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Pesticide Reregistration

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Introduction

The Environmental Protection Agency (EPA) is required by law to reregister existing pesticides that originally were registered years ago when the standards for government approval and the test data requirements were less stringent than they are today. This comprehensive reevaluation of pesticide safety in light of current standards is critical to protecting human health and the environment. Initially, approximately 600 groups of related pesticide active ingredients, or "cases," required reevaluation. These 600 cases involved about 45,000 formulated products. Early efforts to reregister chemicals proved to be a complicated and cumbersome undertaking.

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to strengthen EPA's pesticide regulatory authority and responsibilities regarding the reregistration of pesticides. The new law, known as FIFRA '88, mandated an accelerated reregistration scheme to be carried out in five phases, concluding in the late 1990s. Under the phased approach, a substantially complete scientific data base is generated for each pesticide product before it is evaluated by the Agency and reregistered.

FIFRA '88 imposed explicit duties and deadlines on EPA and the pesticide industry alike. The amendments required, for the first time, that pesticide producers (or registrants) bear a significant part of the cost of the program by paying reregistration fees. These and other provisions are described in detail in EPA's plan for implementing the FIFRA '88 amendments, which was published in the *Federal Register* on April 26, 1989.

The pesticide reregistration program mandated by FIFRA '88 has made tangible progress during its first three years, and will result in a full complement of reregistration decisions and actions near the end of this decade.

"Pesticide Reregistration" provides an overview of the reregistration process, relevant FIFRA '88 provisions, and the current status of EPA's reregistration program. A more detailed account of the Agency's progress in implementing the reregistration provisions of FIFRA '88 is provided quarterly in the "Pesticide Reregistration Progress Report." A comprehensive, chemical-by-chemical, "Status of Pesticides in Special Review and Reregistration" (or "Rainbow Report") also is available. To obtain copies of these documents, please contact the Special Review and Reregistration Division (H-7508W), Office of Pesticide Programs, US EPA, Washington, DC 20460; telephone 703-308-8000.

The Registration Standards Program

EPA began a systematic reevaluation of existing pesticides in 1980 through a process called the Registration Standards program. A Registration Standard document summarized the Agency's evaluation of the available data on an existing chemical, identified and required submission of additional data, and set forth other conditions a registrant had to meet in order for EPA to reregister pesticide products containing the active ingredient. These other conditions typically included modifications to registrations, labeling and tolerances (food residue limits), as necessary. In some cases, Registration Standard review also resulted in restricting the use of a pesticide to certified applicators, or beginning a Special Review to assess and reduce identified unreasonable risks. Pesticides that did not comply with a Registration Standard's requirements were subject to suspension or cancellation action.

When EPA established the Registration Standards program, it gave priority to the review of those pesticides with the highest potential for human and environmental exposure—that is, high-volume and food-use chemicals. By December 1988, EPA had issued 194 Registration Standards, roughly 25 per year since 1980. Because chemically-related active ingredients had been grouped into Registration Standard "cases," these 194 Standards actually represented 350 individual active ingredients.

Once EPA received the data required by a Registration Standard, the Agency thoroughly reviewed those data and the pesticide's uses, and decided whether to modify the conditions of registration, require additional data or take other regulatory action. This review of data was called a second round review.

In 1984, EPA revised and expanded its data requirements for pesticide registration and its testing guidelines. Consequently, in completing second round reviews for many pesticides, the Agency found it necessary to levy additional data requirements, thus further postponing reregistration decisions.

By the late 1980s, it became apparent that under the Registration Standards program, EPA would not be able to complete reregistration until well beyond the year 2000.

Accelerated Reregistration

Congress acted in 1988 to substantially change EPA's approach to pesticide reregistration. The FIFRA '88 amendments were signed into law by the President on October 25, 1988, and became effective on December 24, 1988.

The reregistration provisions of FIFRA '88 established mandatory timeframes and duties for reregistration of pesticides. The law requires EPA to complete, over approximately a 9-year period, the reregistration review of each registered product containing any active ingredient initially registered before November 1, 1984. (Congress assumed that, since EPA's most recent data requirements for registration were published in November 1984, most pesticides registered after then would have up-to-date data bases.) Congress directed EPA to carry out reregistration in five phases (see **Figure 1**). The five phases, and activities to implement each of them to date, are described below.

Phase 1:
Listing of Active Ingredients

Phase 1 required EPA to publish lists of pesticide active ingredients subject to reregistration, and to ask registrants of pesticide products containing those ingredients whether they intended to seek reregistration. These lists had to be published within 10 months after the effective date of the amendments.

EPA completed this phase of accelerated reregistration by publishing four lists of pesticides subject to reregistration (see **Table 1**). List A, by law, contains the 194 pesticide active ingredient cases (350 individual active ingredients) for which Registration Standards were issued prior to December 24, 1988.[1]

[1]The List A pesticides are not subject to Phases 2, 3 and 4 of the FIFRA '88 accelerated reregistration scheme, although they are subject to the fee provisions. Congress did not set a phased data submission schedule for List A chemicals because a large part of the work required of registrants for reregistration under FIFRA '88 had already been completed during the Registration Standards program. Instead, EPA conducted an inventory of active ingredients on List A to determine their readiness for reregistration, as discussed later in this document.

Figure 1—Pesticide Reregistration Process

Phase 1 EPA	Phase 2 Registrant	Phase 3 Registrant	Phase 4 EPA	Phase 5 EPA
Publish List of Pesticides	Commit To Register	Summarize And Reformat Existing Studies	Review Phase 1 & 2 Submissions	After All Studies In, Review In 1 Year And Issue Red
	Identify Missing Studies	Certify Access To Raw Data	Identify Any Other Needed Studies	Product Specific Studies Due 8 Mos. Later
	Agree To Do Studies	"Flag" Adverse Effects Information	Publish Lists Of Missing Studies	Review Product Specific Studies In 3 Months
	Pay Fee	Pay Fee	Require Missing Studies (Issue DCIs)	Register Products Or Take Other Action In 6 Months
		EPA Guidelines 12/24/89		

Table 1—Lists of Pesticides Initially Subject to Reregistration

List	Date Published	# Active Ingredients	# Cases
A	2/22/89	350	194
B	5/25/89	229	149
C	7/24/89	288	150
D	10/24/89	286	118
TOTAL		1,153	611

Lists B, C and D were developed by applying the following criteria (which gave priority to pesticides with the highest potential for exposure): use on food or feed; residues of concern in drinking water, edible fish or shellfish; significant outstanding data requirements prior to December 24, 1988; and worker exposure. The Agency added several listing criteria including: Special Review status; restricted use pesticides; effects on non-target or endangered species; and dioxin/furan contamination problems. Thus, second only to those on List A, the pesticides on List B have the highest potential for human and environmental exposure and risk, and are of the highest priority for review, followed by pesticides on Lists C and D respectively.

Phase 2: Declaration of Intent and Identification of Studies

Phase 2 required registrants to declare (within 3 months after publication of each List) whether they intended to seek reregistration of their products. If so, they had to notify EPA, identify applicable data requirements and missing studies, commit to submitting new studies or replacing inadequate existing data, and pay the first installment of the reregistration fee. If a registrant did not seek reregistration, EPA cancelled the appropriate product registration(s).

EPA issued detailed guidance to registrants for preparing their Phase 2 responses. The Agency also sent individual responses to registrants who supported their registrations during Phase 2, in order to improve their Phase 3 submissions.

Phase 2 required EPA to issue guidelines to assist registrants during Phase 3 in summarizing and reformatting their studies, in identifying studies which may be inadequate but still may be considered, and in "flagging" adverse effects data. The Agency issued these guidelines on December 24, 1989.

EPA and the industry completed Phase 2 activities for Lists B, C and D pesticides in 1990. Many pesticides were not supported by their registrants during this Phase, and so were cancelled.

Phase 3: Summarization of Studies

Phase 3 added to the responsibilities of registrants who decided to support their products for reregistration during Phase 2. During the nine months after the Phase 2 deadlines, registrants were required to resubmit existing studies that had been reformatted and summarized according to Agency guidance, to certify the availability of raw data, to "flag" studies that indicated adverse effects, to make additional commitments to satisfy all applicable data requirements, and to pay the final installment of the reregistration fee. Registrants who failed to comply were subject to cancellation action. Phase 3 activities were completed in October 1990.

Phase 4: EPA Review and Data Call-In's

During Phase 4, EPA must review all Phase 2 and 3 submissions and determine independently whether all applicable data requirements have actually been satisfied, and if not, require registrants to fill any unfulfilled data requirements. This activity is well underway for the List B, C and D pesticides.

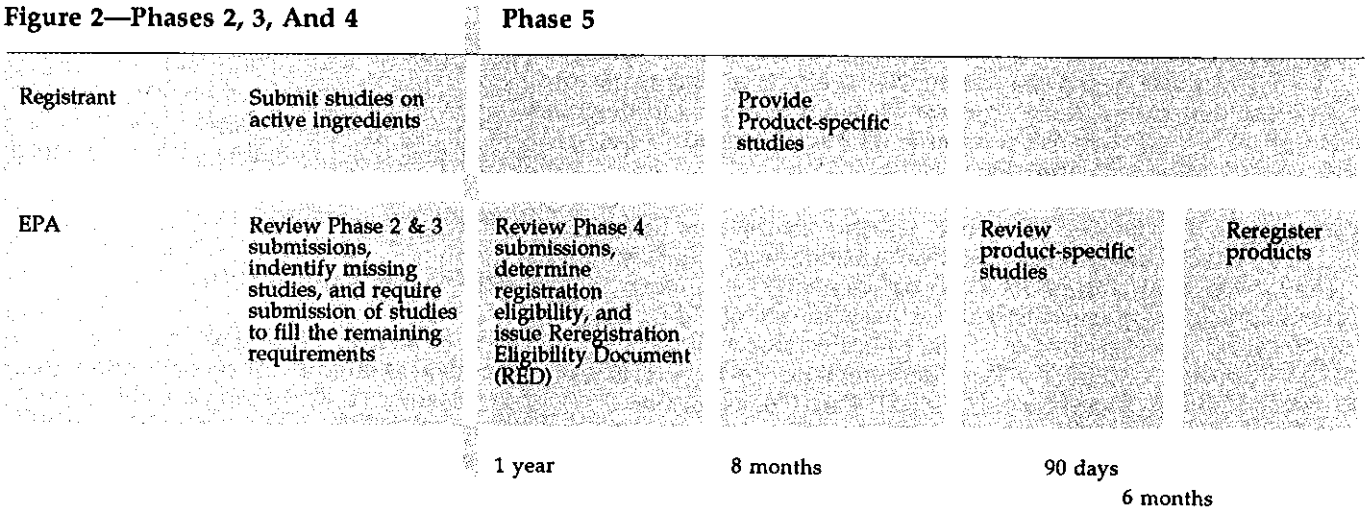
When a registrant committed to submitting new studies in Phase 2 or 3, or when EPA requires new studies during its Phase 4 review, those studies must be submitted according to schedules established by EPA, but no later than four years after the date of a registrant's commitment. Time extensions may be granted only if there are "extraordinary circumstances" beyond the registrant's control.

Phase 5: Reregistration Decisions

In Phase 5, EPA must conduct a comprehensive review of all the studies submitted in support of an active ingredient, decide whether pesticide products containing the active ingredient

are eligible for reregistration (and if so, under what conditions), decide whether product-specific studies are needed (and if so, obtain and review these studies), and reregister products or take other appropriate regulatory action. **Figure 2** shows the steps and time periods involved in the Phase 5 process.

Figure 2—Phases 2, 3, And 4



What Does Reregistration Mean?

Criteria for Reregistration Eligibility

Before a pesticide product may be reregistered, its active ingredient(s) must be declared "eligible" for reregistration. EPA has adopted two broad criteria for eligibility:

(1) The pesticide's data base is substantially complete; and

(2) The pesticide does not cause unreasonable adverse effects to people or the environment when it is used according to the product label directions and restrictions.

The first criterion ensures that EPA has sufficient information with which to conduct a risk assessment. To support reregistration, a pesticide's target data base consists of all applicable studies listed in EPA's "Data Requirements for Registration" set forth in 40 CFR Part 158, as further defined in Part B of the Reregistration Phase 2 Response Worksheet, issued by EPA for each pesticide active ingredient undergoing reregistration. As science progresses, EPA may impose new data requirements. However, EPA will not delay a reregistration eligibility decision because a study that is not part of a pesticide's target data base has not yet been submitted.

The second criterion implies that EPA has thoroughly reviewed the available information, has found that no further, in-depth review or regulatory action is needed, and believes that present uses of the pesticide do not pose an unreasonable risk to people or the environment when the pesticide is used in accordance with its approved labeling.

Tolerance Reassessment

EPA also is in the process of reassessing pesticide tolerances (the maximum amounts of pesticide residues that lawfully may remain in or on food or animal feed), and will be making any necessary changes in existing tolerances at the eligibility stage of the reregistration process. Lowering a pesticide's tolerances can reduce human exposure to the chemical, so this measure may be used to mitigate any unreasonable risks.

EPA is committed to improving consistency between U.S. tolerances and international food standards established by the CODEX Alimentarius Commission. The Agency's determination of reregistration eligibility, therefore, may include changes in the pesticide's established U.S. tolerances, either to reduce risks or to achieve harmonization with international standards.

Product Reregistration

When EPA determines that an active ingredient is eligible for reregistration, the Agency issues a Reregistration Eligibility Document (RED), summarizing the studies reviewed and the findings reached. Through the RED, EPA requests any needed generic data, product-specific studies and revised labeling. Once such data and labeling are received and accepted by the Agency (about 14 to 24 months after the RED was issued), pesticide products are reregistered.

Products containing more than one active ingredient will be reregistered when *all* of their active ingredients are eligible for reregistration.

Once a pesticide product is reregistered, it is not regarded as permanently acceptable. EPA does not intend reregistration to eliminate the need for continual reassessment of pesticides; reregistration is only a milestone in the Agency's continuing review process. Reregistered pesticides will be reassessed as new data are received, or as new risk concerns are identified.

List A Pesticides

What they Are

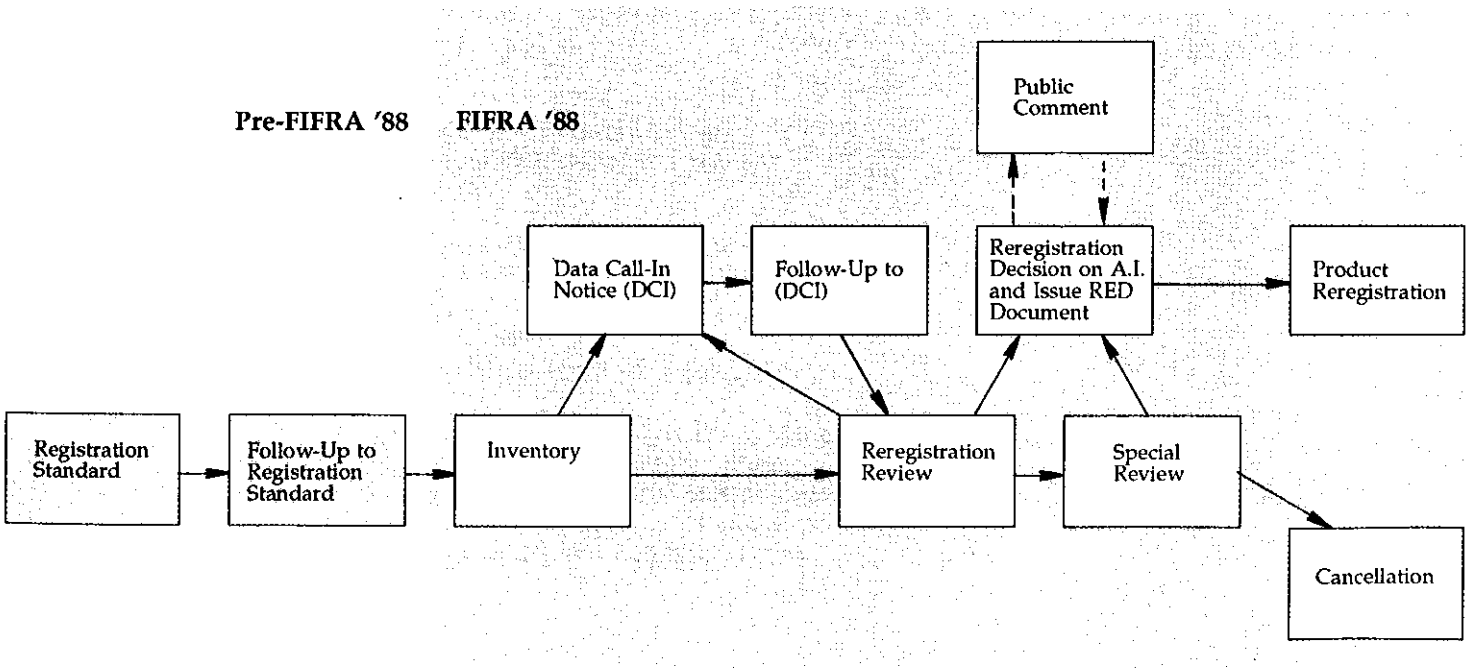
The pesticides on List A are those 194 active ingredient cases, or those 350 individual active ingredients, for which EPA had issued Registration Standards prior to December 24, 1988, the effective date of the FIFRA '88 amendments. Because of the way in which EPA prioritized pesticides for review under the Registration Standards program, the List A pesticides are primarily food use chemicals. They include approximately 80 percent of the total volume of food use pesticides subject to reregistration. The List A pesticides are EPA's highest priority for reregistration review.

The List A Review Process

In framing the accelerated reregistration scheme of FIFRA '88, Congress recognized that pesticide registrants had already developed a significant amount of new data in support of those pesticides for which Registration Standards had been issued. Therefore, FIFRA '88 specified that the List A pesticides move from Phase 1 of the process directly to Phase 5. Unlike pesticides on Lists B, C and D, they are not subject to the data submission provisions of Phases 2, 3 and 4, but may be considered for reregistration based on relevant studies that have already been submitted or are scheduled to be submitted to EPA.

The reregistration review process for pesticides on List A is illustrated in **Figure 3**. Once EPA is satisfied that appropriate data requirements have been levied for a pesticide active ingredient case, and has received valid studies to fulfill those data requirements, the Agency places the pesticide into the queue of cases awaiting reregistration review.

Figure 3—Reregistration Process for List A Chemicals



The List A Inventory

During 1989, the Agency developed an inventory of all the active ingredient cases in List A, to determine whether the data submitted during Registration Standard and second round reviews were sufficient to conduct a thorough evaluation and make a reregistration decision about each case, or whether further data were needed. The objective of this project was to identify action needed to expedite the reregistration of each List A chemical case.

The List A inventory, issued in March 1990, showed that 11 of the 194 pesticide active ingredient cases on List A were ready for a reregistration decision. At the other end of the spectrum, 28 cases were no longer being supported for reregistration. The remaining 155 cases were in various stages of the data call-in (DCI) and review process. The List A review process and the results of the inventory project were discussed in EPA's March 1990, "Reregistration Plan for Chemicals on List A."

General Status of List A Pesticides

By April 1992, EPA had completed REDs for 8 List A cases, and had begun reregistering products containing active ingredients in several of these cases. Another 144 of the original 194 List A cases remained supported for reregistration (that is, their registrants were providing needed data and paying the requisite fees), and were either awaiting data or in review. 42 cases had become unsupported or cancelled.

List B, C and D Pesticides

What they Are

As directed by Congress through the FIFRA '88 amendments, in addition to List A, EPA constructed three additional Lists—B, C and D—of pesticide active ingredients that were contained in products first registered before November 1, 1984, and for which Registration Standards had not been issued. In developing these three Lists, EPA was directed by Congress to prioritize chemically-related cases, giving precedence to chemicals with the greatest exposure and risk potential.

While List A contains most of the major agricultural pesticides used in the United States today, Lists B, C and D each contain a mix of many types of pesticides—insecticides, fungicides, herbicides, rodenticides, antimicrobials, wood preservatives, and others—used in a variety of agricultural, industrial, commercial, residential, and other settings. Each list consists of pesticides with less potential for human and environmental exposure and risk than those on the preceding list.

Very generally, use patterns are as follows:

List B contains: Less significant food use pesticides; Outdoor non-food uses; Indoor uses.

List C contains: Antimicrobials, including disinfectants and wood preservatives.

List D contains: Other outdoor and indoor uses; Antimicrobials; Microbial pesticides.

List B, C and D Review Process and Schedule

Pesticides on Lists B, C and D are being reviewed through the full five-phase process described earlier in this document. In Phases 2 and 3, registrants identified data gaps, and submitted reformatted studies and summaries of those studies for EPA's review. Activities for Phases 2 and 3 were completed in 1990.

During Phase 4, EPA must review all Phase 2 and 3 submissions and require registrants to meet any additional data requirements within 4 years. As of April 1992, EPA had completed Phase 4 activities for the List B pesticides. The Agency expects to complete its Phase 4 review of the List C pesticides in 1992, and of List D pesticides in 1993.

In addition, EPA is conducting Phase 5 reregistration eligibility reviews for some List B, C and D chemicals, where data bases are essentially complete.

General Status of List B, C and D Pesticides

Since the original Lists B, C and D were published in 1989, many of the pesticides have become unsupported for reregistration or cancelled. As of April 1992, EPA had completed REDs for 6 List D cases. However, only 261 of the 418 List B, C and D cases still were supported for reregistration. (Please see **Table 2**.)

At the end of Phase 4, (as the Agency did at the end of Phases 2 and 3), EPA will give public notice regarding the unsupported uses to see if anyone wishes to support them through reregistration.

Overall Status of List A, B, C and D Pesticides

With the enactment of FIFRA '88, EPA made significant efforts to plan the reregistration program, hire new staff, build an appropriate infrastructure, and complete the first Phases of the program. As a result, the Agency was able to make reregistration eligibility decisions and issue REDs for 14 pesticide cases in 1991 through early 1992. The first several products have been reregistered, precursors of the significant activity anticipated over the next several years. EPA plans to make reregistration eligibility decisions and issue REDs for approximately 88% of all reregistration cases by the end of fiscal year 1997, and to complete reviews of the remaining cases by the end of fiscal year 2002.

Rejection Rate Analysis

According to a reregistration recosting analysis conducted by the Agency in 1991, rejected studies have the most significant potential for causing delays in EPA's production of REDs. A significant reduction in rejection rates for most disciplines must be achieved in order for EPA to meet the REDs production schedule discussed above.

To issue a RED, EPA must be able to review a "substantially complete" data base for a pesticide, and conclude that the chemical does not pose unreasonable risks. In many instances, however, studies submitted as part of a pesticide's target data base are found to be inadequate, and are rejected. They must be replaced in order to be included in the target data base supporting the pesticide through reregistration. Conducting a replacement study can take several years, delaying EPA's review of a pesticide and issuance of its RED.

EPA has undertaken a guideline-by-guideline Rejection Rate Analysis, to identify factors that most frequently cause studies required for reregistration to be rejected. The results will provide registrants information that will enable them to improve the quality and increase the acceptability of future studies. The analysis also will enable EPA to reassess the adequacy of its guidance to registrants, make any needed internal changes in review criteria and procedures, and determine the appropriate enforcement response to future rejected studies. The Rejection Rate Analysis should be completed during the summer of 1992.

Trend Toward Fewer Registered Pesticides Levels Off

The overall trend for all four reregistration Lists during the first three years of the program has been a substantial reduction in the number of pesticides being supported for reregistration; however, this downward trend seems to be leveling off in fiscal year 1992. As **Table 2** shows, since EPA began implementing the accelerated reregistration program under FIFRA '88, the number of cases in review has decreased by nearly one third.

This decline in numbers of pesticide active ingredients and cases generally has not had a negative impact on pesticide users or on agricultural or other types of production. Most of the pesticides that dropped out of the reregistration process were ones that had not been produced or marketed in the United States for many years, but remained registered and were carried in EPA's records. However, some of the products cancelled during the reregistration process were the last to contain particular active ingredients. The loss of these registrations could have a negative impact on some growers and other pesticide users who depend on certain "minor uses," as discussed later in this document.

Table 2—List A, B, C, and D Pesticides Supported Over Time

	Supported in Dec. 1988		Supported in April 1992	
	AI's	Cases	AI's	Cases
List A	350	194	269	152**
List B	229	149	140	105
List C	288	150	137	85
List D	286	118	130	71**
Total	1,153	611*	676	413**

* The total number of reregistration cases has increased to 612, as one case was removed from List C and two cases were added to List D.

** Includes REDs completed.

Please note that numbers of supported and unsupported active ingredients and cases can change frequently.

Fees

FIFRA '88 provided EPA new resources to conduct the reregistration program, requiring fees payable by pesticide registrants. The overall cost of the FIFRA '88 reregistration program will likely be approximately $355 million. To help support the cost of accelerated reregistration and other provisions of the new law, FIFRA '88 established two types of fees: a one-time reregistration fee for each active ingredient, and an annual registration maintenance fee to be paid for each registered product.

Reregistration Fees

For each active ingredient used on major food or animal feed crops, registrants were required to pay a one-time reregistration fee totalling $150,000. In most cases, an initial payment of $50,000 was due during Phase 2, and the balance in Phase 3. For pesticide active ingredients not intended for major food or feed uses, registrants had to pay a fee of not more than $150,000 and not less than $50,000. The exact fee depended on, among other factors, whether a Registration Standard had been issued for the pesticide and the extent of data required for reregistration. These active ingredient fees were apportioned among the registrants of each active ingredient, based on their market shares.

Reregistration fee reductions or waivers were granted for certain pesticide active ingredients--for example, those contained only in products registered for agricultural or nonagricultural minor uses, or for low value or low volume uses. The reregistration fee for small businesses was based on a graduated rate.

EPA initially projected that reregistration fees would provide over $32 million to support the program. However, as of April 1992, nearly all reregistration fees have been collected, and revenues total only $29.4 million. EPA now anticipates that final receipts will total no more than $30 million.

Maintenance Fees

The objective of the maintenance fee program is to generate approximately $14 million annually for the Agency's revolving fund, which is used to support the reregistration program. Unlike the one-time reregistration fee, which was levied on the basis of active ingredients, the maintenance fee is assessed annually for each registered pesticide product.

In 1989, for up to 200 products per company, the maintenance fee was $425 per product for the first 50 products and $100 per product for the rest. In 1990, the fee was raised to a flat $1,300 per product, with a fifty percent reduction applied to the first product only. In both years, there was a maximum limit or "cap" on the total annual maintenance fee payable by any registrant; registrants with up to 50 registrations could be charged no more than $20,000, and those with more than 50 registrations could be charged no more than $35,000 each.

Due to the caps in place, the maintenance fee program generated only $11.5 million in 1990 and $10.8 million in 1991, far below the $14 million anticipated in FIFRA '88. To address this shortfall, in late 1991, EPA and pesticide industry groups agreed upon a proposal to increase the maintenance fee caps, which will allow EPA to collect the full $14 million annually. Congress enacted this proposal in November 1991.

Currently, the maintenance fee still is $1,300 per product, but the caps have been raised so that registrants with up to 50 registrations can be charged up to $55,000, and those with more than 50 registrations can be charged up to $95,000. (For small businesses, the caps are $38,500 for up to 50 registrations, and $66,500 for over 50 registrations.)

Applying these new caps, the maintenance fees collected in January 1992 totalled approximately $15 million. Revenues may not continue to be generated at this level, but EPA anticipates

that the new caps should allow the Agency to collect at least $14 million annually through fiscal year 1997, as envisioned by FIFRA '88.

Impact on Product Registrations

Although the maintenance fee provisions of FIFRA '88 had a massive "house-cleaning" effect on EPA's product registration files and records during the first year of the program, the effects during the second and third years became less drastic. In October 1989, EPA cancelled about 20,000 products for nonpayment of maintenance fees. In January 1991, EPA cancelled an additional 4,500 products for nonpayment of 1990 maintenance fees. Most recently, the Agency cancelled 1,500 products for nonpayment of the 1991 maintenance fees. The effect of this provision on product registrations is believed to have leveled off.

While most of the cancellations were for inactive registrations of products that had not been produced for some time, some active registrations also were involved. EPA recognizes the potentially serious impact that these cancellation actions could have on people who depend on pesticide "minor uses," if needed active ingredients were to disappear from the market entirely. Therefore, in all three years, EPA deferred cancellation for certain products and provided a grace period during which affected users could pursue alternatives to cancellation.

Funding Shortfall

EPA's latest cost estimates indicate that a deficit of approximately $42 million remains for conducting the reregistration program. Should this deficit persist, EPA estimates that the REDs production schedule will continue through the year 2002.

Minor Uses And Reregistration

Definition of "Minor Use"

A "minor use" generally is considered to be any pesticide use which generates insufficient economic return to offset the regulatory costs of registration or reregistration.

A pesticide use may be "minor" because it is for a specialty crop grown by only a few persons on small acreages (that is, it is a minor use on a specialty or minor crop), or because the use is infrequently needed or is limited to a small percentage of the total acreage of a major crop (that is, it is a minor use on a major crop, like wheat, soybeans or corn). Minor use pesticide registrations include most pesticide uses on fruit and vegetable crops, as well as uses on commercially-grown flowers, ornamentals, trees and turf grass.

Minor uses are especially vulnerable during the reregistration process, as fees are levied and data requirements are imposed. Pesticide registrants may choose to delete minor uses from their product labels rather than develop the data needed to support those uses during reregistration. Or, they may voluntarily cancel registrations of minor use products. Either way, users may be left without needed pest management tools.

EPA Programs to Assist Minor Uses

EPA recognizes and is concerned about the minor use problem. The Agency needs data about the effects of any pesticide to make a reasonable reregistration eligibility decision. However, EPA tries to be flexible in imposing data requirements, and innovative in helping find ways to remedy minor use problems. There is no "miracle cure" to save needed minor uses. But focused, cooperative efforts among users, industry and government agencies will help.

EPA is doing its part to assist minor uses in several ways:

- The Agency is working with and evaluating proposals from the Minor Use Crop Farmer Alliance, a coalition of grower groups formed recently to seek legislative solutions and work with EPA and USDA on regulatory and policy issues;

- EPA participates in other joint government/industry/user initiatives to coordinate efforts supporting minor uses, such as the intra-agency Minor Use Working Group, and the reregistration notification networks sponsored by USDA and the National Agricultural Chemicals Association (NACA);

- EPA has issued low volume/minor use data waivers, whenever possible;

- EPA is evaluating the need for minor use maintenance fee waivers beginning in 1992, as mandated by the 1990 Farm Bill;

- EPA notifies grower and user groups of impending voluntary cancellations and use deletions through the notification networks mentioned above. EPA provides them an opportunity to support reregistration of minor uses that are of interest by publishing and distributing copies of *Federal Register* notices which allow 90 days for public response;

- EPA supports and promotes "third party registrations," through which grower groups assume liability for their members' use of a pesticide;

- EPA offers, and is attempting to improve, its crop grouping scheme for setting minor use tolerances;

- EPA developed and distributes information to growers describing how they can participate in the reregistration process;

- EPA answers questions about minor uses and reregistration. Call 1-800-552-8879.

- EPA supports IR-4, as described below.

The IR-4 Program

Interregional Research Project Number 4 (or IR-4), a cooperative effort supported by USDA, Rutgers University, EPA and others, serves as a national coordination point for identifying minor use needs and developing data (especially residue chemistry data) to support minor uses.

IR-4 has a strategy for developing residue data in support of reregistration of as many as 1,000 priority minor uses. IR-4 estimates that about $14 million in Federal funds will be needed annually for the next several years to support all priority uses. Funding is well below this level but is increasing, from less than $2 million in fiscal year 1989 to $6 million in fiscal year 1992, and $9 million requested in fiscal year 1993. (This Federal funding is matched by State resources at approximately a 1:3 ratio.) EPA supports increased funding for IR-4, as this affords the best long-term solution for ensuring the continued availability of essential minor uses.

EPA is continuing to work closely with IR-4 in giving minor uses special consideration during the reregistration review process. EPA is preparing data submission schedules which will allow full utilization of IR-4 resources. The Agency is advising IR-4 of the status of pesticide reregistration activities throughout the process. For example, EPA notifies IR-4 of voluntary cancellations and use deletions prior to publication of *Federal Register* notices, and provides IR-4 copies of all data call-in notices.

Conclusion

The accelerated pesticide reregistration process mandated by FIFRA '88 is well underway. In addition to planning the program, staffing up, and establishing an appropriate infrastructure, EPA has completed the first several reregistration Phases, as prescribed by the statute. The Agency also has made a number of reregistration eligibility decisions, by issuing Reregistration Eligibility Documents (REDs), and recently has reregistered the first several pesticide products. During the next five years, EPA plans to complete reviews and make decisions about the majority of the remaining reregistration cases. Even after completing the FIFRA '88 reregistration program, however, EPA will continue to examine pesticide health and environmental effects, to ensure that reregistered pesticides continue to meet the scientific and regulatory standards of the future.

References And Additional Information

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as Amended, October 1988.

"Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988; Schedule of Implementation," *Federal Register*, April 26, 1989.

Federal Register publication of Lists A, B, C and D:

List A: *FR* 2/22/89, pages 7740-7750.
List B: *FR* 5/25/89, pages 22706-22714.
List C: *FR* 7/24/89, pages 30846-30855.
List D: *FR* 10/24/89, pages 43388-43396.

"FIFRA Accelerated Reregistration. Phase 3 Technical Guidance," OPTS/EPA, December 24, 1989.

"Reregistration Plan for Chemicals on List A," EPA, March 1990.

Materials prepared for EPA's first Pesticide Reregistration Workshop, September 24-25, 1990, Arlington, VA.:

- Status of Reregistration Activities
- Pesticide Reregistration Policy Proposals
- Slides for Pesticide Reregistration Policy Meeting

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Reregistration Eligibility Documents (REDs) and RED Fact Sheets:

- Fosetyl-Al (Aliette) January 1991
- *Heliothis zea* NPV January 1991
- Methoprene March 1991
- Sulfur May 1991
- Potassium Bromide June 1991
- Warfarin June 1991
- Sodium and Calcium Hypochlorite Salts September 1991
- Dried Blood September 1991
- Inorganic Nitrate/Nitrite (Sodium and Potassium Nitrates) September 1991
- Carbon and Carbon Dioxide September 1991
- Silicon Dioxide and Silica Gel September 1991
- Propionic Acid September 1991
- Sodium Diacetate September 1991
- Heptachlor March 1992

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