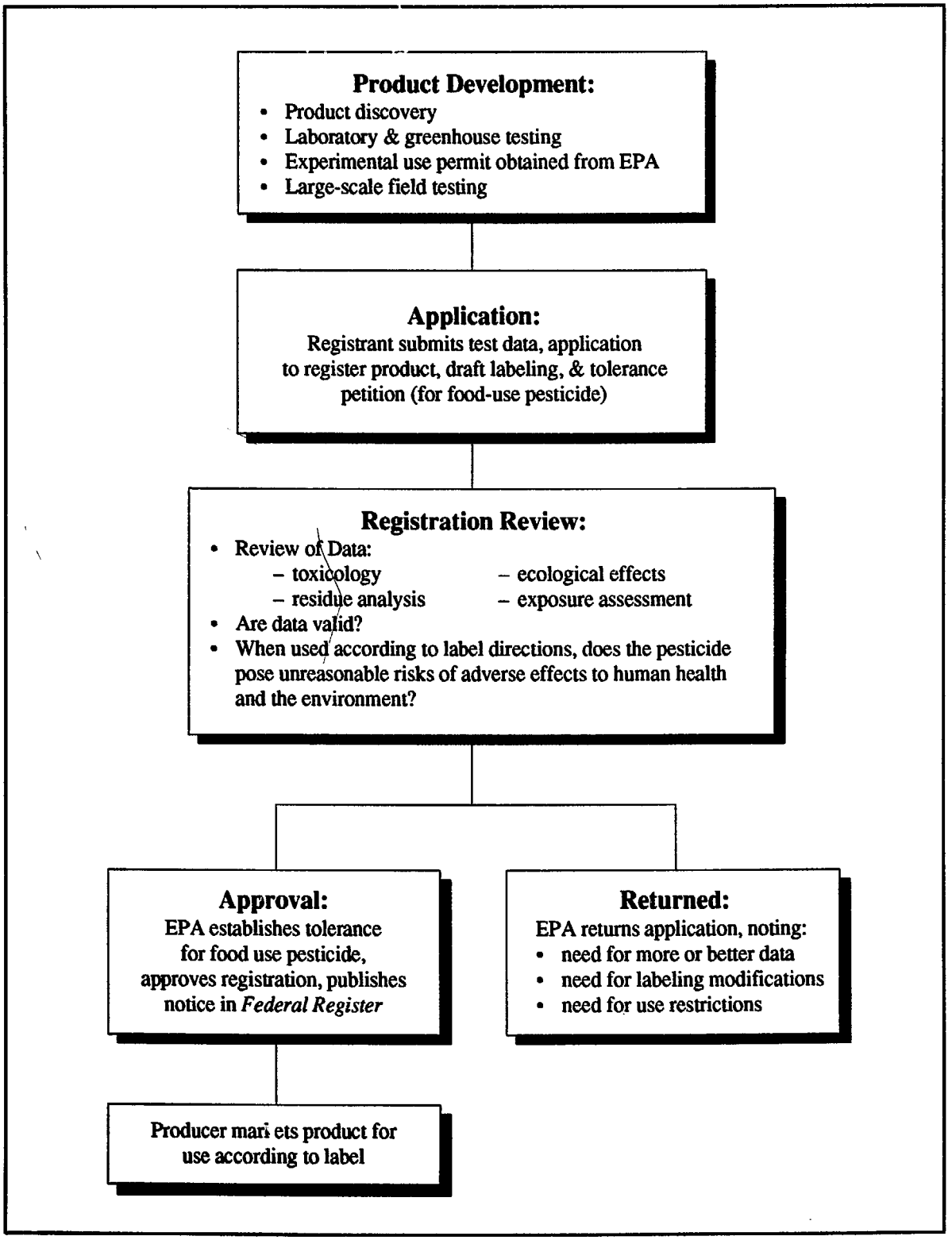


Figure 4 - Pesticide Registration Process for New Chemical

Evaluating Scientific Studies

Because virtually all of EPA's decisions relating to the registration of pesticides depend on the Agency's evaluation of scientific studies, EPA has developed a standardized review process and established procedures and testing guidelines to ensure the quality and consistency of toxicity studies.

How much data to require in the first place and how much should be generated again in the reregistration process are important issues. For example, long-term animal studies usually require two or more years to complete, at a significant cost to the registrant, and using significant numbers of animals. Thus, it is not a trivial matter to require additional studies to be performed. At the same time, it is crucial that registration decisions be based on conclusive scientific information and that all products be evaluated consistently.

In light of these considerations, EPA has set forth four types of documents governing the generation and review of data. These are:

(1) *Data requirements* — what data must be generated to support registration and reregistration;

(2) *Data guidelines* — protocols for how to conduct the studies;

(3) *Standard evaluation procedures* — guidelines for Agency reviewers on what to look for in the data and how to reach consistent conclusions; and

(4) *Good Laboratory Practices* — regulations that specify how studies must be conducted to assure the quality and integrity of data submitted to support pesticide registration and reregistration. EPA's laboratory audit program also serves as a further check on the quality of pesticide safety data.

Nevertheless, there still may arise differences in professional judgment about whether a particular study satisfies a data requirement or whether data can be used from multiple studies to fill data requirements. Therefore, major evaluations made by EPA's staff may be submitted for review to an independent panel of experts, known as the Scientific Advisory Panel. In addition, the bases for EPA's regulatory decisions are subject to public review so that everyone has an opportunity to look at the science supporting the Agency's decisions.

Special Review, Cancellations, and Suspensions

New data on registered products sometimes reveal the existence of a problem or a potential for hazard that was not known at the time of registration. Congress and EPA have developed various mechanisms to reach sound scientific decisions in these situations.

Special Review: Under the law, if EPA seeks to revoke the registration of a pesticide, the Agency must first announce its reasons and offer the registrant a formal hearing to present opposing evidence. Because the cancellation process can be very time- and resource-consuming, EPA often will employ a more informal and often more productive process known as Special Review.

Special Review is an intensive and systematic examination process that offers opportunities for interested parties on all sides to comment and present evidence on the risks and benefits of a pesticide. In many cases, the Special Review results in an agreement to modify the registration to sufficiently reduce risk so that a formal hearing is no longer necessary.

Cancellation: If the Special Review process fails to resolve the issues, however, or if EPA decides that the problem is severe enough to warrant cancellation, EPA may issue a proposed notice of intent to cancel without holding a Special Review. The Agency also is required by FIFRA to send the proposed notice to the Scientific Advisory Panel and the U.S. Department of Agriculture (USDA), and must evaluate their comments before proceeding with a final Notice of Intent to Cancel Registration.

If no hearing is requested within 30 days of the notice, the pesticide's registration is cancelled immediately. If a hearing is requested, it is conducted in a trial-like administrative proceeding before an EPA Administrative Law Judge, who issues a recommended decision to the EPA Administrator. At the end of the cancellation process, which may take two years or more, the decision may still be challenged in a federal court of appeals. If there is no appeal to a decision to cancel, all pertinent registrations of the pesticide are automatically cancelled, and the products may no longer be sold or distributed in the United States.

Suspension: During the entire cancellation process, the pesticide remains on the market and no regulatory restrictions are imposed on the pesticide or its use. In some cases EPA may believe that allowing the pesticide to stay on the market — during a Special Review and/or a cancellation hearing — would pose an unacceptably high risk. In such cases, EPA may issue a suspension order that bans sale or use of the pesticide while the ultimate decision on the pesticide's status is under review.

In order to issue a suspension order, EPA must find that use of the pesticide poses an imminent hazard. In most cases, EPA must first offer the registrant an expedited hearing on the suspension issues. However, if EPA finds that an emergency exists (i.e., that even during the time needed for a suspension hearing, use of the pesticide would pose unreasonable adverse effects), the Agency can ban the sale and use of a pesticide effective immediately.

Under current law, even in an emergency suspension, EPA must assess the benefits of the pesticide as well. This provision makes emergency suspension difficult to use, and EPA has been able to make these findings only three times for major pesticides — ethylene dibromide (EDB); 2,4,5-T/Silvex; and dinoseb. Proposals have been made that would streamline the existing cancellation process and make the suspension process more flexible.

Food Safety

The food supply of the U.S. is among the safest in the world. Although many of the foods we consume may contain low levels of pesticide residues as a result of the legal use of these products, numerous safeguards are built into EPA's pesticide regulatory process to ensure that the public (including infants and children) are protected from unreasonable risks posed by eating pesticide-treated foods.

EPA regulates the safety of the food supply by setting tolerance levels, or maximum legal limits, for pesticide residues on food commodities and animal feed available for sale in the United States. The purpose of the tolerance program is to ensure that U.S. consumers are not exposed to unsafe levels of pesticide residues in food.

Pesticides can be registered under FIFRA for use on a food or feed crop only if a tolerance (or exemption from tolerance) is first granted, under authority of sections 408 and/or 409 of the Federal Food, Drug and Cosmetic Act. EPA has approved about 300 pesticides for food uses; about 200 of them are in common use in the U.S.

Setting Pesticide Tolerances

Pesticide tolerances are being reassessed as part of EPA's reregistration process. Since

residue chemistry and toxicology are far more advanced now than when pesticides were first registered in this country, EPA is upgrading its traditional tolerance system.

To evaluate the risks posed by pesticides in the diet, EPA follows Agency risk assessment guidelines. For non-cancer effects, when using the results of animal tests, EPA determines the highest level of exposure to a pesticide at which there are no observed adverse effects in animals. An "uncertainty factor" is applied to that level (most often, by dividing by 100) in order to estimate a level of daily exposure to the pesticide acceptable for humans. This level is called the Reference Dose (once known as the Acceptable Daily Intake).

EPA also estimates the levels of people's exposure to pesticide residues in food, based on pesticide residue studies as well as studies of how much food people consume. Using data on both toxicity and exposure, the Agency sets tolerances at levels that will not pose significant dietary risks to the consumer. EPA usually will deny a registration if the anticipated exposure from a proposed new food use of a pesticide, when added to estimated exposure from other food uses of that pesticide, significantly exceeds the pesticide's Reference Dose.

In cases where a food-use pesticide is a carcinogen (cancer-causing agent), EPA uses a second approach in addition to that discussed above. EPA assesses the cancer risk specifically associated with exposure to the pesticide in food over the course of a lifetime. EPA then determines whether that cancer risk can be considered "negligible." In general, EPA will grant a tolerance and register any pesticide that poses a negligible or no-cancer risk.

The concept of a negligible risk is the attempt to set a standard below which the cancer risk is so small that there is no cause for worry from a regulatory or public health perspective. EPA's pesticide program defines a risk as negligible if a person has a one-in-a-million or less chance of getting cancer as a direct result of a lifetime of exposure to a particular substance. (By contrast, the overall risk to the U.S. public of getting cancer, from all factors, is on the order of one in four or one in five.)

For pesticides that pose a cancer risk that is greater than negligible, there are two different policies, depending on the situation. For pesticides that require only a section 408 tolerance (i.e., residues in raw agricultural commodities), EPA will register the pesticide if its benefits outweigh the risks posed by its use. If, however, a pesticide also requires clearance under the food additive provisions of FFDCA (section 409), then EPA cannot by law grant a tolerance or register the pesticide if it poses a greater-than-negligible risk, no matter how significant the benefits.

> *I am encouraged by the increased interest and participation of the public in the issues of food safety. . . Informing the public accurately and truthfully about risks is in itself an essential part of protecting the public interest.*
>
> -- Linda Fisher, EPA Assistant Administrator, Pesticides and Toxic Substances

Monitoring Residues

The pesticide tolerances set by EPA are enforced by the Food and Drug Administration, which monitors all domestically produced and imported foods traveling in interstate commerce except meat, poultry, and some egg products. FDA conducts a Total Diet Study, also known as a Market Basket Study, which measures the American consumer's daily intake of pesticide residues from foods that are bought in typical supermarkets and grocery stores, and prepared or cooked as they would be in a household setting. The findings of the ongoing Total Diet Study show that dietary levels of most pesticides are less than one percent of the Reference Dose.

Imported foods receive special attention in FDA's monitoring program. Above-tolerance residues in 1987 and 1988 were found in less than one percent of import samples. Even so, FDA has tightened its import policy in the last few years: if a single shipment from a given source is found to violate U.S. tolerance regulations, all shipments from the same source are subject to automatic detention.

Monitoring of meat and poultry products is conducted by USDA's Food Safety and Inspection Service (FSIS). Each year, FSIS conducts 10,000 to 20,000 pesticide residue analyses. Currently, fewer than one percent of these tests show illegal residues, and the violation rate has been declining steadily over the last two decades. State regulatory agencies are also involved in monitoring the safety of the food supply; some states have their own pesticide residue regulations for food produced and sold within state boundaries.

In summary, EPA believes that foods containing legal levels of pesticides are safe, that continued regulatory review and action are serving to reduce and eliminate unnecessary risks, and that the overall risks from pesticides in the diet are small compared to the benefits of the plentiful, nutritious, and affordable food supply that we enjoy in the United States.

EPA's tolerance-setting system is designed to protect the average person against both short-term and any long-term harmful effects of exposure to pesticides in food.

However, some people, especially infants and children, tend to receive significantly higher than average exposures, at least for some portion of their lives. Children and infants typically eat more food in relation to their body weight and more of certain types of food (such as milk) than the average adult. In setting tolerances, therefore, EPA takes into account the potential risks to children and infants, as well as to over 20 other subgroups in the population.

Although EPA believes that its approach to setting tolerances adequately protects the young, the Agency has contracted with the National Academy of Sciences to study this issue and report on any recommended changes in approach. This study is due in the spring of 1991.

Other Pesticide Programs

Farmworker Safety

EPA is making a concerted effort to safeguard farmworkers' health through a combination of regulatory, educational, and research programs. Despite regulations issued in 1974, significant numbers of pesticide poisonings among agricultural workers continue to occur every year. In 1988, EPA proposed new Worker Protection Standards to strengthen the earlier worker protection provisions, reduce risks of exposure to pesticides, and extend coverage to include persons who engage in hand labor tasks or handle pesticides on farms, or in forests, nurseries, and greenhouses. Final new regulations will be issued in 1991.

The proposed new standards will reduce the risk of exposure to pesticides by:

- Requiring that general pesticide safety rules be posted in a prominent location and that workers be notified of all pesticide applications.
- Requiring training for pesticide handlers and use of appropriate personal protective equipment during handling activities.
- Prohibiting workers (other than handlers) from being present in a pesticide-treated area during application.
- Imposing interim reentry intervals for the most acutely toxic chemicals until these chemicals can be evaluated in the reregistration process.
- Requiring that potable water, soap, and disposable towels be made available to pesticide handlers and workers in treated areas for washing off pesticide residues.

EPA also is undertaking a variety of outreach activities, including preparing a user's guide to the regulations, poster materials, and slide and tape programs in English and Spanish that will help communicate these safety measures to farm workers and farm owners.

Information on the health effects of pesticides and pesticide poisonings is available 24 hours a day from operators at the EPA-funded National Pesticide Telecommunications Network operating out of the Texas Tech University School of Medicine.

Call toll-free:
1-800-858-7378

Home, Lawn, and Garden Pesticides

A wide variety of pesticides used in homes and on lawns and pets are readily available to consumers in retail stores. No special training is required to use these products; consumers are expected to follow the instructions on the pesticide label. However, many of these products can be hazardous if improperly stored, handled, or applied.

Household pesticides are coming under a systematic review as part of the Agency's reregistration process. EPA also is studying whether household pesticide labels are adequate to fully inform the user of potential health or environmental hazards.

Indoor Air

An emerging concern is the level of pesticide residues in indoor air. EPA recently conducted a limited monitoring study, the Non-Occupational Pesticide Exposure Study (NOPES), which measured exposures in some 250 households in Florida and Massachusetts. Of the 32 pesticides monitored, all were detected at least once in an air sample, but the levels found were minute and were determined to present little or no concern for adverse health effects. This study was too limited to draw any broad conclusions about residential air quality, but it will help set the Agency's course for future research.

Lawn Care

As part of the reregistration process, EPA is reviewing individually the 35 major lawn pesticides. In addition, EPA is reviewing the current set of data requirements for lawn care products in order to determine if additional potential hazard information should be generated.

EPA believes that homeowners and residents are unlikely to receive long-term or chronic exposure to lawn care pesticides. Even intensively managed lawns generally receive a maximum of five pesticide applications a year. Furthermore, highly toxic pesticides are not registered for home use.

Nevertheless, EPA encourages homeowners and the pest control industry to follow integrated pest management (IPM) practices that reduce reliance on pesticides while still allowing healthy, attractive lawns to be maintained. For example, in properly maintained lawns, the thick healthy turf will crowd out many weed species; if grass is cut at the proper height, watered, aerated, and fertilized properly, the incidence of fungus disease will be lessened. A number of pest-resistant grass varieties and low-maintenance ground cover plants are available commercially.

EPA is working with state and local governments to develop IPM plans, guidance documents, and research papers on IPM technology for home lawns and golf courses. (See the appendix for recent IPM publications and fact sheets on home gardening and lawn care.)

Even though pesticides are familiar and frequently used items in a household, reading the label is ALWAYS necessary.

For tips on the safe use of pesticides, write for the free brochure, "A Citizen's Guide to Pesticides," U.S. EPA, Public Information Center, 401 M Street SW, Washington, DC 20460.

Pesticide Storage and Disposal

Pesticide wastes result from the use of pesticides in agriculture, industry, households, and various other pest control operations. Pesticide wastes appear in a variety of forms: empty containers, left-over pesticides, and excess dilute pesticide solutions resulting from left-over tank mixes, spray equipment rinsate, and rinsing of empty containers.

FIFRA '88 significantly expanded EPA's authority and responsibility to regulate the packaging, storage, transportation, and disposal of pesticides. EPA may now require pesticide producers to submit data on storage and disposal methods; EPA may also establish labeling requirements for transportation, storage, and disposal of pesticides and their containers. The new law also strengthens EPA's ability to take direct enforcement action against violations of storage, disposal, and transportation requirements. Under FIFRA '88, registrants will have significant new responsibilities in assuring that pesticide wastes are minimized and that any eventual disposal is carried out in an environmentally sound manner.

If a pesticide is suspended and cancelled, EPA now has the authority to order the recall of the product and its eventual disposal at the producer's expense. The recall of products by manufacturers is the most efficient

and environmentally sound method of consolidating stocks of cancelled and suspended products.

EPA also will be studying the problems associated with pesticide container disposal, and examining options to encourage or require:

- The return, refill, and reuse of pesticide containers
- The development and use of pesticide formulations that facilitate the removal of pesticide residues from containers
- The use of refillable containers to reduce the number of pesticide containers requiring disposal.

This study was due to be submitted to Congress by December 1990, with regulations on the design of pesticide containers to follow in 1991. The regulations are intended to facilitate the safe use, disposal, and refill and reuse of pesticide containers. FIFRA '88 also authorizes EPA to establish procedures for storage, transport, and disposal of containers, rinsates, or other materials used to contain or collect excess or spilled pesticides.

Recycling Pesticide Containers in Mississippi

In a pilot project begun in May 1989 in Washington County, Mississippi, pesticide users were asked to rinse, collect, and recycle their empty pesticide containers. Metal containers were hauled to a metalwork plant in Greenville, Mississippi, where they were melted at a high temperature, destroying all remaining residues. Plastic containers were crushed and baled in an old cotton gin, then shipped to Ohio and pulverized into flakes and pellets for recycling.

Certification and Training

Pesticides with a restricted use classification can be applied only by a certified applicator or under a certified applicator's direct supervision. There are currently over 100 federally registered restricted use pesticides and some 1.25 million applicators holding valid certification. Applicators include both "private" applicators (mostly farmers) and "commercial" applicators.

Because FIFRA gives the states the opportunity to administer their own certification program, certification requirements vary from state to state. All states, however, must meet the minimum federal requirements established by EPA.

Certification programs currently are conducted by all states except Colorado (where EPA administers the program for private applicators) and Nebraska (where EPA administers the program for all applicators).

The law does not require pesticide applicators to be trained; however, the law does require certified applicators to demonstrate competency with respect to the use and handling of pesticides. EPA has issued standards for determining the competency of commercial and private applicators for certification purposes.

Both EPA and USDA fund, develop, and distribute training materials for certified applicators. Under an interagency agreement between EPA and USDA, EPA funds are passed through USDA to state extension service training programs. Each state has at least one extension specialist on pesticide use and safety. Efforts are underway to strengthen state training programs, particularly in relation to ground-water contamination and endangered species protection.

State Enforcement

FIFRA includes provisions for monitoring the distribution and use of pesticides, and imposing civil as well as criminal penalties for violations. For example, it is unlawful under FIFRA to use a registered pesticide product in a manner inconsistent with its label, to alter the label, or to distribute in commerce any adulterated or misbranded product. FIFRA also authorizes "cooperative enforcement agreements" between EPA and the states.

Since 1978, the states have been given primary enforcement responsibility for pesticide use violations, subject to oversight by EPA. Through cooperative enforcement agreements, all states except Nebraska and Wyoming have now assumed primary enforcement responsibility. EPA sets FIFRA enforcement policy and conducts compliance monitoring and enforcement programs in these two states.

On an annual basis, EPA issues national Consolidated Pesticide Cooperative Agreement Guidance, which outlines the national enforcement priorities and activities that every state, tribe, and territory must address under its enforcement cooperative agreement. EPA also issues national compliance monitoring strategies in follow-up to every major pesticide regulatory action to help ensure consistency in enforcement activities across the country.

Cases of pesticide misuse or accidents should be reported to the state agency with responsibility for pesticides — generally the state department of agriculture (see appendix at the back of this booklet). Such cases also may be reported to an EPA regional office (see appendix).

Pesticides in Ground Water

Ground water is the vast underground accumulation of reservoirs that supplies wells and springs. Nearly half of all Americans get their drinking water from private or community wells that tap ground water. Our dependence on ground water to meet drinking water needs is growing. In some rural areas, ground water accounts for up to 95 percent of the water used for domestic purposes.

Pesticides can enter ground water in a variety of ways — through pesticide spills, improper storage, or even as a result of normal application of pesticides in the field. The extent to which ground-water contamination can occur depends on a variety of factors: the chemical/physical properties of the pesticide, the frequency and quantity of pesticide applied, the characteristics of the soil, and the geology of the area. These factors, working singly or in combination, influence the movement of a pesticide through the soil and whether or not it will leach into ground water.

When pesticides do enter ground water, there may be a potential risk to the health of those who drink and use the water. In 1988, the Agency's Pesticides in Ground Water Data Base showed that 46 pesticides had been found in

ground water in 26 states as a result of normal agricultural use.

In response to these findings, EPA has undertaken a number of activities. In 1989 EPA published Health Advisories for 55 pesticides to assist federal, state, and local officials in responding to the contamination of drinking water. The Health Advisories contain information about the pesticides and their uses, the health risks associated with drinking water containing particular concentrations of pesticides, and testing and treatment methods for removing the pesticides from the water. Summaries of the Health Advisories can be obtained by the public through EPA's Safe Drinking Water Hotline (1-800-426-4791).

Recently, EPA set standards that regulate 17 pesticides in drinking water, setting Maximum Contaminant Levels for the pesticide contaminants in community water system wells and establishing monitoring and reporting requirements.

In addition, in a major effort to determine the extent of the problem of pesticides in drinking water wells, EPA has undertaken a National Pesticide Survey of drinking water wells (see box).

EPA also is preparing to publish a final Pesticides in Ground-Water Strategy based on extensive analysis and consultation with farmers, other business organizations, environmentalists, and government officials at all levels. The strategy will define the Agency's goal of preventing adverse effects on current and potential sources of drinking water. States play a key role in achieving this goal by developing and implementing state management plans to identify areas most vulnerable to contamination and by tailoring appropriate prevention and management measures to local conditions. EPA will issue guidance for the management plans that will specify the necessary components of an acceptable plan.

National Pesticide Survey

The National Pesticide Survey was the first study of its kind to be conducted on a national scale. Between 1988 and 1990, EPA sampled 1,350 wells located in all 50 states for the presence of over 100 pesticides and for nitrates.

Preliminary results indicate that 10 percent of the nation's community drinking water wells and about four percent of rural domestic drinking water wells have detectable residues of at least one pesticide. However, fewer than one percent of all wells have concentrations of pesticides above levels of health concern. (Of the wells with detectable levels of one or more pesticides, EPA estimates that 10 percent of community wells and 20 percent of rural domestic wells exceed health advisory or maximum contaminant levels.) The most frequently detected pesticides were dacthal metabolites and atrazine. More than half the nation's wells contain nitrates, but fewer than three percent have concentrations above the level of health concern.

A final report on the survey will be available in 1991. Detailed information collected in the survey — on hydrogeological conditions, patterns of pesticide use, and well characteristics — will help EPA regulate pesticides that can contaminate well water.

Endangered Species

Each species plays an interdependent role in the dynamic functioning of a healthy and stable environment, storing a wealth of genetic information that has taken millions of years to develop and perfect. Despite increased concern over the need to protect endangered and threatened species, the world continues to lose entire species at an alarming rate. Over 500 plants, animals, fish, and birds currently are listed as endangered or threatened in the United States; some of these species may be harmed directly or indirectly by exposure to pesticides.

A steady rise in bald eagle populations has occurred since EPA cancelled the registrations of DDT for most uses in the early 1970's. Absorption of these pesticides through the food chain had brought the birds to the brink of extinction. From estimates as low as 400 nesting pairs in the early 1960's, their numbers improved to over 2,660 nesting pairs in the lower 48 states in 1989. On the basis of this recovery, the Fish and Wildlife Service is considering whether or not to reclassify the bald eagle as threatened rather than endangered.

Under the Endangered Species Act, federal agencies must ensure that any action they carry out or authorize is not likely to jeopardize the continued existence of any listed species, or to destroy or adversely modify its critical habitat. EPA's registration of pesticides is considered to be "authorization" under the Endangered Species Act. Therefore, EPA is required to ensure that the registration of pesticides and their use are not likely to jeopardize endangered species.

In July 1989, EPA proposed an Endangered Species Protection Program aimed at protecting listed species from harmful exposure to pesticides, while avoiding placing any unnecessary limitations on pesticide use.

EPA's new program evaluates potential pesticide impacts by focusing first on listed species whose status is most fragile. In cooperation with USDA and the Fish and Wildlife Service (FWS), EPA will gather information on the habitats and locations of these species, and determine whether the species may be affected by pesticides to which they are likely to be exposed. If so, as required by the law, EPA will formally consult with FWS to determine if these pesticides will jeopardize the continued existence of the species. In cases where FWS finds that EPA actions are required to protect the species, EPA will institute use limitations on the pesticides.

The Endangered Species Protection Program will be implemented through product labeling and county bulletins. The pesticide labels will instruct users that use of the product within each county must comply with the limitations set forth in the bulletin for that county. The label will also list a toll-free phone number that pesticide users can call to find out whether or not their county is affected by the program. Bulletins will be made widely available through a variety of outlets.

EPA is encouraging states to recommend protective measures tailored to the listed species located within each state. Until a final program is developed and pesticide registrants are required to modify their labels, EPA will be relying on a voluntary interim program to help protect endangered species.

Biological Pesticides

Natural and Genetically Engineered Microbials

Certain microorganisms, including bacteria, fungi, viruses, and protozoa, have been found effective as pesticidal active ingredients. EPA has registered over 20 naturally occurring microbial pesticides, which are currently used in over 100 products in agriculture, forestry, mosquito control, and home and garden applications.

As a class, natural microbial pesticides usually exhibit several desirable characteristics — they tend to be effective in controlling the target organisms without adversely affecting other organisms; they usually do not have toxic effects on animals and people; and they do not leave toxic or persistent chemical residues in the environment. Because of this "safe" use history, natural microbial pesticides are not subject to the same stringent registration requirements as chemical pesticides. However, manufacturers are still required to register them as pesticides if they are intended for commercial use, and the microbials must still undergo certain testing requirements.

With recent advances in biotechnology, there has been considerable interest in genetic engineering of microorganisms to produce pesticides that are as effective and less toxic than chemical pesticides. At the same time, there has been concern that the experimental applications of genetically altered microbes could result in unforeseen risks to the environment. Such microbes, for example, may not be subject to natural biological or environmental control mechanisms when introduced into the environment.

As a result of this concern, EPA evaluates certain genetically engineered microbial pesticides before they are applied in the environment. Manufacturers are always required to obtain experimental use permits (EUPs) for any large-scale field study of a pesticide. In addition, in 1984, EPA published a notice requiring the Agency to be notified at least 90 days prior to small-scale field testing of genetically engineered pesticides. Regulations specifying the notification and information requirements for small-scale field tests of genetically engineered pesticides are being prepared.

Biochemicals

Biochemicals are chemicals that are either naturally occurring or identical to naturally occurring substances. Examples include hormones, pheromones, and enzymes. Biochemicals function as pesticides through non-toxic, non-lethal modes of action, such as disrupting the mating patterns of insects, regulating growth, or acting as repellents. Like many microbials, biochemicals tend to be more environmentally compatible and are thus important to integrated pest management programs. They tend not to disrupt beneficial organisms and do not generally pose risks of mammalian toxicity or human health effects.

Over 30 biochemical pesticides have been registered by EPA. Although these substances must still go through the registration process, EPA allows for reduced testing requirements for biochemicals in order to promote their use.

Inert Ingredients

In addition to containing active ingredients, virtually all pesticide products contain one or more inert ingredients. Typical inerts are solvents (water, petroleum distillates, or alcohols), carriers (talc, sand, or corn meal) and surfactants (soaps or detergents). By definition, inert ingredients are not "active" in attacking a particular pest. However, some inert ingredients are chemically or biologically active and may cause health and environmental problems. Prior to 1987, the majority of inert ingredients had received EPA clearance but had been subject to relatively little scientific scrutiny.

In 1987, EPA published an Inerts Strategy which calls for the use of the least toxic inert ingredients available. For new inerts, clearance requests must include a minimum "base set" of data that allows EPA to determine whether or not exposure to the inert will result in unreasonable adverse effects. Existing inerts have been placed in groups based on their known toxicity and the need for additional toxicity testing.

EPA is concentrating its attention on the higher priority inerts. Of some 50 substances identified by EPA as presenting potential toxicological concern, all but a few have now been eliminated by registrants from their products; in the interim, manufacturers must relabel products to identify the presence of these toxic inerts. A second group of about 65 inerts has been identified as representing potential toxic concern and a high priority for testing. EPA is evaluating these chemicals as additional information becomes available to determine the risks of their continued use.

Preventing Pollution

In line with an Agency-wide priority on preventing pollution, EPA is promoting the development, and expediting the registration, of safer alternatives in pest control. EPA is also looking to build into the review process for existing pesticides an increased emphasis on non-chemical alternatives to problem pesticide uses. Other specific initiatives are being developed in integrated pest management and in sustainable agriculture.

Integrated Pest Management

For the urban environment, EPA has been developing an integrated pest management (IPM) strategy. Elements of that strategy over the next few years will likely include:

- Support for research to develop biological and cultural alternatives to traditional pesticides
- An emphasis on the development of integrated systems to forestall the build-up of resistance to any single control measure
- Building strong public/private partnerships involving government, industry, users, universities, and private organizations to promote rapid transfer of new pest management and crop production technologies to growers and other users.

EPA is participating in the International Pest Resistance Management Congress, to be held late in 1991, which will bring together representatives from both industrialized and developing countries. The Congress will establish a global communication network and data base on pesticide resistance and successful management strategies.

Sustainable Agriculture

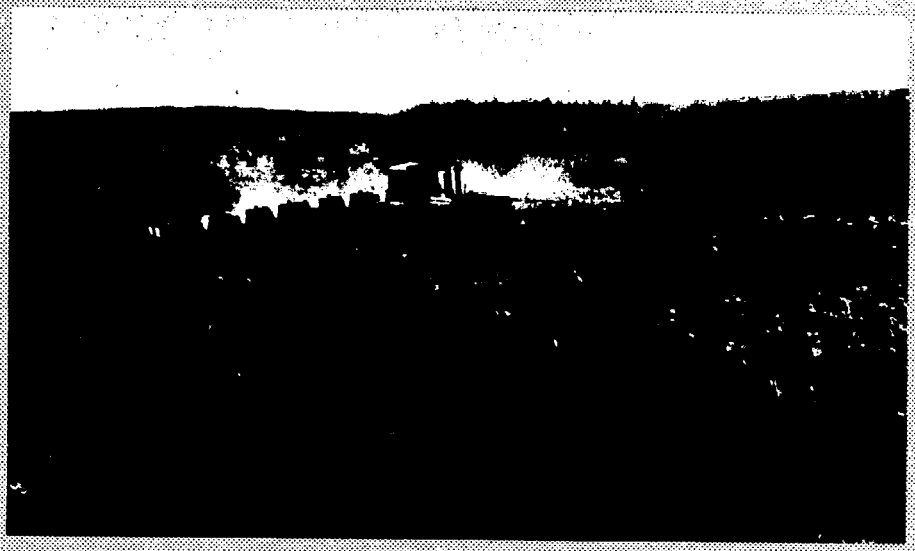
Pesticide use in agriculture is increasingly coming under scrutiny in the context of preventing pollution and achieving a sustainable agricultural system.

Several features of the current system of American agriculture detract from its "sustainability" over the long term. These include a heavy reliance on fossil fuels; cropping systems that degrade soils and water; chronically low economic returns that continue to force some

farmers, particularly family farmers, out of business; and environmentally damaging use of synthetic pesticides and inorganic fertilizers.

The long-term solutions to agricultural pollution, like the sources themselves, are highly diverse. But certain methods hold considerable promise. They include: rotating crops, scouting fields to determine actual pest populations, the use of pest resistant crop varieties, recycling animal manures, and the use of biologically based methods of pest control. The intent is to minimize the need for pesticides, conserve soil or enhance soil productivity, and make farming systems more sustainable.

To support USDA in fostering sustainable agriculture, EPA is generating and distributing information that will assist in a voluntary shift in agricultural practices over the long term. Particularly important are demonstration and education projects emphasizing more environmentally benign production practices which also sustain yield and net farm income. EPA is working with USDA officials to increase their emphasis on these programs and to use their field presence to educate farmers on pollution prevention and sustainable agriculture.



A Sustainable Agriculture Initiative

A joint project was initiated in March 1991 to allow farmers, extension agents, and crop consultants to use a computer model in their weed management decisions. Participating in the project are EPA Regions 7 and 8, EPA's Office of Pesticide Programs, the U.S. Department of Agriculture, and agriculture experiment stations and universities in Minnesota, Illinois, and Colorado.

The computer model to be distributed is an expert system containing ten years of research data with over 150 herbicide/cultural options for corn and corn rotations, plus their projected yields and costs. Growers can use this information to reduce their reliance on chemical herbicides. The benefits of reducing herbicide usage in corn production include cost savings to farmers; reduced exposure to herbicides during mixing, loading, application, and cleanup; and a reduced risk of ground-water contamination associated with corn production in the Central Great Plains and Midwestern Corn Belt.

A Closing Word

The next few years will require an enormous level of effort by EPA and our state partners to develop a more comprehensive system to implement the provisions of the FIFRA '88 amendments. The effort calls for equally active roles by a wide variety of individuals and groups affected by pesticides.

State agencies play a critical role in ensuring compliance with regulations, as well as in providing guidance to users and educating the public concerning pesticide issues. In the next several years, states will have a new and critical role in ground-water protection, endangered-species protection, and farmworker safety. In all areas of pesticide regulation, EPA hopes to build on existing EPA/state partnerships.

Environmental and public interest groups are encouraged to monitor the progress of particular pesticides through the reregistration process and to provide input in the development of EPA's forthcoming regulations on storage, transport, and disposal of pesticides and containers.

EPA also encourages environmental and public interest groups to work closely with the public and with pesticide users to promote better understanding of pesticide usage and to encourage more integrated pest management.

Pesticide registrants will be required to play a much more active role in the regulatory process than in the past, particularly in reregistration. They are being asked to make financial commitments in the form of fees and testing costs, and to meet statutory deadlines for submitting as complete and accurate data as possible. Registrants will need to keep lines of communication open with growers about the pesticide industry's intentions for reregistering old products and for registering new products.

Pesticide users will benefit from the increased protection that reregistration will offer, but they may experience temporary disruptions in the availability of familiar products. Grower groups have a role to play in:

- Providing information to EPA early on about critical pesticide uses
- Assisting in conducting more residue studies in the marketplace so that exposure data are more realistic
- In some cases, supporting the development of data for "minor uses" of a pesticide for which the basic registrant does not intend to seek reregistration
- Actively supporting and trying IPM and other techniques of sustainable agriculture to reduce the overall burden to the environment.

The food industry should note that EPA's accelerated review of older pesticides may uncover risk concerns in some cases. Food industry representatives are urged to be as responsive as possible to consumer inquiries and to help in educating consumers on pesticide issues. The food industry may also be asked to assist in improving exposure data through increased residue studies.

Finally, *individual members of the public* will have the opportunity to contribute information to the decisions on pesticides made by EPA. Ultimately the public will benefit from greater confidence in our national pesticide regulatory process and the enhanced safety of our food supply that will result from the implementation of FIFRA '88.

Appendices

Glossary

Active Ingredient: In any pesticide product, the component which kills, or otherwise controls, target pests. Pesticides are regulated primarily on the basis of their active ingredients.

Acute Toxicity: The capacity of a substance to cause a poisonous effect (such as skin or eye irritation or damage to an organ) or death as a result of a single or short-term exposure.

Cancellation: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 6(b) authorizes cancellation of registration if, when used according to widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment, or if its labeling or other material required to be submitted does not comply with FIFRA provisions.

Cholinesterase: An enzyme that helps regulate nerve impulses. Cholinesterase inhibition is associated with a variety of acute symptoms such as nausea, vomiting, blurred vision, stomach cramps, and rapid heart rate, and can lead to death in severe cases.

Chronic Toxicity: The capacity of a substance to cause harmful health effects after long-term exposure.

Endangered Species: Animals, birds, fish, plants, or other living organisms threatened with extinction by man-made or natural changes in their environment. Requirements for declaring a species endangered are contained in the Endangered Species Act.

Experimental Use Permit: Pesticide manufacturers are required to obtain experimental use permits for testing new pesticides or new uses of pesticides whenever they conduct experimental field studies to support registration of the pesticide on 10 acres or more of land or one acre or more of water.

Inert Ingredient: A component of a pesticide such as a solvent or carrier that is not active against target pests.

Microbial Pesticide: A microorganism that is used to control a pest. Microorganisms are living organisms so small that individually they usually can be seen only through a microscope.

Pest: An insect, rodent, nematode, fungus, weed, or other form of terrestrial or aquatic plant or animal life or virus, bacteria, or microorganism considered to be an annoyance and which may be injurious to health or the environment.

Pesticide: Substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Also, any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

Reentry Interval: The period of time immediately following the application of a pesticide to an area during which unprotected workers should not enter the area.

Registrant: Any manufacturer or formulator who obtains registration for a pesticide active ingredient or product.

Registration: Under the Federal Insecticide, Fungicide, and Rodenticide Act (as amended), the formal listing with EPA of a new pesticidal active ingredient prior to its marketing or distribution in intra- or inter-state commerce.

Registration Standards: Published documents which include summary reviews of all the data available on a pesticide active ingredient, data gaps identified, and the Agency's existing regulatory position on the pesticide.

Reregistration: The reevaluation and relicensing of existing pesticidal active ingredients originally registered prior to current scientific and regulatory standards.

Residues: The pesticide remaining after natural or technological processes have taken place.

Restricted Use: When a pesticide is registered, some or all of its uses may be classified under FIFRA for restricted use if the pesticide requires special handling because of its toxicity. Restricted-use pesticides may be applied only by trained, certified applicators or those under their direct supervision.

Suspension: EPA's act of prohibiting the use of a pesticide in order to prevent an imminent hazard resulting from continued use of the pesticide. An emergency suspension takes effect immediately; under an ordinary

An emergency suspension takes effect immediately; under an ordinary suspension, a registrant can request a hearing before the suspension goes into effect.

Tolerance: The maximum amount of pesticide residue allowed by law to remain in or on a harvested crop. EPA sets these levels so that the chemicals do not pose an unreasonable risk to consumers.

Toxic: Harmful to living organisms.

Toxicity: The inherent capability of a substance to cause adverse effects in human, animal, or plant life.

Unreasonable Risk: Under FIFRA, "unreasonable adverse effects on the environment" means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

For Further Information:

Brochures

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U.S. EPA. Inert Ingredients in Pesticide Products; Policy Statement. 52 FR 13305 (April 22, 1987).

U.S. EPA, Worker Protection Standards for Agricultural Pesticides; Public Meetings and Proposed Rule. 53 FR 25970 (July 8, 1988).

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Supervisor, Pesticide Section
Division of Plant Industry
Colorado Dept. of Agriculture
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Lakewood, CO 80215-5894
(303) 239-4140

Montana
Administrator, Montana Dept. of Agriculture
Environmental Management Division
Agriculture-Livestock Building
Room 317, Capitol Station
Helena, MT 59620-0205
(406) 444-2944

North Dakota
Director, Pesticides and Noxious Weed Division
Department of Agriculture
600 East Blvd.
Bismarck, ND 58505-0020
(701) 224-2231

South Dakota
Director, Division of Regulatory Services
South Dakota Dept. of Agriculture
Anderson Building
445 East Capitol
Pierre, SD 57501-3188
(605) 773-3375

Utah
Director, Division of Plant Industries
Department of Agriculture
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Salt Lake City, UT 84116
(801) 538-7100

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Wyoming
Manager, Technical Services
Wyoming Dept. of Agriculture
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Region 9

Arizona
Associate Director, Division of Agricultural Chemicals and Environmental Services
Arizona Dept. of Agriculture
1688 West Adams Street
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(602) 542-3579

California
Assistant Director, Division of Pest Management, Environmental Protection, and Worker Safety
California Dept. of Food and Agriculture
1220 N Street, Room A414
Sacramento, CA 95814
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Hawaii
Head, Division of Plant Industry
Hawaii Dept. of Agriculture
Post Office Box 22159
Honolulu, HI 96823-2159
(808) 548-7124

Nevada
Administrator, Division of Plant Industry
Nevada Dept. of Agriculture
Post Office Box 11100
Reno, NV 89510
(702) 789-0180

Guam
Director, Air and Land Programs Division, Guam Environmental Protection Agency
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Agana, GU 96910

American Samoa
Director, Dept. of Agriculture
Post Office Box 366
Pago Pago, American Samoa 96799

Trust Territory of the Pacific Islands
Executive Officer, Trust Territory Environmental Protection Board
Office of the High Commissioner
Saipan, Mariana Islands 96950

Commonwealth of Northern Mariana Islands
Environmental Engineer, Division of Environmental Quality
Dr. Torres Hospital
Saipan, Mariana Island 96950

Region 10

Alaska
Alaska Dept. of Environmental Conservation
Post Office Box 1088
Palmer, AK 99645
(907) 745-3236

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Agrichemical Standards Bureau Chief
Division of Agricultural Technology
Idaho Dept. of Agriculture
Post Office Box 790
Boise, ID 83701
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Oregon
Assistant Administrator, Plant Division
Oregon Dept. of Agriculture
635 Capitol Street, NE
Salem, OR 97310-0110
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Washington
Pesticide Specialist
Washington Dept. of Agriculture
406 General Administration Building
Olympia, WA 98504
(206) 735-5064

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Environmental Protection Agency
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