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SL-53

Regulation of Pesticide Use[1]

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Organic and inorganic chemicals used as pesticides include: insecticides, herbicides, fungicides, rodenticides, fumigants, disinfectants, plant-growth regulators and other related substances. At the present, about 45,000 pesticide products are marketed in the U.S. Approximately 1.2 billion pounds of pesticides, valued at $6.5 billion, are sold in the U.S. each year. The U.S. Environmental Protection Agency (EPA) estimates that about 70 percent of all pesticides used in this country are applied in agricultural production, 7 percent in home and garden settings, and the remaining 23 percent in forestry, industry, and government programs (Figure 1).

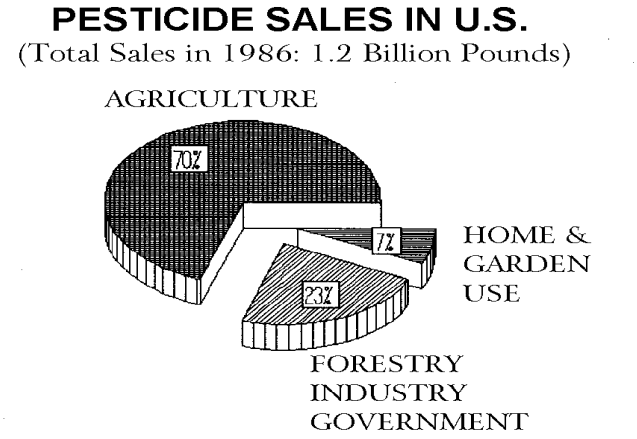

Figure 1.

Before any pesticide product is sold or distributed in intra- or inter-state commerce, it must be registered by EPA and certain state regulatory agencies. This fact sheet provides an overview of how pesticide use is regulated in the U.S. The role of federal and state agencies in development and enforcement of the regulatory policy is discussed.

What Products Are Regulated

In any of the commercial pesticide products, the component that actually kills, or otherwise controls, the target pest is called an active ingredient. The commercial products also contain inert ingredients, such as solvents, surfactants, carriers, etc., that are not active against the target pests. However, not all inert ingredients are innocuous, and may be subject to control or regulation because of environmental or health concerns. Most of the products on the market today are organic chemicals, while the use of inorganic pesticides, such as arsenical compounds, has declined steadily.

EPA regulates the use of pesticide products on the basis of their active ingredients. About 1,400 active ingredients are found in products on the market, and these can be placed into about 600 distinctive groups, each of which must be regulated separately.

In addition to the organic and inorganic pesticides discussed above, certain naturally occurring microorganisms (NOMs), such as bacteria, fungi, viruses, and protozoa, are also used as pesticides. The use of NOMs as pesticides was first approved in the late 1940s, and 14 NOMs are found in about 100 pesticidal products

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used in agriculture, forestry, mosquito control, and home and garden applications. These microbial pesticides are known to be pest-specific and of low toxicity to man.

Recent advances in biotechnology have also made it possible to genetically alter certain microorganisms to induce pesticidal properties. The use and regulation of genetically engineered micro-organisms (GEMs) is the focus of much public and scientific debate. GEMs have been used primarily in laboratory and greenhouse tests; limited field-scale testing has been approved only recently. Therefore, the regulatory aspects of GEMs will not be covered in this fact sheet.

Who Is Regulated

Practically anyone who manufactures, formulates, markets and uses any pesticide is covered by some federal or state regulation. About 30 major pesticide manufacturing companies, another 100 smaller companies that market active ingredients, 3,300 product formulators and over 29,000 distributors are subject to EPA's health and safety regulations. In addition, all pesticide users, including farmers and private citizens, are subject to EPA regulations.

It is unlawful for any person to use a pesticide in a manner inconsistent with its label directions. Certain pesticides labeled as "Restricted Use Pesticides" (RUPs) must be used by or under the direct supervision of a certified applicator. A certified applicator is any individual who is recognized as competent by a certifying agency and thus is authorized to use or supervise the use of RUPs. Applicators are certified upon meeting the standards of competency established by EPA and the state pesticide regulatory agencies for certified applicators.

Federal law requires that all commercial applicators pass an examination. Federal law does not require private applicators to pass an examination, but some states, including Florida, do. The Florida Department of Agriculture and Consumer Services (DACS) is the pesticide regulatory agency in Florida. In Florida both private applicators (farmers) and commercial applicators must pass an examination in order to be certified to use or supervise the use of RUPs.

Training is not required for certification, but is strongly encouraged to help the applicators meet the certification standards. Whether the applicators meet the standards is measured by the examinations. The Institute of Food and Agricultural Sciences (IFAS) at the University of Florida offers training courses and also offers the certification examinations for those applicators who wish to be certified in Florida.

Who Regulates

The U.S. Congress mandated that EPA regulate the use and disposal of pesticides in this country. Through its Office of Pesticide Programs, EPA regulates pesticide use and disposal under two federal statutes:

- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), administered by EPA, governs the licensing or registration of pesticide products. This act was last amended by Congress in 1980, and major revisions are currently being debated.
- The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances for pesticide residues in raw and processed foods. The Food and Drug Administration (FDA) of the Department of Health and Human Services monitors and enforces these tolerances.

A history of the federal regulation of pesticides in the U.S. is summarized in Table 1.

FIFRA, as amended in 1972, authorizes "cooperative enforcement agreements" between EPA and the appropriate state regulatory agencies. In 1978, FIFRA was amended to give state governments the primary enforcement responsibility, subject to oversight by EPA, for pesticide-use violations. The state regulatory agencies may set local standards, but they can be no less stringent than those established by EPA. Some states (e.g., California, Florida, and Wisconsin) have adopted state regulations which are more strict than the federal guidelines for the use of certain pesticides.

How New Pesticides Are Regulated

Pesticide registration is a pre-market review and licensing program for all pesticide products marketed in the U.S., whether of domestic or foreign origin. EPA annually reviews about 15,000 registration applications. Most of these requests are for new formulations containing active ingredients which are already registered or for new uses of existing products. Only about 15 new active ingredients are registered each year.

Decisions on registration of new compounds are made on the basis of test data submitted to EPA by the applicant

(or registrant). Basic data required by the EPA on physical-chemical, toxicological, ecological, and environmental properties of the pesticides are summarized in Table 2. These data are used by EPA to evaluate whether the use of a product, according to the label directions, will not present unreasonable risks to human health and the environment. The law also requires EPA to consider economic, social, and environmental benefits in making such regulatory decisions.

It may take up to six to nine years for a new active ingredient to move from the laboratory, through completion of all EPA registration requirements, and finally to the retail shelves. This time-frame includes two or three years needed to obtain registration from EPA. The complete registration process is schematically presented in Figure 2.

EPA estimates that the average cost for a registrant to comply with EPA's data requirements varies between $2.4 to $4 million per active ingredient, and that this represents about 4 to 7 percent of the $50 to 70 million incurred in total research and new-product development costs. Industry estimates these costs are somewhat higher. Registration of a new formulation containing an active ingredient that has already been approved may be completed within six to nine months; hence, the associated costs are proportionately lower.

For products containing active ingredient(s) that are already approved by EPA, the Agency also grants conditional registration, pending the submission of all the data shown in Table 2. Conditional registration is based on the determination that the use of the new formulation or product is in the public interest and will not significantly increase the level of risks compared to the use of similar products already on the market. However, the conditional registration is subject to immediate cancellation if the outstanding data are not submitted by the specified date. EPA may also temporarily authorize federal or state agencies to use a particular product to combat emergencies (e.g., outbreak of a disease) or to meet "special local needs."

How Existing Pesticides Are Regulated

In addition to regulating new pesticides, EPA is also charged with protecting human health and environment from any "unreasonable adverse effects" associated with the use of pesticides that are already registered and currently in use. To ensure that previously registered pesticides meet current scientific and regulatory standards, FIFRA requires re-registration of all existing pesticides. EPA has come under criticism for not being able to re-register all pesticides as rapidly as was originally envisioned by Congress when it enacted FIFRA. The re-registration process is completed through three EPA programs: (a) Registration Standards; (b) Data Call-In; and (c) Special Review.

The Registration Standards Program is EPA's approach to the reassessment and re-registration of pesticide products as mandated by Congress. The reassessment involves a thorough review of the data supporting pesticide registrations and identification of important, but missing, scientific studies which may not have been required when the product was initially registered. The standards process involves making broad regulatory decisions at one time for a group of pesticide products containing the same active ingredient rather than on a product by product basis. About 600 active ingredients contained in 35,000 products could require registration standards review. At the currently planned rate, by the late 1990's registration standards will be developed for all existing active ingredients. By the end of 1987 EPA had issued standards for 169 active ingredients.

Each standard explains EPA's regulatory position on the use of the active ingredient in all pesticide products containing the same chemical. The standard contains: (1) an analysis of the data on which the regulatory position is based; (2) a description of the agency's rationale for the regulatory position; and (3) a statement of conditions that must be met to obtain the product registration. Such conditions might include changes in labeling, application directions or packaging, and submission of additional data.

The Data Call-In program requires existing registrants of active pesticidal chemicals to provide EPA with studies needed to reassess the chemical during the re-registration process or to resolve special concerns such as whether the chemical contaminates groundwater. Such studies include long-term health effects (i.e., chronic toxicity); product chemistry; and residue and environmental effects. The purpose of Data Call-In is to assure that these data are available or that the studies are well underway before the pesticide is reassessed for re-registration under the Registration Standards Process. EPA began the Data Call-In program in 1981, and by the end of the 1985 fiscal year EPA had completed "calling-in" chronic toxicity data for pesticides that were applied to food crops. A special data call-in was completed for 141 existing pesticides

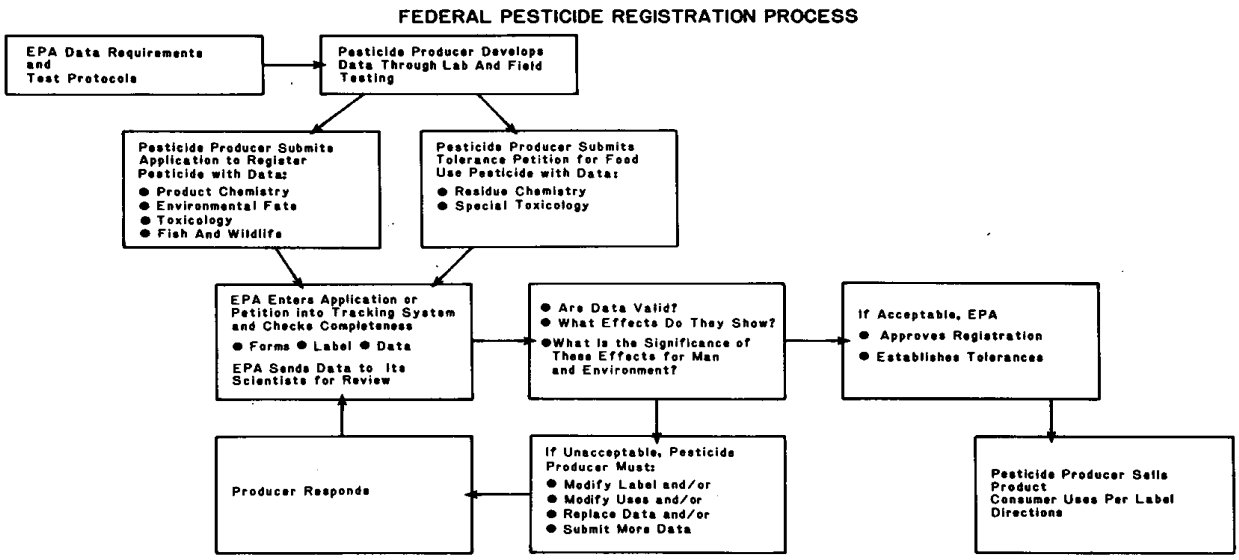

Figure 2.

which are known to contaminate or were suspected of contaminating aquifers.

Existing pesticides suspected of posing unreasonable risks to human health, nontarget organisms and the environment are subject to a Special Review by EPA. The relationship of the Registration Standards process with the Special Preview process is that if the analysis of data shows that a Special Review criterion has been met, then a standard is issued announcing that a Special Review will be initiated for some or all uses of the chemical. All interested parties, including the manufacturers, users, scientists, and the general public, can participate in such a review. Depending on its findings, EPA may implement various regulatory options available under FIFRA. Rather than initiating cancellation or suspension proceedings to reduce the risks associated with the use of the pesticide product(s), EPA often exercises less drastic options. These include: restricting the use of a product to certified applicators; requiring protective clothing; and prohibiting certain application methods or use in certain areas.

If risk-reduction measures are found to be unnecessary, EPA may decide to continue the registration of the product. However, a notice of intent to cancel the registration is issued if the Special Review reveals that the continued use of the product causes "unreasonable adverse effects." The affected parties are given 30 days to appeal. If such an appeal is not made, the registration is automatically canceled. If a hearing is requested, the cancellation proceedings may take up to two years.

In the event that continued use of the product(s) presents an imminent hazard, the use may be suspended. Such action requires evidence that the risks of continued use during the two or more years it takes to complete a cancellation hearing are unacceptable. Two kinds of suspensions are possible under FIFRA: an ordinary suspension, and an emergency suspension. Both can be appealed and the use of the product is permitted during the hearing for an ordinary suspension, but not for an emergency suspension. Unlike the cancellation hearings, the proceedings for an ordinary suspension hearing may take only 6 months. The emergency suspension is the most drastic step EPA can take under FIFRA.

Pesticide Levels In Food And Feed Crops

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is responsible for establishing maximum permissible residue levels, or tolerance levels, for pesticides in raw agricultural products and processed foods. Whenever a pesticide is registered for use on a food or feed crop, a tolerance level, or an exemption from such a requirement, must be established. Tolerance levels apply to domestically produced or imported food and feed stuffs.

The purpose of establishing such tolerance levels is to ensure that U.S. consumers are not exposed to unsafe levels of pesticide residues. Tolerance levels for agricultural commodities are enforced by the Food and Drug Administration, whereas tolerance levels for poultry and meat products are enforced by the U.S. Department of

Agriculture. Any commodities with residue levels in excess of the tolerance level are subject to immediate seizure.

Pesticide Levels In Groundwater

Depending on their physical-chemical properties, patterns of use, and local conditions, some pesticides may leach through the crop root zone and eventually contaminate groundwater at certain locations. The two most important factors which control whether a pesticide presents a threat to groundwater are its persistence and mobility in soil [see Reference 2 for a detailed discussion of these factors].

EPA is developing a comprehensive "Agricultural Chemicals in Groundwater Strategic Plan," which is focused on evaluating existing problems and on preventing future problems. EPA is cooperating with the U.S. Geological Survey and various state regulatory agencies in order to detect and correct existing problems with pesticides that are already registered. EPA is conducting a nationwide survey of pesticides in drinking water wells in order to provide a comprehensive picture of the extent of agricultural chemical contamination. In this three-year survey, samples from about 1,500 drinking water wells from across the country, including about 750 wells in rural areas and about 500 community wells, will be analyzed for 62 priority pesticides. For new pesticides that are submitted for registration, EPA uses computer projections to evaluate the potential for groundwater to be contaminated by a specific use of a particular chemical at various locations in the U.S.

Where groundwater contamination is identified, EPA or a state agency may take regulatory action, ranging from selective restriction to outright bans against the manufacture and use of a pesticide. EPA also issues "Health Advisories" to state and local health officials regarding pesticide-residue levels in drinking water. See References 3 and 4 for a discussion of health effects from drinking water contaminated with organic pollutants, and for methods used to evaluate such risks.

Pesticide Registration In Florida

The Department of Agriculture and Consumer Services (DACS) is responsible for regulation of pesticide use in the state of Florida. Four main programs within DACS carry out this responsibility: (1) pesticide registration; (2) pesticide enforcement; (3) scientific evaluation; and (4) laboratory analysis.

Manufacturers of pesticides are required to submit environmental fate data to DACS in accordance with EPA or DACS guidelines. These data and other information gathered by independent institutions (e.g., university researchers) are evaluated and an initial assessment is made by the department's scientists as to potential risks (adverse effects) to public health or the environment from the use of these chemicals in Florida. If serious problems are suspected, the manufacturer may be required to conduct specific laboratory and field studies under Florida conditions in order to collect pertinent environmental data.

Pesticides registered for use in Florida carry a label which specifies the maximum allowed application rates, approved application methods and times, and crops, pests, and locations for safe and effective use. Use and disposal of pesticides according to the label is required by state and federal laws. The pesticide enforcement programs in DACS, in cooperation with EPA, deal with enforcing existing state and federal statutes to ensure that registered pesticides are used and disposed of properly.

DACS also analyzes field samples of soils and water, as well as raw agricultural products collected in the field and from grocery outlets to determine if pesticide residues are below acceptable levels. (See Reference 4 for a discussion on how such limits are set.) Samples of tank mixtures and formulations are analyzed to provide protection to the consumers from these products.

Who To Contact For More Information

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Acknowledgments

This fact sheet is based substantially on a recent USEPA publication "Pesticide Fact Book" (see Reference 1). We thank EPA for granting us permission to reproduce portions of that publication here.

References & Additional Reading

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Table 1. History of Federal Pesticide Regulation. (Adapted from Reference 1.)

1910	Federal Insecticide Act protects consumers against fraudulent goods.
1947	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires federal registration of pesticides prior to marketing in interstate commerce.
1954	Miller amendment to Federal Food, Drug, and Cosmetic Act (FFDCA) requires establishment of tolerances for pesticide residues in food, feed, and fiber crops.
1959	Amendments broaden scope of products covered by FIFRA.
1964	Amendments tighten provisions regulating marketing pesticides.
1972	Federal Environmental Pesticides Control Act (FEPCA) shifts emphasis from consumer to public health and environmental protection.
	Amendments to FIFRA authorize "cooperative enforcement agreements" between EPA and appropriate state regulatory agencies.
1975	Amendments to FIFRA require review by USDA of major pesticide decisions and regulations, and establish a Scientific Advisory Panel (SAP) for review of major pesticide decisions and regulations.
1978	Amendments to FIFRA authorize a generic system of pesticide regulation based on active ingredients common to numerous pesticide products, and introduce conditional registration.
	Other amendments to FIFRA delegate primary enforcement responsibility to states.
1980	Wampler amendment to FIFRA requires peer review of major scientific studies funded by EPA and used in making regulatory decisions.
1986	Based on a joint proposal from the National Agricultural Chemicals Association (NACA) and the Campaign for Pesticide Reform (CPR), the latter an umbrella organization representing 41 environmental, labor, and consumer groups, a bill (HR-2462) was introduced to restructure FIFRA, in order to speed up the safety review of chemicals, broaden labeling requirements, and levy new fees on industry to pay for review of its products. This bill was passed by the House of Representatives, but not by the Senate. The bill was reintroduced in 1987 as HR-2463.

Table 2. Summary of Basic Data Required for a New Major Food or Feed Crop Pesticide. (Adapted from Reference 1.)

CHEMISTRY:	
--	List of Ingredients (active, inert, impurities)
--	Description of manufacturing process
--	Discussion of formation of impurities
--	Physico-chemcial properties (e.g., melting point; solubility in water; flammability; pH; etc.)
--	Residue studies (original and confirmatory tests for each commodity or commodity group)
--	Analytical methods (used in setting tolerances, and to detect residues for tolerance enforcement)
--	Results of analytical procedures
ENVIRONMENTAL FATE:	
--	Hydrolysis; Leaching; Terrestrial dissipation; Photodegradation; Metabolism (aerobic and anaerobic degradation); Rotational crop study.
TOXICOLOGY:	
--	Acute toxicity (oral, dermal, respiratory)
--	Ocular irritation
--	Chronic toxicity (2-year testing of rats)
--	Subchronic oral toxicity (6-month testing of dogs)

Table 2. Summary of Basic Data Required for a New Major Food or Feed Crop Pesticide. (Adapted from Reference 1.)

--	Reproduction and fertility (2-generation study)
--	Metabolism (testing of rats)
--	Mutagenicity
--	Teratogenicity (2 species tested)
--	Oncogenicity (2 species tested)
ECOLOGICAL EFFECTS:	
--	Freshwater aquatic invertebrates and fish (2 species)
--	Birds (dietary; 2 species)
NOTE: Many other tests may be also conditionally required depending upon chemical class, site, physico-chemical properties, biological activity, and the results of basic test requirements.	