

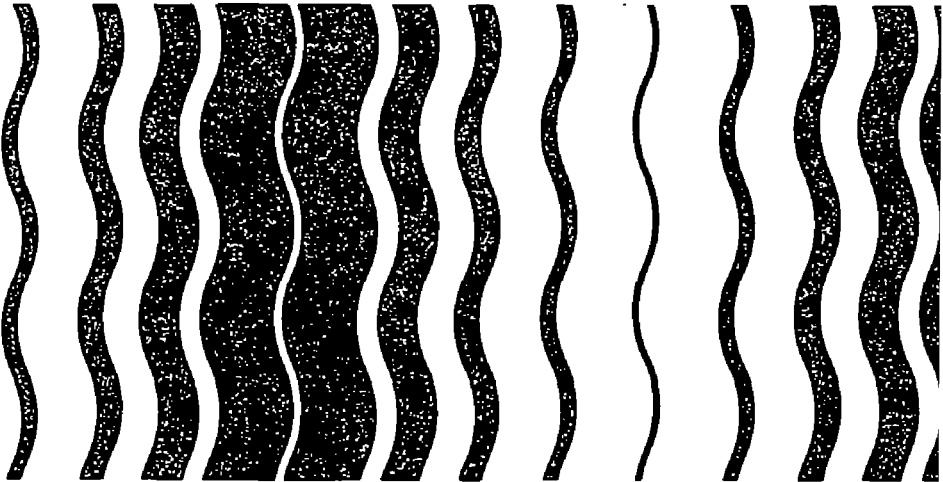
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Pesticides

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# The Federal Pesticide Act of 1978



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## **A New, More Workable Law**

On September 30, 1978 President Carter signed into law the Federal Pesticide Law of 1978, amending the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). That was the final step in a process which had begun some 18 months previously with the submission of Administration proposals to the Congress. Congress and the U.S. Environmental Protection Agency (EPA), which has chief responsibility for administering FIFRA, have worked together to refine this legislation to make government's regulation of pesticides more efficient, more effective, less costly and less time consuming.

The amendments build and improve upon all the major areas covered by the previous law.

- Registration (premarket clearance) of pesticides to prevent unreasonable hazards to humans or the environment.
- Classification of pesticides for general or restricted use.
- Certification of users of restricted use pesticides.
- Informative and accurate labeling of pesticide products.
- Enforcement of FIFRA to ensure proper pesticide practices.

## **The Registration Process**

The most significant and far-reaching of the amendments bear upon the registration process, particularly in regard to the kinds of information required to register a product, the sharing of information between registrants, and the review and validation of the data base supporting some 35,000 pesticide products now on the market.

The cornerstone of the new, more efficient approach authorized in the amended law is a program of *generic pesticide registration*. In the past, registration entailed an examination of risk of each product one at a time. However, generic registration of pesticides entails a single, comprehensive evaluation of risks and benefits of the technical material common to numerous products based on all data relevant to the registration decision. The new system will demand less time and money both from EPA and the registrant.

Development of pesticide generic standards will take time and until such standards are developed and the complete new

reregistration program is put in place, Congress has authorized a program for EPA to grant *conditional registrations*. Conditional registration will allow EPA to process applications for registration of new products which are like ones already registered, and thus permit the new products to enter the market on an equal footing with others already registered and in turn provide consumers with a wider range of comparable products. Ultimately, all products will be reviewed comprehensively when *reregistered* under generic pesticide registration standards.

New uses of "old" chemicals and new chemicals will also be eligible for conditional registration if EPA determines that enough information is available to evaluate unique hazards that may be posed by the new uses. The Agency is also authorized to issue conditional registration of new chemicals if the public interest would be served by a registration, and if risks during the period required to complete and submit additional studies are not unreasonable.

In the future, conditional registration will be useful for allowing time to meet new data requirements or in some special cases, for permitting early registration of brand new chemicals

## **Solving Data Problems**

In addition to authorizing generic and conditional registration, the new law clarifies many matters relating to use of data:

- \**compensation* by one registrant for use of data owned by another registrant;

- \**exclusive use* of data submitted for registration of new pesticide chemicals,

- \*protection of specified *trade secrets*;

- \*several issues pertaining to *efficacy* data, and registration data for "*minor uses*"

All data submitted from 1970 on are eligible for *compensation* for a period of 15 years following the submission of the data. This means that subsequent applicants must offer to pay compensation to data originators in order to rely on their data. If registrants cannot agree on fair compensation, the

dispute will be settled by binding arbitration. Previously the Agency was responsible for settling disputes over compensation.

The new law will also give 10 years "exclusive use" of data to the original registrant after a *new chemical* is first registered. That means that no one can use that data for 10 years without the express permission of the data developer. This aspect of the law rewards innovation in the industry, and may be especially useful in encouraging development of biological pesticides and other compounds for which patent protection was difficult to achieve in the past.

The amended law provides that the *basic* health and safety data underlying pesticide registrations are *open to the public* and thus the public will have access to the information on which EPA's regulatory decisions are based. Other data, however, are now specifically protected from public disclosure. EPA or other government workers, including those under contract to the government, who wrongfully disclose such data are subject to imprisonment or a fine.

Data as to the *efficacy* of a pesticide have generally been required for registration. EPA now has relatively broad discretion to waive submission of efficacy data. That will simplify the registration process for the registrant and reduce Federal manpower required to register and reregister pesticides. This new policy is more or less an experiment in permitting the marketplace to police efficacy. If it does not stand the test of time, EPA will reconsider the new approach as appropriate. In any case the agency will continue to consider efficacy when performance of the product bears upon public health.

The new law also gives States broader authority and responsibility for registering pesticides. States automatically have authority to register products for use within a State for "special local needs." Formerly, States had that authority only with EPA approval. EPA may disapprove State registration if the use is dissimilar from Federal registration, if an imminent health hazard exists or if the State has authorized use on crops for which no tolerance, or allowable residue level, on crops, has been established by EPA.

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**Classification  
and  
Certification**

Congress has amended two other separate but related areas in FIFRA — *classification* of pesticides and applicator *certification*.

In order to make full use of the state programs for training and certification of applicators to use "restricted use" pesticides, EPA is authorized to classify uses by regulation, apart from the registration process. This will help realize the objectives of the applicator certification program, since almost all States have worked hard to train and certify applicators to handle the restricted products. Restriction of use also gives EPA an option short of cancellation to reduce pesticide risks. Also in connection with the training and certification programs, EPA is authorized to pay up to 50% of the costs for each State program.

**Some Special  
Issues**

For users of all pesticides the new amendments have clarified an issue of broad concern: the legality of pesticide uses or practices not addressed in the label directions. Several important pesticide use practices have been specifically excluded from the definition of "use inconsistent with the label", and the Agency may identify other uses which will be considered consistent through not in literal accord with the label.

Pesticide exporters must now comply with special label requirements including a requirement that pesticides not registered for use in this country must be labelled, "not registered for use in the U.S.". *Importers* must also sign a statement acknowledging that they know such products are not registered in the United States, a copy of which must be sent to an appropriate official in the importing country.

Congress has required EPA to study and report on:

- the feasibility of charging fees to cover the registration
- method of pesticide application including the advisability of ultra-low volume application
- the problems of minor uses of pesticides.

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## Enforcement

Violations of FIFRA, like those of an , may come to the attention of the government through various avenues — complaints, accident reports, general inspections of areas where pesticides are made or used, specific investigations where violations are suspected. Among the most common violations are misuse of a product through failure to follow labeling directions, deliberate misuse, misbranding, mislabelling and selling adulterated or unregistered pesticides. Violations may involve penalties under FIFRA ranging from fines of small amounts of money to imprisonment.

The new amendments set up a three tier penalty structure for applicators. Pesticide registrants, dealers, retailers and commercial applicators (those applicators, other than private applicators, using restricted use pesticides) are subject to civil penalties of up to \$5,000 for their first violation.

Those applicators in the business of applying pesticides, using only general use pesticides could be fined up to \$500 for first offense violations. Private applicators (generally farmers who use restricted pesticides) and others such as homeowners would first receive a warning letter. As before in assessing fines, EPA must take into account the size of business the appropriateness of the penalty to the violation, and the ability of the person to pay.

The new amendments transfer to States the primary responsibility for prosecuting pesticide use violations. The responsibility will be transferred to a state if it has entered into a cooperative enforcement agreement with EPA or if the Agency has determined that the state has pesticide use laws, regulations, and implementing procedures.

Regardless of transfer of responsibility, if a state is unwilling or unable to effectively act upon a violation, EPA may act. In addition, EPA could revoke all or part of the State's responsibility for pesticide use enforcement if the Agency found that the State's program was deficient. Also, in the event of an emergency where the State was not capable of quickly responding, EPA could step in.

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For users of pesticides, the best rule to promote safety and avoid violations of FIFRA is: Read and follow label directions. If you have any question about FIFRA or safe pesticide practices contact:

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