

Highlights Of the 1988 Pesticide Law

The Federal
Insecticide,
Fungicide, and
Rodenticide Act
Amendments
Of 1988

On October 25, 1988, the President signed into law the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Amendments of 1988. The 1988 amendments to FIFRA, which is administered by the Environmental Protection Agency (EPA), strengthen the Agency's authority in several major areas of pesticide regulation. Among other things, the amendments require a substantial acceleration of the reregistration process for previously registered (licensed) pesticides and authorize the collection of fees to support reregistration activities. The law also changes EPA's responsibilities and funding requirements for the storage and disposal of suspended and cancelled pesticides and the indemnification of holders of remaining stocks of such cancelled pesticides. Most provisions of the 1988 amendments are effective December 24, 1988.

Background on FIFRA

Under FIFRA, all pesticides must be registered with EPA before they may be sold or distributed in commerce. FIFRA sets an overall risk/benefit standard for pesticide registration, requiring that pesticides perform their intended function, when used according to labeling directions, without posing unreasonable risks of adverse effects on human health or the environment. In making pesticide registration decisions, EPA is required by law to take into account the economic, social, and environmental costs and benefits of pesticide uses.

FIFRA was first enacted in 1947. Thousands of pesticide products have been registered since then. However, the standards for pesticide registration have not remained the same since 1947, but have evolved in tandem with science and public policy. In particular, test data requirements for pesticides have become increasingly stringent in light of advances in such areas as toxicology and analytical chemistry. Under FIFRA, pesticide registrants (companies that hold pesticide registrations) are responsible for providing all test data necessary to satisfy EPA's registration requirements.

To ensure that previously registered pesticides measure up to current scientific and regulatory standards, FIFRA requires the review and "reregistration" of all existing pesticides. This has proved to be a massive undertaking. A combination of factors has impeded the Agency's progress in carrying out the reregistration

mandate, including inadequate resources and the sheer magnitude of the task. Of the approximately 600 pesticide active ingredients that require reregistration under FIFRA, EPA has issued "Registration Standards" for about 185. 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.

FIFRA authorizes EPA to cancel the registration of an existing pesticide if test data show that it causes unreasonable adverse effects on human health or the environment. In addition, under certain circumstances, EPA may take action to suspend the registration of a pesticide to prevent an imminent hazard.

Until the 1988 amendments, EPA was required under FIFRA to accept certain suspended and cancelled pesticides for disposal at government expense. In addition, an indemnification provision required EPA to reimburse holders of such suspended and cancelled pesticides for financial losses suffered, up to the cost of the pesticide.

The 1988 FIFRA Amendments

Reregistration Provisions

Reregistration provisions are the principal focus of the 1988 amendments. These provisions establish requirements with very tight deadlines. A sequence of deadlines applies to pesticide registrants, who are responsible for supplying the complete test data bases necessary for EPA to make pesticide reregistration decisions. EPA must also meet very specific deadlines in analyzing data submissions and deciding whether or not to reregister currently registered pesticides. Reregistration will take place in five phases, as follows:

- *Phase 1:* EPA is required to publish lists of pesticide active ingredients subject to reregistration and to ask registrants of pesticide products containing those active ingredients whether they intend to seek reregistration. These lists must be published in four installments over a 10-month period after the effective date of the 1988 amendments.
- *Phase 2:* Registrants are required to respond to EPA concerning their intention to seek reregistration. For each active ingredient,

registrants seeking reregistration must also identify missing and inadequate scientific studies required to satisfy EPA's current data requirements, formally agree to fill these "data gaps" according to prescribed deadlines, and pay the first portion of a reregistration fee. Phase 2 responses are required within three months after EPA publishes each chemical list. If a registrant decides not to seek reregistration, the registration will be cancelled.

- *Phase 3:* Registrants are required to summarize and reformat key existing studies to facilitate EPA review, to certify that they possess or have access to "raw data" (such as laboratory records) from studies, to "flag" any studies that indicate adverse effects, to make a commitment either to generate or to share the cost of generating new test data where studies are missing or inadequate, and to pay the final reregistration fee. Registrants are required to accomplish these Phase 3 requirements within one and one-half to two years after passage of the 1988 amendments. Registrants must then fulfill remaining data requirements within designated time periods.

- *Phase 4:* EPA is required to complete its review of submissions made by registrants under Phases 2 and 3, to independently identify data gaps, and to issue requirements for registrants to fill those gaps. This will take place over a period of two to four years after enactment of the 1988 amendments.

- *Phase 5:* This phase culminates the reregistration process under FIFRA as amended in 1988. It requires EPA to conduct a thorough, comprehensive examination of all data submitted in support of pesticide reregistration. Based on this review, the Agency will either reregister a pesticide or take other appropriate regulatory action. This phase will occur over a span of approximately three to nine years after enactment of the 1988 amendments, depending on such variables as the complexity of the studies required for reregistration and the time required for registrants to complete and for EPA to review these studies.

Expedited Registration

The 1988 amendments also require EPA to give expedited consideration to applications for initial

or amended registration of products which are similar to pesticides already registered with EPA. "Similar" products include not only those which are identical in composition to currently registered products, but also those which differ from registered products only in ways that would not significantly increase the risk to public health and the environment. In addition, the Agency is required to expedite certain minor amendments to existing product registrations.

Under the expedited review provisions, an applicant will be notified, within 45 days after the Agency receives an application, whether the application is complete. Within 90 days after the Agency has received a fully complete application, the registrant will be notified in writing whether the request is granted or denied; if it is denied, the specific reasons for denial will be given. A portion of the fees collected by EPA will be made available to the Agency for the purpose of carrying out expedited processing of similar applications and minor amendments to registrations.

Fees

Reregistration is a complex regulatory process that is expected to cost about \$250 million over the nine years of the 5-phase process. Approximately \$110-120 million of that cost is expected to come from a continuation of the current level of EPA's budget for reregistration activities. The remaining funds will come from the pesticide industry through two kinds of fees: a reregistration fee for each active ingredient, and an annual fee for registration maintenance to be paid for each registered product.

For each active ingredient intended for use on major food or animal feed crops, registrants will be required to pay reregistration fees totalling \$150,000. In most cases, an initial payment of \$50,000 is due during Phase 2, and the balance in Phase 3. For pesticide active ingredients not intended for major food or feed uses, registrants will be required to pay a fee of not more than \$150,000 and not less than \$50,000. (The exact fee depends on, among other things, whether a Registration Standard has already been issued for the pesticide and the extent of data required for reregistration.) Active ingredient fees are to be apportioned among registrants of each active ingredient, based on market share.

Reregistration fee reductions or waivers will be

granted for certain pesticide registrants. Any antimicrobial active ingredient for which the annual level of production does not exceed 1 million pounds is exempt; also exempt is any active ingredient for which the value or volume of use is considered minor. In addition, for any "small business" registrant (any company with 150 or fewer employees and average annual chemical sales of \$40 million or less over the three-year period prior to reregistration), the reregistration fee will be based on a graduated rate ranging from 0.5 to 1.5 percent of average annual pesticide sales.

Unlike the reregistration fee, which is levied on the basis of active ingredients, the annual maintenance fee is assessed for each individual pesticide product. For up to 50 product registrations held by a registrant, the annual fee has been tentatively calculated to be \$425 per product. For up to 200 products, the fee would be \$425 per product for the first 50 and \$100 for the rest. However, there are maximum limits on the total annual maintenance fees payable by any registrant: the maximum possible total in maintenance fees for any registrant for up to 50 product registrations is \$20,000; and the absolute maximum total in maintenance fees for any registrant for any number of product registrations is \$35,000.

The objective of the maintenance fee program is to generate approximately \$14 million annually in additional operating funds for the Agency. In the event that there are not enough pesticide product registrations to raise \$14 million, EPA must increase these annual maintenance fees. However, regardless of any increase in per-product fees, the maximum limits of \$20,000 and \$35,000 will continue to apply.

During the nine-year period that these fee provisions are in effect, the Agency is prohibited from levying any other fee for the registration of a pesticide. (The registration fees established by regulation in May 1988 will be in abeyance during this period.) However, the payment of fees for the establishment of tolerances (maximum legal limits) for pesticide residues in food or feed products, required by the Federal Food, Drug, and Cosmetic Act, is not affected by the 1988 amendments to FIFRA.

Storage and Disposal of Suspended or Cancelled Pesticides

The 1988 amendments expand EPA's authority to regulate the storage, transportation, and disposal of pesticides. In addition to the authority to require data on storage and disposal methods, EPA is authorized to establish labeling requirements for transportation, storage, and disposal of the pesticide and its container. The new law also enables EPA, for the first time, to take direct enforcement action against violations of storage, disposal, and transportation requirements.

The 1988 amendments eliminate from FIFRA the requirement that EPA, upon request, must accept suspended and cancelled pesticides and dispose of them at government expense. Under the new law, EPA may require registrants and distributors to recall suspended and cancelled pesticide products. The Agency is authorized to require registrants to give evidence of their financial capacity to carry out such a recall. To facilitate any recalls of this kind, EPA may require all persons who sell, distribute, or commercially use pesticides to notify EPA and state and local officials of the quantities and locations of suspended and cancelled pesticides in their possession.

A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall must submit a plan for storage and disposal of the pesticide that meets criteria to be established by EPA. Registrants will be reimbursed for portions of their storage costs that are attributable to delays in approval of storage plans.

In order to lessen the problems associated with pesticide container disposal, the amendments require EPA to conduct a study of 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 bulk storage facilities to reduce the number of pesticide containers requiring disposal.

The 1988 amendments also authorize EPA to regulate procedures for storage, transport, and disposal of containers, rinsates (such as water used to clean a pesticide container), or other materials used to contain or collect excess or spilled pesticides. Additionally, in order to promote the safe storage and disposal of pesticides, EPA is directed to issue, within three years, regulations for the design of pesticide containers. These forthcoming regulations will facilitate the safe use, disposal, and refill and reuse of pesticide containers.

Indemnity Payments

Prior to the 1988 amendments, if EPA suspended and cancelled the registration of a pesticide, the Agency was required under FIFRA to indemnify holders of the pesticide for losses suffered, up to the cost of the pesticide. Moreover, FIFRA was silent as to the source of funding for any indemnification (or disposal) payments that might occur. Persons previously covered by indemnification included "end users" (such as farmers and commercial pesticide applicators) as well as pesticide formulators, pesticide dealers and distributors, and registrants.

The 1988 amendments end automatic entitlement to indemnity payments for all persons other than certain end users, and provide that all indemnity payments made will come from the Judgment Fund of the Treasury, not from EPA's operating budget. End users, such as farmers, will continue to be eligible for indemnification through the Judgment Fund.

Indemnification to anyone other than an end user may be paid under the 1988 amendments, only if Congress provides a line-item appropriation. The 1988 amendments also require all sellers of a pesticide (including registrants and wholesalers) to reimburse the buyer for the purchase price of a product whose registration is suspended and cancelled, unless at the time of purchase the seller told the buyer in writing that the seller would not make such refunds. If EPA determines that a business insolvency or bankruptcy makes such reimbursements impossible, dealers and/or distributors will also be eligible for indemnification from the Judgment Fund.

Miscellaneous Provisions

The 1988 amendments also contain a number of other provisions designed primarily to make it easier for EPA to implement the major provisions described above, including:

- *Penalties:* Criminal penalties are increased for registrants, applicants for registration, or other pesticide producers who knowingly violate the pesticide law.
- *Unlawful acts:* The 1988 amendments provide that certain acts, such as submitting false test data, violating suspension or cancellation orders, and failure to submit required records or allow inspection, will be unlawful.
- *Records and inspection:* To help ensure compliance with storage and disposal provisions, additional authority is provided for EPA to request records and to inspect places where pesticides are being kept.
- *Unregistered pesticides:* The Agency is given new authority to regulate unregistered pesticides.
- *Scientific Advisory Panel (SAP):* The 1988 amendments provide that the FIFRA SAP, a panel of outside experts convened by EPA to review major pesticide decisions or regulations, will be permanent. Prior to the 1988 amendments, the SAP required reauthorization every five years.
- *Congressional review:* The 1988 amendments shorten the period of Congressional review of final regulations from 60 days of continuous Congressional session to 60 days.