United States General Accounting Office

GAO

Report to Congressional Requesters

May 1993

PESTICIDES

Pesticide Reregistration May Not Be Completed Until 2006

GAO/RCED-93-94

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-203051

May 21, 1993

The Honorable Patrick J. Leahy
Chairman, Committee on Agriculture,
Nutrition, and Forestry
United States Senate

The Honorable Mike Synar
Chairman, Environment, Energy, and
Natural Resources Subcommittee
Committee on Government Operations
House of Representatives

People and the environment are exposed to many pesticides that have not been fully evaluated for their potential to cause cancer, reproductive disorders, birth defects, and environmental damage. Under the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Congress required the Environmental Protection Agency (EPA) to reassess and reregister thousands of older pesticide products on the basis of current scientific standards. The process requires the pesticides' registrants—generally producers—to complete studies of various health and environmental effects. EPA then reviews the results of these studies to determine whether the products can be reregistered and thus remain on the market.

Because EPA had not fully reevaluated any pesticide product since 1972, in 1988 the Congress mandated an accelerated program in which the active ingredients (the pesticides) would generally be reassessed by July 1997 and the products containing these pesticides would be reregistered by September 1998. The new law—the 1988 amendments to FIFRA, known as FIFRA '88—imposed explicit responsibilities and strict deadlines on both EPA and the pesticides' registrants. It also provided for the additional resources that EPA estimated it would need to complete the program within the time specified.

Concerned about whether EPA is fulfilling its responsibilities under FIFRA '88, you requested that we (1) examine the progress EPA has made in meeting the law's deadlines and (2) identify the factors that have affected the agency's ability to complete the program in 1998 as expected. We also present, in appendixes I and II, case studies of two of the most widely used pesticides—chlorothalonil and atrazine—and describe the major steps EPA

has taken to reassess their health risks and make decisions about their reregistration and continued use.

Results in Brief

While EPA has made progress in completing the first several steps of the reregistration process, the agency will be unable to complete pesticide reassessment in 1997 and product reregistration in 1998 as expected. Through fiscal year 1992, EPA had reregistered 31 pesticide products and completed the reassessment of active ingredients—the components that destroy or control the pest—affecting about 2,370 more products. However, about 20,000 pesticide products, containing 642 active ingredients, need to be reregistered. According to EPA, the program may not be completed until 2006. Meanwhile, most of these products may continue to be sold and distributed even though knowledge of their health and environmental effects is incomplete.

EPA will be unable to complete the program in 1998 because it did not take into account the complexity and magnitude of the reregistration task or the resources needed to conduct the program. Also, a large number of the studies that the registrants submitted as part of the reregistration process are insufficient to allow pesticides to be fully reassessed. In its program projections, EPA estimated that 10 percent of the required studies would be rejected as unacceptable. In fact, the rejection rate for unacceptable studies has been as high as 45 percent. These unacceptable studies will need to be redone, requiring years of additional work. Nevertheless, EPA does not plan to adjust its estimated completion date of 2006 or its estimated program costs to include the additional delays and study review costs that may result from the high percentage of rejected studies.

Additionally, EPA's progress in reregistering products containing pesticides that had undergone substantial review before FIFRA '88 was enacted has been much slower than expected. These pesticides—mainly used on food products—have the greatest potential to cause serious health problems. Concentrating its efforts on these high-priority pesticides could help EPA assess their risks more quickly and accelerate actions to reduce those risks.

Background

Federal efforts to reassess pesticide safety began with the 1972 amendments to FIFRA. Under these amendments, the Congress required EPA to reregister all pesticide products that were registered under older, less stringent standards for assessing a pesticide's long-term effects on health

and the environment. Primarily because of insufficient resources, EPA's early attempts to develop a reregistration program were unsuccessful.[1] The Congress has amended FIFRA several times since 1972, reaffirming the need for expeditious reregistration and giving priority to pesticides used on food.

In 1986, we reported that EPA had not completed a final reassessment of any pesticide and recommended that the Congress consider amending FIFRA to (1) shift to industry the burden of identifying and submitting missing or invalid studies, (2) establish reasonable deadlines for the registrants to submit studies and for EPA to review them, and (3) provide EPA with additional resources to accelerate the process.[2] After considering these and similar recommendations EPA had made for accelerating reregistration, the Congress amended FIFRA in 1988, directing EPA to establish a five-phase reregistration program to be completed within about 9 years. (App. III shows the phases of the reregistration process and the steps in each phase.) The aim of the phased approach is to generate a substantially complete base of scientific information for each pesticide before EPA reassesses it for reregistration. FIFRA '88 also required the registrants to accept part of the cost of reregistration by paying fees and compiling information according to guidance provided by EPA.

Under the accelerated program, before EPA reregisters a pesticide product, it issues a reregistration eligibility document (RED) on the pesticide in that product. Issuing a RED means that EPA has evaluated the information submitted on the pesticide and determined that the pesticide poses no unreasonable risk to humans and the environment when used under the terms and conditions EPA has established. These terms and conditions can include restrictions on certain uses or exposure times. The registrant then submits information on the acute health effects and chemistry of a specific product containing the pesticide.[3] After reviewing this information, EPA can reregister the product.

Not all pesticide products awaiting reregistration are subject to the five-phase accelerated process required by FIFRA '88. The 1978

[1]For information on early problems in reregistration, see Delays and Unresolved Issues Plague New Pesticide Protection Programs (GAO/CED-80-32, Feb. 15, 1980).

[2]Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, Apr. 18, 1986).

[3]Generally, EPA has waived all requirements for registrants to submit information on a pesticide product's efficacy (i.e., effectiveness) except for products such as disinfectants that are used to protect public health and certain other products. However, EPA does require registrants to submit data on demand showing the efficacy of their products.

amendments to FIFRA directed EPA to give priority for reregistration to products containing certain pesticides used on food—that is, those with the greatest potential for human exposure and risk. Because a large part of the reregistration work for these pesticides had already been completed by 1988, they were expected to move directly to phase 5 of the reregistration process. EPA assigned these pesticides "list-A" status after FIFRA '88 was enacted.

FIFRA '88 directed EPA to compile three other lists—which EPA called B, C, and D—of pesticides used in products subject to reregistration. In compiling these lists, EPA ranked the pesticides according to their potential for human exposure and risk. Pesticides on list A have the greatest potential for exposure and risk, and those on list D have the least.

Under FIFRA '88, EPA must determine whether products containing pesticides on these lists are eligible for reregistration—that is, it must issue REDs—by October 1995 for pesticides on list B, July 1996 for those on list C, and July 1997 for those on list D. The deadlines for reregistering the products containing these pesticides are December 1996 for list B, September 1997 for list C, and September 1998 for list D. FIFRA '88 did not establish deadlines for list-A pesticides. However, EPA has made a commitment to reassess list-A pesticides and to reregister products containing them no later than the deadlines imposed for list D. Thus, reregistration was generally expected to conclude in 1998.

Despite Progress, EPA Will Not Complete Reregistration as Expected

EPA has made some progress in reregistering pesticide products and issuing REDs, and it is currently reassessing many more pesticides. Much work remains to be done, however, particularly in reviewing studies submitted for list-A pesticides. EPA now estimates that all pesticides may not be reassessed until 2004, and all products may not be reregistered until 2006.

EPA Has Reregistered Only 31 Products, but Thousands Are Being Processed

Through fiscal year 1992, EPA had reregistered 31 pesticide products. However, it had issued REDs—that is, completed reassessment of the pesticides—affecting about 2,370 more products. Under FIFRA '88, EPA has 14 months from the date the RED is issued to reregister the product

containing the pesticide, so that studies on the specific product can be submitted and reviewed.[4]

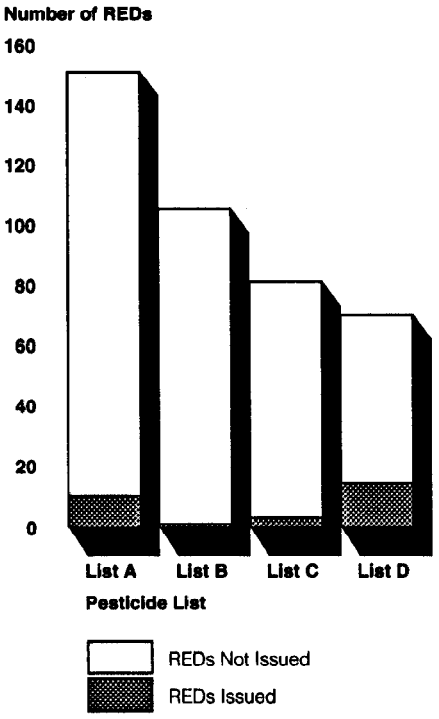
For pesticides on list A, EPA had issued REDs affecting about 2,200 products through fiscal year 1992. List-A pesticides affecting another 460 products are candidates for REDs in fiscal year 1993, according to EPA. The candidates for REDs are pesticides for which EPA has a substantially complete base of information to use in assessing risk. About 15,000 products containing list-A pesticides await reregistration.

For pesticides on lists B, C, and D, EPA had issued REDs affecting 210 products through fiscal year 1992, and pesticides on lists C and D affecting another 1,113 products are candidates for REDs in fiscal year 1993. However, many of the pesticides for which REDs have been issued are on the lowest-priority list (list D) and include such substances as garlic, dried blood, and putrescent egg solids. In terms of their potential to cause adverse health and environmental effects, these are the pesticides of least concern. Figure 1 shows the number of REDs that EPA had issued for pesticides on each list through fiscal year 1992.[5]

[4]EPA may grant time extensions to registrants submitting data for product reregistration. Since 1991, EPA has granted extensions for about 200 pesticide products. In addition, many products contain more than one active ingredient and must await REDs for all active ingredients before product reregistration can proceed.

[5]EPA issues REDs for pesticide "cases"; a case may include a single pesticide or a group of related pesticides. EPA grouped the 642 pesticides to be reassessed into 407 cases to expedite reregistration.

Figure 1: Status of REDs by Pesticide List



Note: Status through fiscal year 1992.

Source: Based on EPA data.

In addition to issuing REDs, EPA has made progress in collecting all the information it needs to issue REDs for pesticides on lists B, C, and D. As shown in appendix III, in the fourth phase of the program, EPA requests the registrants to fill any gaps in the information it needs to assess risk. (The registrants have 4 years to comply.) EPA had requested this information for the list-B pesticides as of October 1991, requiring the registrants to submit about 4,000 studies. EPA expects to complete phase-4 activities for the list-C and -D pesticides by July 1993.

All the REDs issued have already resulted in measures that reduce risk. For example, about a third of the REDs imposed a requirement that protective clothing be worn to reduce the health risks to those who apply the pesticides; about two-thirds of the REDs required changes in the products' labels to reduce environmental risks. Also, in some cases EPA is dealing

with risks as they are identified rather than waiting for all studies to be completed and the RED issued. For example, the agency achieved voluntary cancellation of almost all uses of parathion, a list-A pesticide, after a significant number of agricultural workers were poisoned. The information base for parathion will not be complete until September 1994.

Many Studies for List-A Pesticides Must Still Be Reviewed

Despite EPA's progress, much work remains to be done, particularly in reviewing the studies submitted on list-A pesticides. As of January 1993, EPA had received 10,845 studies on these pesticides but had not reviewed about 3,900, or 36 percent, of them. The studies were submitted in response to formal requests that EPA had issued before FIFRA '88 became effective. Furthermore, EPA requested about 3,000 additional studies between 1990 and 1992, when it identified gaps in the information it needed on many of the list-A pesticides. EPA has received about 2,000 of these studies and reviewed about 1,200, or 60 percent, of them. A total of about 2,300 more studies will need to be reviewed once all of the studies have been received. Meanwhile, products containing list-A pesticides remain on the market, although knowledge of their health and environmental effects is incomplete.

EPA Estimates That Reregistration May Not Be Completed Until 2006

According to program projections EPA made in March 1993, the agency will not reassess and reregister all pesticide products as expected. EPA has estimated that it could complete the reassessment of all 642 pesticides only in 2001 or 2004 and complete product reregistration only in 2003 or 2006, depending on whether projected funding limitations are addressed. The factors that have affected program funding are discussed in greater detail below.

Several Factors Have Contributed to Extending Reregistration Beyond the Expected Completion Date

The delay in completing pesticide reassessment and reregistration by the expected dates can be attributed to three factors: (1) reregistration has proved to be a lengthy and complex task, (2) more resources are needed for the program than EPA initially estimated, and (3) a large number of the studies that the registrants have submitted on the pesticides are insufficient to allow them to be fully reassessed. These studies will need to be repeated or replaced, often requiring years of additional work. In addition, reregistration of products containing the highest-priority, food-use pesticides—list-A pesticides—has been delayed because EPA did not identify the gaps in the information it needed on these pesticides until March 1990, 17 months after FIFRA '88 had been enacted.

Reregistration Is a Lengthy and Complex Process

As we reported in 1986, reregistration is a lengthy and complex process. The pesticides' registrants must conduct numerous health and environmental studies for EPA's review. Over 100 studies may be required to provide the information EPA needs to assess a food-use pesticide. The studies, some of which take up to 4 years to complete, include information on the chemical and physical characteristics of the pesticides and on their potential to cause adverse effects on human health and/or the environment. EPA is required to review the registrants' studies, determine the acceptability and utility of each piece of information, identify gaps in the information, and, when the information on a pesticide is sufficient, determine whether the pesticide can be used without posing unreasonable health and environmental risks.

Determining whether a study fulfills the relevant information requirements for a pesticide—for example, whether it provides sufficient data to allow evaluation of a pesticide's potential to cause cancer—is a difficult and time-consuming task. It requires scientific judgment of data that frequently do not provide direct evidence of risk to humans. For example, in 1978 the National Cancer Institute identified the potential of chlorothalonil to cause cancer in laboratory animals. EPA, however, did not classify the pesticide as a probable human carcinogen until 1986 because previous laboratory studies did not provide sufficient evidence to warrant this classification and additional studies had to be conducted. Also, because the registrant challenged EPA's cancer classification for chlorothalonil, in order to reaffirm the classification the agency had to review and evaluate additional laboratory data that the registrant submitted after 1986.

The complexity of the process has been compounded by a lack of adequate automated information systems at EPA. In November 1992, we reported that after 3 years of effort and more than $14 million worth of investments in systems, EPA's pesticide information was still not being managed in a manner that facilitated efficient, reliable assessments of the status of pesticides in the reregistration process.[6] Consequently, substantial time and effort are still required to assemble current and accurate information on a single pesticide. For example, in July 1991 EPA requested the registrant of chlorothalonil to submit studies to satisfy certain data requirements on the pesticide's environmental effects. The registrant replied that it had received a letter from EPA in 1989 stating that the data requirements had already been satisfied.

[6]Pesticides: Information Systems Improvements Essential for EPA's Reregistration Efforts (GAO/IMTEC-93-5, Nov. 23, 1992).

In an effort to reduce the complexity of the process and quicken the pace of reregistration, in October 1992 EPA decided to modify its approach to managing "ecological" risk—that is, the risk to birds, fish, and other aquatic organisms—from pesticide use. Except in unusual circumstances, field tests on fish and wildlife will no longer be required before a reregistration decision is made. Instead, EPA will make decisions on the basis of laboratory toxicity tests and modeling estimates of residue levels in the environment. EPA believes that field tests provide few useful data and add considerably to the time taken for testing and review. According to EPA, it does not have test methods that would allow the registrants to accurately measure, within the deadlines specified for reregistration, a pesticide's effects on fish and wildlife. EPA believes that this decision will permit it to assess the risks to animal species more quickly and therefore accelerate actions to reduce those risks. We did not determine how this decision may affect EPA's revised program projections.

Our case studies on chlorothalonil and atrazine illustrate in more detail the complexity of the testing and review process and its effect on the pace of reregistration. (See apps. I and II.) Appendix IV describes the reregistration process and the factors that contribute to its complexity.

Funding Limitations Could Extend Reregistration to 2006

Although EPA has received additional funds as a result of FIFRA '88, the agency has estimated that it cannot complete pesticide reassessment until 2001 or 2004 and reregistration until 2003 or 2006, depending on whether projected funding limitations are addressed. When FIFRA '88 was enacted, EPA anticipated that the accelerated reregistration program would cost about $260 million over 9 years. However, this initial cost estimate was not based on complete program costs. Until 1991, EPA had not moved a single pesticide or any product completely through the reregistration process. Because EPA had only a partial understanding of the complexity of the tasks involved, the earlier cost estimates did not include such costs as support provided by other EPA offices—for example, the Office of General Counsel and the Office of Enforcement—to EPA's Office of Pesticide Programs, which administers the reregistration program. EPA included these costs for the first time in its 1989 cost estimates. In 1991, after gaining 3 years' experience with the program, EPA began including other items in its estimates, such as additional data review costs for studies that had to be repeated.

EPA also receives fewer fees from the registrants than it expected, compounding the problem of its higher-than-anticipated program costs. To

help fund the reregistration program, FIFRA '88 authorized two types of fees to be paid by the registrants: a one-time reregistration fee for each active ingredient and an annual registration maintenance fee for each registered product.[7] Over 9 years, registrant fees were expected to raise a total of about $160 million, or 61 percent, of the $260 million EPA said it needed. The balance was to be funded from EPA appropriations. Instead, the agency will collect only about $150 million during that period, or $10 million less than projected. Fee revenues are lower because many registrants have chosen not to reregister their products; EPA has cancelled the registrations of about 26,000 products for nonpayment of the annual maintenance fee.[8] According to EPA, most of these cancellations were for products that had not been produced for some time.

As of March 1993, EPA estimated that it would cost about $332 million to complete reassessment—that is, issue REDs—for about 60 percent of the pesticide cases and to complete product reregistration for about 35 percent of them through 1997. EPA further estimated that it would cost about an additional $86 million to issue the remaining REDs through fiscal year 2001 and generally complete the program, reregistering most pesticide products, in fiscal year 2003. EPA has funding for all but approximately $20 million of the program's estimated cost through 1997, and it must now seek additional funds.

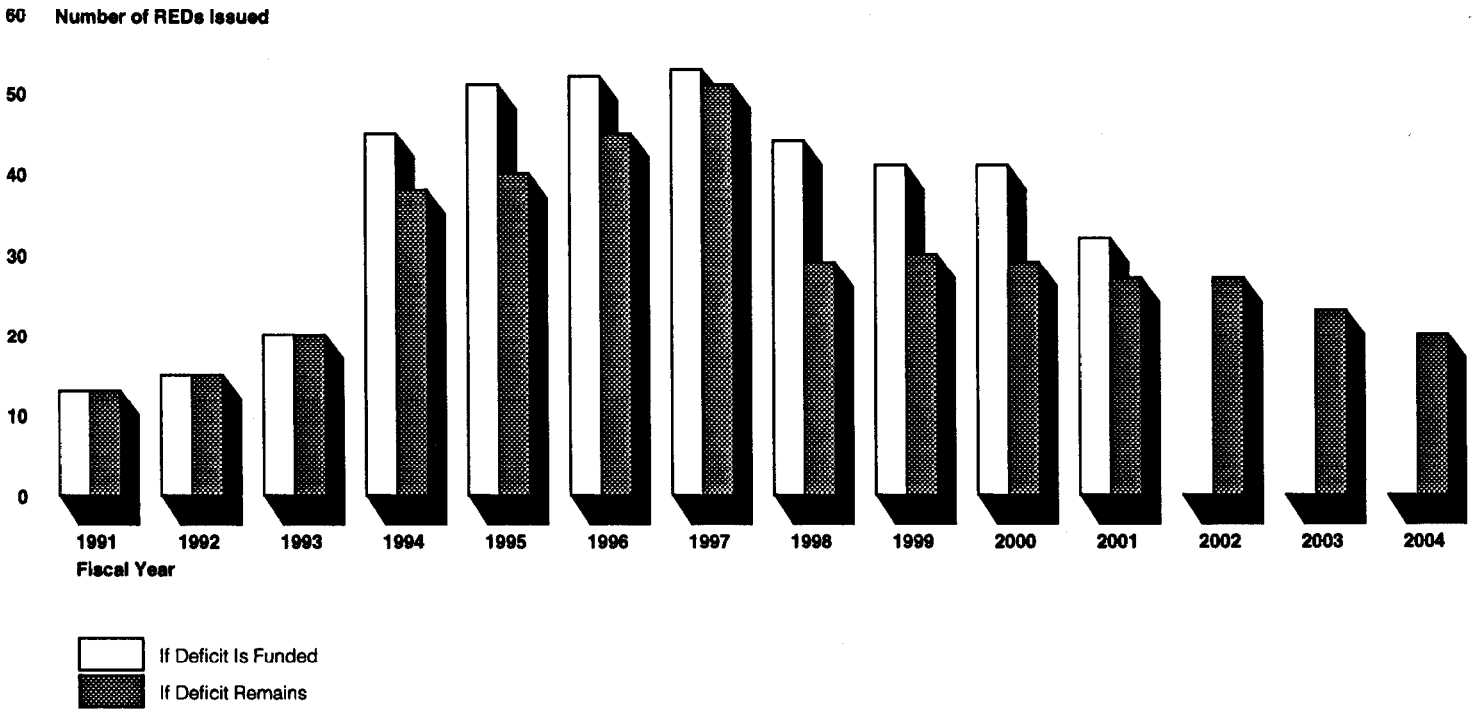
If EPA cannot fund the $20 million deficit it has projected, the agency has estimated that reregistration will not be completed until fiscal year 2006. That is, EPA will be able to issue REDs for only about 50 percent of the cases and complete product reregistration for about 30 percent of them through 1997. According to EPA, because the same amount of work must be accomplished, the cost of completing the program in fiscal year 2006 will be about the same as the estimated cost of completing reregistration in fiscal year 2003: $418 million.

As of March 1993, EPA had not decided how to address the deficit resulting from incomplete cost estimates and reduced fee collections. Figure 2 contrasts the number of REDs that EPA expects to issue each year if the $20 million deficit is funded with the number of REDs it expects to issue if the deficit remains.

[7]Under FIFRA '88, EPA's authority to collect maintenance fees from registrants will end on Sept. 30, 1997.

[8]According to EPA, the percentage of products cancelled for nonpayment of the maintenance fee did not proportionately reduce the agency's resource needs because the reregistration work load depends primarily on active ingredients. Many of the cancelled products had formulations and use patterns identical or substantially similar to those of products that remain on the market and are subject to reregistration.

Figure 2: Schedule of REDs EPA Expects to Issue



Note: Status as of March 1993.

Source: Based on EPA data.

EPA Has Not Accounted for the Effects of Unacceptable Studies in Its Program Projections

In September 1991, EPA reported to your offices that its reassessment of all pesticides (through the issuance of REDs) would not be completed in 1997 because of the volume of unacceptable studies that the registrants needed to repeat or replace. In reporting its revised estimates of the program's completion date and cost, EPA assumed that 10 percent of the studies that the registrants submitted would be rejected as unacceptable. This assumption was based, not on a formal analysis, but on a goal that EPA established for the program. According to EPA, because the number of unacceptable studies is higher than expected, the agency is not likely to achieve this 10-percent goal. Consequently, EPA may not issue all the REDs by its estimated earliest completion date—fiscal year 2001. However, EPA has no plans to revise either its completion date or cost estimates on the basis of the actual percentage of studies the agency has rejected.

The volume of unacceptable studies is far greater than EPA had originally assumed. EPA reported in 1992 that it had rejected 25 percent of about 3,800 list-A studies and 45 percent of about 1,800 list-B studies it had reviewed. EPA also classified another 25 percent of the list-A studies and 16 percent of the list-B studies as either "upgradable" or "supplementary"—that is, more information was required. The need to repeat or replace a rejected study can delay a product's reregistration by as long as 4 years, or more if additional data are required.

To reduce the high rate of rejected studies, EPA has undertaken a study in conjunction with pesticide industry scientists. The aim of this study is to identify the factors that most frequently cause the registrants' studies to be rejected, the reasons these factors occur, and the best method for addressing each problem. Initiated in July 1991, the study is divided into the five scientific disciplines—residue chemistry, toxicology, and studies of environmental fate,[9] ecological effects, and occupational and residential exposure—that provide the kinds of data the registrants must submit for EPA's review.

In June 1992, EPA issued the study's first chapter, addressing the factors that cause the registrants' studies to be rejected in the discipline of residue chemistry. (Residue chemistry studies measure the amount of a pesticide that remains on food and how the pesticide breaks down in the food.) The study found, among other problems, that the registrants need additional guidance from EPA on conducting various tests and in other technically difficult areas. The study also found that in a significant number of instances, the agency's case review managers—the principal liaison between EPA and the registrants—misinterpreted decisions made by EPA scientists on the acceptability of some studies. The case review managers concluded that the scientists had rejected the studies when, in fact, the scientists had found them upgradable or even acceptable. However, EPA believes that because the registrants were sent copies of the scientific reviews in their entirety, these misunderstandings did not result in the registrants' having to repeat a study unnecessarily.

As a result of its analysis of rejected residue chemistry studies, EPA is developing and, in some instances, has issued additional guidance on conducting such studies. EPA has also modified its internal review procedures to make clear when a study is rejected or upgradable and what data are needed to make the study acceptable. Furthermore, EPA has

[9]"Environmental fate" refers to what happens to a pesticide through degradation, metabolism, mobility, dissipation, and accumulation when it is released into the environment.

advised the registrants that if future studies are rejected for reasons considered "avoidable"—that is, in areas in which EPA believes its guidance is adequate—the agency will consider taking appropriate regulatory action against the registrants.

EPA plans to complete the study on rejection rates, issuing chapters for the other four disciplines, by July 1993. EPA believes that while this and other planned actions will improve the quality of the studies conducted by the registrants and lower the percentage of rejected studies, the agency is still not likely to achieve its goal of a 10-percent rejection rate. As a result, the cost and time it takes to complete reregistration could be significantly greater than EPA has estimated.

Information Gaps Have Impeded Progress on List-A Pesticides

When FIFRA '88 was enacted, EPA had already performed substantial reviews of list-A pesticides under its registration standards program—EPA's first major effort to systematically reassess all older pesticides. Since 1988, however, EPA's progress in reassessing list-A pesticides has been slower than expected. The primary reason for the delay is that EPA did not identify the gaps in the information it needed on these pesticides until March 1990.

Between 1980 and 1988, EPA had issued registration standards—that is, it had reviewed much of the preexisting information, identified additional information requirements, and prescribed regulatory requirements—for 194 pesticide cases involving active ingredients used on food. EPA therefore believed that when FIFRA '88 was enacted, these pesticides were ready to move directly to the final review and decision-making phase of reregistration. In early 1990, however, EPA assessed the status of the list-A cases and found that for more than half of them, a substantial amount of required information was either missing or invalid. As a result, EPA has had to postpone making reregistration decisions on most of the list-A cases.

The data EPA has requested since March 1990 demonstrate the extent of the information gap on the list-A cases and the amount of work yet to be accomplished. Of the 151 list-A cases undergoing reregistration as of 1993, EPA identified 89 cases, or about 59 percent, that require additional data before the REDs can be issued. Between 1990 and 1992, EPA asked the registrants to conduct and submit about 3,000 additional studies, many of which require from 2 to 4 years to complete. Among these pesticides are chlorothalonil and atrazine—our case studies. An additional 83 and 48 studies were required for chlorothalonil and atrazine, respectively.

As a result of these gaps in information, EPA has not met the schedules it projected for issuing REDs for many list-A pesticides. For example, in March 1990 EPA reported that it would issue REDs for 11 list-A cases by October 1990. No REDs were issued for list-A cases until January 1991; as of October 1992, REDs had been issued for only 10 cases. Also, as of June 1992, REDs for 62 list-A cases had been delayed by an average of about 18 months. Most of the REDs for the list-A pesticides are now scheduled to be issued over a 4-year period beginning in fiscal year 1994, according to projections EPA made in March 1993.

Data are missing for the list-A pesticides mainly because EPA had reassessed many of them for reregistration before 1985. EPA did not complete and publish the current information requirements until November 1984 and did not issue much of the guidance for satisfying these requirements before 1985. Thus, pesticides for which EPA had issued registration standards before 1985 did not meet all of the current information requirements for reregistration.

EPA cited other reasons for the gaps in information. In some cases, additional studies were needed because existing studies did not disprove the existence of a particular health or environmental effect. In other cases, studies that EPA had rejected as unacceptable had to be replaced. Also, additional studies were needed for pesticides whose uses and thus information requirements had changed over the years.

Conclusions

As we concluded in our 1986 report, EPA faces a formidable task in reassessing the risks of the many thousands of pesticide products registered before November 1984. Identifying gaps in information, reviewing the many studies the registrants are required to submit for each pesticide, and making definitive scientific decisions on risk are complex and time-consuming efforts. Decisions may be further delayed—sometimes by as long as 4 years or more—if new or replacement data are required.

While EPA has made some progress in carrying out the reregistration program envisioned by FIFRA '88, it has been unable to complete its reassessment of the highest-priority, list-A pesticides, mainly because of information gaps it identified only after FIFRA '88 was enacted. As a result, only 10 of the 151 list-A cases have been reassessed, and the registrants are now completing many additional studies required to fill the gaps.

EPA's recent efforts to address the high percentage of unacceptable studies will very likely improve the quality of studies submitted in the future on list-A and other pesticides. Nevertheless, these efforts will not improve the quality of all studies in progress or the thousands of studies already submitted but not yet reviewed by EPA. As a result, the list-A studies currently under way and awaiting review may fall short of providing the complete information base necessary for making reregistration decisions. Furthermore, if EPA does not turn its attention fully to the 3,900 list-A studies now awaiting review, further delays could result if these studies are found to be unacceptable or incomplete. Given the competing demands for its resources, it is important that EPA concentrate its efforts on the highest-priority, list-A cases if the public is to be protected from risk and the credibility of the reregistration program is to be ensured.

Furthermore, the Congress needs accurate information on reregistration program costs and completion dates in order to consider the need for potential program changes. While EPA has adjusted its estimates to include program costs left out of its initial estimate, the agency currently has no plans to revise these estimates to account for the additional data review costs and delays resulting from the high percentage of studies it has rejected and could reject in the future. As a result, the reregistration program could take even longer than EPA currently projects.

Matter for Congressional Consideration

In view of the pace at which EPA is currently reassessing the risks of the highest-priority pesticides and the work that lies ahead to accomplish this objective, the Congress may wish to consider amending FIFRA to require that, except in unusual circumstances, EPA focus its efforts on completing reregistration of the highest-priority, food-use pesticides on list A before it proceeds with reregistration of the lower-priority pesticides.

Recommendation to the Administrator, EPA

To assist the Congress in its consideration of requiring EPA to focus its efforts on reregistering the highest-priority pesticides first and the lower-priority pesticides thereafter, we recommend that the Administrator, EPA, prepare and submit to the Congress an estimate of the time EPA needs to complete reregistration of all the list-A, food-use pesticides. In preparing this estimate, the Administrator should include the additional review costs and delays that may result from the high percentage of studies the agency has rejected and may expect to reject over the remaining years of the program.

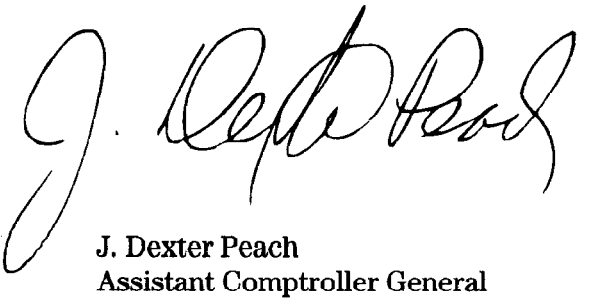
Agency Comments

As requested, we did not provide a draft of this report to EPA officials for written comments. However, we discussed its contents and our findings with the Director of EPA's Office of Pesticide Programs and his staff. These officials generally agreed with the facts presented in the report and with our matter for congressional consideration and recommendation. We have incorporated their comments where appropriate.

We conducted our review between July 1991 and December 1992 in accordance with generally accepted government auditing standards. Appendix V contains details on our objectives, scope, and methodology.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. We will then send copies to other interested congressional committees; the Administrator, EPA; and the Director, Office of Management and Budget. Copies will be made available to others on request.

This report was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues, who may be reached at (202) 512-6111 if you or your staffs have any questions. Major contributors to this report are listed in appendix VI.



J. Dexter Peach
Assistant Comptroller General

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Abbreviations

DCI	data call-in notice
EPA	Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GAO	General Accounting Office
HCB	hexachlorobenzene
OMB	Office of Management and Budget
OPP	Office of Pesticide Programs
RED	reregistration eligibility document
SAP	Scientific Advisory Panel

Case Study: Reassessment of Chlorothalonil

Chlorothalonil is a fungicide used primarily to control fungi (e.g., mold or mildew) on crops such as peanuts, tomatoes, and potatoes. Chlorothalonil was initially registered for use in 1966. By 1984, EPA had identified chlorothalonil as a possible cause of cancer and had determined that it leaches in a degraded form.[1] As of February 1993, EPA had not fully characterized the effects on human health and the environment from exposure to this pesticide. Current estimates indicate that EPA could complete its reassessment of chlorothalonil and decide whether products containing the pesticide are eligible for reregistration in August 1996. Figure I.1 provides a time line of the major steps EPA has taken to reassess chlorothalonil for reregistration.

Figure I.1: Major Steps Taken by EPA to Reassess Chlorothalonil

1966 Initial registration	• Registered pesticide for use on food crops				
September 1984 Initial standard	• Requested data needed to support 71 requirements	• Established deadline of December 1985 for last study	• Identified pesticide's potential to cause cancer	• Identified pesticide's potential to leach and requested expedited data	
September 1988 Draft of final standard	• Identified data needed to support 62 requirements	• Established deadline of December 1991 for last study	• Classified pesticide as probable human carcinogen	• Called for groundwater monitoring study	• Issued draft standard for public comment
March 1990 Draft of final standard	• Identified data needed to support 62 requirements	• Established deadline of September 1994 for last study	• Classified pesticide as probable human carcinogen	• Called for groundwater monitoring study	• Did not issue final standard because of program changes
July 1991 and September 1991 Formal requests for data	• Requested data needed to support 83 requirements	• Established deadline of August 1995 for last study	• Required groundwater monitoring study		

[1]Leaching refers to the movement of a substance downward or out of the soil as the result of water movement. Leaching indicates the potential of a substance to reach groundwater.

Initial Reassessment Identified Data Gaps and Cancer and Groundwater Concerns

EPA completed its first comprehensive reassessment of chlorothalonil in September 1984 under its registration standards program.[2] In its reassessment, EPA concluded that the existing data (135 scientific studies) on chlorothalonil were not sufficient to evaluate the pesticide's long-term health and environmental effects—specifically, the pesticide's potential to cause cancer and contaminate groundwater. As a result, EPA requested the registrants[3] to conduct additional tests that would fill 71 gaps in data the agency had identified. The last study—the registrants' test results—was due in December 1985.

About half of these tests were needed to analyze the pesticide's residue chemistry—that is, the residues remaining in food and feed after they were treated with chlorothalonil. EPA also required additional data to assess the potential of chlorothalonil to cause cancer and birth defects. Data on residue and human health effects are important for setting tolerances—the maximum amount of pesticide residue that lawfully may remain in or on a harvested crop. EPA sets these levels so that the pesticides do not pose an unreasonable risk to consumers.

Existing data indicated three potential concerns associated with the use of chlorothalonil. First, studies conducted in 1978 by the National Cancer Institute indicated that chlorothalonil caused cancer in rats but not in mice. However, deficiencies in laboratory practices and in reporting raised questions about the soundness of the results. Another study submitted by a registrant in 1979 reported that chlorothalonil caused tumors in mice, but the evidence was not clear. Because the data evaluated were either deficient or unclear, EPA believed it could not reach a final decision concerning the potential of chlorothalonil to cause cancer until it reviewed a required study due in 1985. However, EPA took steps—such as restricting new uses—to minimize additional public exposure to the pesticide.

Second, data showed that repeated application of chlorothalonil could cause the buildup of hexachlorobenzene (HCB), a manufacturing impurity, in the tissues of plants and animals. Because the existing data were insufficient to assess potential human health effects from exposure to HCB, EPA required additional data. In the interim, EPA limited the amount of HCB that chlorothalonil products could contain.

[2]Under the registration standards program, EPA prepared a document called a standard that summarized the available data on a pesticide, required submission of additional data, and outlined other conditions a registrant had to meet for EPA to reregister products containing the pesticide.

[3]A pesticide may be produced by more than one registrant. The primary registrant—the company that produces the largest volume of the pesticide—may take the lead in providing EPA with the required studies.

Finally, studies completed in 1976 and 1982 identified the potential for a degraded form of chlorothalonil to leach in most soils. Because of the importance of assessing the potential environmental impact, EPA, in its September 1984 standard, required the registrants to submit data on the rate of degradation and on the movement of the pesticide on an expedited basis. However, EPA did not require the registrants to conduct groundwater monitoring studies, nor did it identify other actions to be taken on this issue.

Second Reassessment Outlined Data Gaps and Confirmed Other Concerns

EPA completed its second comprehensive reassessment of chlorothalonil in September 1988. On the basis of studies submitted by registrants in response to the 1984 standard, EPA classified chlorothalonil and HCB as probable human carcinogens and determined that groundwater monitoring studies were needed. Although EPA drafted a new standard in 1988 outlining data to be submitted and regulatory actions to be implemented, the standard was not issued in final form. EPA identified new studies that registrants had to conduct to fill 62 data gaps. As had been the case in the 1984 standard, residue chemistry accounted for nearly half of the data gaps. Because of insufficient data, EPA still could not reach final conclusions on the adequacy of all existing tolerances.

The additional studies were needed for several reasons. For example, after further review, EPA concluded that studies on residues, the environment, and wildlife and aquatic organisms judged to support reregistration in the past only partially fulfilled 11 data requirements. Therefore, several new studies were required. Additional studies were also needed because of concerns raised by earlier studies or uses added by the primary registrant. For example, studies were needed to address increased concern about chlorothalonil's effects on wildlife and aquatic organisms.

Data submitted by the registrants in response to the 1984 standard confirmed the potential of chlorothalonil to cause cancer and to contaminate groundwater. Although EPA tentatively classified chlorothalonil as a probable human carcinogen (referred to as a B2 carcinogen) in 1986, the agency took over 2 years to finalize this classification because of lengthy reviews and evaluations of studies and because of requests for additional data.

For example, in September 1987, the FIFRA Scientific Advisory Panel (SAP)[4] reviewed the B2 classification and recommended that EPA defer classification because the agency had not reviewed data submitted 3 months earlier. The primary registrant argued that the new data would lower the classification. EPA finished reviewing the data in April 1988—approximately 10 months after the data were submitted. In May 1988, an EPA peer review committee examined the issue raised by the SAP and reaffirmed the classification of chlorothalonil as a probable human carcinogen. EPA assessed the cancer risk for consumers and workers and concluded that the risk was within EPA's acceptable limits.

EPA also classified HCB as a probable human carcinogen. Data submitted in response to the 1984 standard showed an increased incidence of malignant tumors in laboratory animals exposed to HCB. These data were used to estimate possible cancer risks to humans from dietary exposure. The 1988 draft standard identified additional data that would allow a more complete assessment. As a precautionary measure, EPA said it would not consider registration of any significant new uses of chlorothalonil while data were being developed and evaluated.

Finally, data indicated that chlorothalonil and several of its degraded forms reached groundwater. In fact, chlorothalonil had been found in groundwater in two locations. In addition, several of the degraded forms of chlorothalonil were also detected in groundwater. According to the 1988 draft standard, EPA planned to require that registrants submit monitoring studies to determine the extent to which chlorothalonil contaminates groundwater. However, as noted earlier, the 1988 standard was never issued in final form.

Various Factors Caused Reregistration Delays

Review procedures and program changes contributed to delays in the reregistration process for chlorothalonil. In accordance with federal regulations, EPA notified the public on October 28, 1988,[5] that a draft registration standard was available for comment. EPA received comments from three affected registrants who submitted volumes of data, including information that EPA had previously reviewed. According to an EPA official, the effort was time-consuming because EPA responded to each point—even those to which it had previously responded. EPA made minor changes to

[4]The FIFRA Scientific Advisory Panel is an independent group of scientists authorized under FIFRA to render scientific opinions on pesticide issues and to advise EPA.

[5]53 Fed. Reg. 43766, Oct. 28, 1988.

the draft standard where appropriate in response to the comments received.

In March 1990, EPA finished drafting a final standard for chlorothalonil, essentially reaffirming the 1988 draft standard. But the 1990 draft standard identified additional data that were needed to replace studies EPA would no longer accept as valid. EPA needs the additional data to determine whether chlorothalonil could cause reproductive disorders and birth defects. However, because the standard was not issued, registrants were not required to submit any of the studies identified. Had registrants been required to comply with this standard, the last study would have been due approximately in September 1994.

EPA did not issue the 1990 standard because of program changes made to meet the accelerated schedule called for in FIFRA '88: EPA replaced registration standards with reregistration eligibility documents (RED) and formal data requests—known as data call-in notices (DCI)—and stopped issuing standards. Because of the gaps in the data on chlorothalonil, EPA issued two DCIs, in July 1991 and September 1991, to require 83 missing studies. The last study is due in August 1995.

Issuing the two DCIs rather than the standard delayed the reregistration process for chlorothalonil by approximately 16 months. This delay reflects the time taken to prepare, review, and issue the first DCI in July 1991. Approximately half of the time (8 months) was used by the Office of Management and Budget (OMB) to review the draft of this DCI. As required, the draft DCI was sent to OMB for review in the fourth quarter of fiscal year 1990 and cleared on May 8, 1991. According to EPA officials, the requirement that OMB review the DCI was time-consuming because of the additional work imposed on the agency. For example, EPA had to obtain clearance from OMB for every data request it made.[6]

Delays in Reregistration Could Continue

Similar factors could further delay the reregistration process for chlorothalonil. For example, a significant number of data gaps (65)[7] remains. Potentially difficult studies include those that measure residues and help assess tolerances and those that assess effects on wildlife, aquatic organisms, and the environment. One of these studies, groundwater monitoring, is the last study due. This study is complicated

[6]In May 1991, EPA and OMB reached an agreement on OMB's role in reviewing EPA's data requests. For additional information see app. IV.

[7]The registrants have fulfilled 18 of the 83 data gaps identified in the 1991 DCIs.

because a test must be completed for each individual site. However, ongoing studies may not completely fulfill data requirements or may indicate the need for additional tests. For example, if the studies show contamination, EPA and the registrants may have to determine the extent of groundwater contamination where chlorothalonil is used—thus potentially delaying EPA's ability to reregister all uses of chlorothalonil.

Furthermore, in 1989 EPA rejected a study it had previously accepted to fulfill the requirement for data on the potential impacts of chlorothalonil on the human reproductive system. EPA rejected the study because of deficiencies in the way it was conducted. EPA required a new study in July 1991, although a registrant believes it had submitted data to fulfill the requirement in November 1990. As of November 1992, EPA had not determined whether the requirement was fulfilled. A new study could take 4 years and is needed before a reregistration decision on chlorothalonil can be made.

According to an EPA official, HCB contamination is one of the most significant factors in a potential delay in the reregistration process for chlorothalonil. In March 1992, a registrant requested waivers for at least 10 studies designed to measure HCB residues, because the company believes it has complied with risk-reduction measures EPA required that may negate the need for new data. As of February 1993, EPA had not decided whether to approve or deny the waiver requests, although EPA has been in frequent communication with the registrant regarding the request. If EPA denies the waiver requests, it will probably give the registrant an additional 2 years to complete the studies.

Finally, EPA's ability to make a reregistration decision on chlorothalonil is significantly affected by EPA's internal reviews as well as by the registrants' actions. For example, the primary registrant requested that EPA review certain worker exposure data before the company initiated a needed study. Several months after making the request, the registrant decided to initiate the study even though EPA had not reviewed the data 7 months after submission. In March 1992, the registrants requested waivers for several related studies that are complex and require up to 36 months to complete. As of January 1993, EPA had reviewed all of the waiver requests with the following results: Four are likely to be approved, two require review of other data before a decision is made, and one is still under consideration. For those waivers that are not approved, registrants are likely to request time extensions in order to complete the needed studies.

Case Study: Reassessment of Atrazine

Atrazine is an herbicide used to control weeds on crops such as corn, sorghum, sugarcane, and wheat. Initially registered for use in 1959, atrazine is among the two or three most heavily used pesticides in the United States. By 1983, EPA had identified the potential of atrazine to contaminate groundwater. As of February 1993, EPA had not fully characterized the effects on human health and the environment of exposure to this pesticide. According to current estimates, EPA could complete its reassessment of atrazine and decide whether products containing the pesticide are eligible for reregistration in August 1995. Figure II.1 provides a time line of the major steps EPA has taken to reassess atrazine for reregistration.

Figure II.1: Major Steps Taken by EPA to Reassess Atrazine

1959 Initial registration	• Registered pesticide for use on food crops			
November 1983 Initial standard	• Requested data needed to support 48 requirements	• Established deadline of November 1987 for last study	• Identified pesticide's potential for groundwater contamination	• Required warning labels to mitigate groundwater contamination concerns
November 1988 Formal request for data	• Requested data needed to support 35 requirements	• Established deadline of November 1990 for last study	• Called for groundwater monitoring and residue chemistry data	
August 1989 Formal request for data	• Requested dog feeding study needed to help assess risk to workers	• Established deadline of March 1991 for study		
September 1989 Draft standard	• Identified data needed to support 51 requirements	• Established deadline of September 1992 for last study	• Did not issue final standard because of program changes	
September 1990 Formal request for data	• Requested data needed to support 48 requirements	• Established deadline of August 1994 for last study	• Noted that additional data may be required depending on results of data requested	

Initial Reassessment Identified Data Gaps and Groundwater Concerns

EPA completed its first comprehensive reassessment of atrazine in November 1983 under its registration standards program.[1] In its reassessment, EPA concluded that the existing data (129 scientific studies) on atrazine were not sufficient to evaluate the pesticide's long-term health and environmental effects—specifically, the pesticide's potential to cause cancer and to contaminate groundwater. As a result, EPA requested the registrants[2] to conduct additional tests that would fill 48 data gaps that the agency had identified. The last study—the registrants' test results—was due in November 1987.

About 35 percent of the tests were needed to assess the pesticide's residue chemistry—the residues that remain in food or feed after they are treated with atrazine. Twelve tests were also required to determine atrazine's environmental fate.[3] Ten additional studies were required to assess human health effects, such as the pesticide's potential to cause cancer, birth defects, and reproductive disorders. Nine tests were required to determine atrazine's product chemistry, which includes the composition, formation of ingredients, and corrosion characteristics.

Data on residue and human health effects are important for setting tolerances—the maximum amount of pesticide residue that lawfully may remain in or on a harvested crop. EPA sets these levels so that the pesticides do not pose an unreasonable risk to consumers.

EPA was concerned about atrazine's potential to leach into groundwater supplies. While the agency mitigated these concerns by requiring that labels on products containing atrazine carry a statement warning of potential groundwater contamination and by advising that atrazine not be used in certain soils, it also informed the registrants that these measures might not be sufficient to resolve its concerns.

[1]Under the registration standards program, EPA prepared a document called a standard that summarized available data on a pesticide, required submission of additional data, and outlined other conditions a registrant had to meet for EPA to reregister products containing the pesticide.

[2]A pesticide may be produced by more than one registrant. The primary registrant—the company that produces the largest volume of the pesticide—may take the lead in providing EPA with the required studies.

[3]"Environmental fate" refers to what happens to a pesticide through degradation, metabolism, mobility, dissipation, and accumulation when it is released into the environment.

EPA Asked for Additional Data Needed If Atrazine Undergoes Special Review

Studies submitted in response to the 1983 standard, along with other data, indicated the potential of atrazine to contaminate groundwater and surface water and to cause cancer and heart disorders. As a result, in 1988 and 1989 EPA issued formal data requests—known as data call-ins (DCI)—requiring additional data so that the risks and benefits of atrazine use could be assessed if a special review were initiated.[4]

On August 17, 1988, EPA informed the registrants that it was considering initiating a special review on the basis of several of the concerns mentioned above. EPA was concerned about the potential risks resulting from dietary exposure to atrazine and from mixing, loading, or applying the pesticide. EPA said it would consider the registrants' response in determining whether to initiate a special review.

On September 20, 1988, the primary registrant responded that although it was concerned about atrazine's potential to cause cancer and contaminate groundwater, it disagreed with EPA's characterization of the magnitude of these problems. The registrant proposed several measures to reduce exposure, such as restricting use to certified workers, limiting the amount used on certain crops, and requiring workers to wear protective clothing. Although EPA welcomed these voluntary risk-reduction measures, it made no suggestion to the registrants that additional data would not be required if necessary. On November 2, 1988, EPA issued a DCI requiring the registrants to submit 35 studies. Approximately 26 studies were needed to measure the residue remaining on crops treated with atrazine. The last study was due in November 1990.

In August 1989, EPA issued a letter informing the registrants of EPA's conclusions, based on an earlier study using dogs, that heart disorders resulted from exposure to atrazine. Consequently, EPA was concerned about potential risks to persons working with atrazine. EPA also issued a DCI requesting one study to better understand at what level of exposure these heart disorders occurred. The study was due in March 1991. On September 27, 1989, the primary registrant responded to EPA's letter. The registrant asked to meet with EPA to discuss, in more detail, EPA's concerns about heart disorders observed in the earlier dog study. The registrant did not address EPA's concerns about worker exposure in this letter. According to EPA officials, EPA did not initiate a special review of atrazine because the registrant provided data that supported its position that the level of

[4]Special review is a separate process for reviewing a pesticide's risks and benefits if the pesticide is suspected of posing an unreasonable health or environmental risk (e.g., suspected of causing cancer, birth defects, or genetic effects). At the conclusion of a special review, EPA may decide to continue, restrict, or cancel certain uses of the pesticide.

exposure—that is, the level at which there were no observable effects—EPA used to calculate worker risks should have been higher. While this change did not totally eliminate EPA's concerns about worker exposure and possible cardiac effects, it did lessen these concerns.

Second Reassessment Identified Data Gaps and Confirmed Other Concerns

EPA completed its second comprehensive reassessment of atrazine in September 1989 under its registration standards program. EPA's second reassessment concluded that the existing data (143 scientific studies) on atrazine were not sufficient to evaluate the pesticide. On the basis of studies submitted by the registrants in response to the 1983 standard, EPA had classified atrazine as a possible cause of cancer and determined that groundwater monitoring studies were needed. Although EPA prepared a draft standard in 1989 that identified data needed for atrazine's reregistration, this standard was never issued.

In the 1989 draft standard, EPA identified approximately 51 tests that the registrants had to conduct to fill gaps in the data on atrazine. Residue chemistry accounted for over one-third of these gaps. Because of insufficient data, EPA still could not thoroughly reassess existing tolerances. The 1989 draft standard also stated that two new environmental fate studies were needed because existing studies did not conform to EPA's revised guidelines.

EPA informed us that the 1989 draft standard was never issued because of program changes made to meet the accelerated reregistration schedule mandated in FIFRA '88. EPA replaced registration standards with reregistration eligibility documents (RED) and DCIs and stopped issuing standards.

On September 28, 1990, EPA issued a DCI requiring the registrants to submit the vast majority of data identified in the 1989 draft standard. EPA determined that approximately 48 tests were still needed before reregistration could take place. The data gaps that occurred most frequently concerned residue chemistry (19). Although EPA had required residue chemistry data in the 1988 DCI, new tests were needed because the metabolites[5] that must be identified had changed. The 1990 DCI also required data on worker exposure. The last study is now due in August 1994.

[5]A metabolite is any substance produced by metabolism—the process by which chemicals are transformed and stored.

Same Issues Are Still Causing Reregistration Delays

Factors that delayed the reregistration process for atrazine in the past still persist today. For example, as of November 1992, there were still a significant number of data gaps (45). Particularly difficult studies include those designed to measure residues remaining on treated crops. In addition, EPA noted in the 1990 DCI that depending on the results of the studies requested, new tests may be required. If new studies are required, reregistration decisions will probably be further postponed.

Furthermore, human health and environmental concerns have not been resolved. According to EPA, the possibility of a special review is the greatest factor affecting the issuance of the RED for atrazine. EPA may still initiate a special review of atrazine because of concerns identified in 1988.

While a special review may only apply to specific uses of a pesticide, the pesticide cannot be reregistered for these uses until the special review is completed. EPA told us that unresolved issues such as the cancer potential and dietary residues are among those that have added to the complexity of the decision on initiating a special review of atrazine. The agency said that the results of studies may provide the data needed to assess carcinogenic and dietary risks. EPA added, however, that its upper management must now decide whether to initiate a special review before the data are available that could help resolve the uncertainties. According to one EPA official, it is highly likely that the agency will initiate a special review of atrazine before the end of fiscal year 1993.

The last study due pertains to human health concerns and is being done voluntarily by one of the registrants in an effort to lower atrazine's cancer classification. If results from this study warrant it, the registrant will prepare another study to determine to what extent the public is exposed to atrazine through diet. Such a study, if undertaken, would be due in 1995. EPA will review these data before making reregistration decisions.

Phases in Pesticide Reregistration

Phase	Reregistration task			
Phase 1: EPA	• Publish lists of pecticides subject to reregistration			
Phase 2: Registrant	• Commit to reregister pesticide product (s)	• Identify missing and inadequate studies according to EPA guidance	• Agree to do studies	• Pay fee
Phase 3: Registrant	• Summarize and reformat existing studies	• "Flag" adverse effects information	• Pay fee	
Phase 4: EPA	• Review phase-2 and -3 submissions	• Identify any other needed studies	• Publish lists of missing studies	• Formally request missing studies
Phase 5: EPA	• After all studies are in, review within 1 year and issue RED[a]	• Review product-specific studies and reregister products or take other action within 6 months		
Registrant	• Submit product-specific studies 8 months after the RED is issued			

[a]A reregistration eligibility document (RED) is issued when EPA determines that a product's active ingredient does not cause unreasonable adverse effects to humans or the environment when it is used according to approved product label directions and restrictions.

The Reregistration Process

The reregistration process can be broken down into two principal stages: In the first stage, EPA must determine whether a pesticide product is eligible for reregistration on the basis of required health and environmental studies submitted on the product's active ingredient—the pesticide—and issue a reregistration eligibility document (RED). In the second stage, the specific product(s) containing the active ingredient is reregistered. A number of factors, such as requests by the registrants for waivers and time extensions on required studies, compound the complexity of the reregistration process.

Determining Reregistration Eligibility

To determine reregistration eligibility, EPA conducts a risk assessment. That is, by reviewing and evaluating studies submitted by the registrants, EPA determines that the pesticide does not cause unreasonable adverse effects when it is used according to approved directions and restrictions on the product's label. Label requirements are the primary mechanism by which EPA regulates pesticide use. Labels are required to provide use directions, warnings, precautionary statements, and other needed restrictions, as well as the percentage by weight of the active ingredient(s) the product contains.

If significant concerns arise as a result of EPA's risk assessment, the agency may choose to initiate a special review of the pesticide. Special reviews are triggered by perceptions of unacceptable risk based on health or environmental data and may require the registrants to submit additional data. At the conclusion of a special review, EPA may decide to continue, restrict, or cancel certain uses of the pesticide.

Determining reregistration eligibility may require EPA to review and approve test protocols submitted by the registrants that outline how new or special studies will be conducted. For example, because groundwater monitoring studies are not routinely required for all pesticides—but only for those such as chlorothalonil that are known to leach in most soils—the studies lack established protocols. The registrants of such pesticides are required to design groundwater monitoring studies and submit them for EPA's approval. Reviewing test protocols for new or special studies is time-consuming and requires EPA to consider, among other things, whether (1) sufficient numbers of measurements will be made to achieve statistical reliability, (2) sufficient controls have been built into all phases of the study, and (3) the results will be reproducible. Reviewing test protocols submitted for groundwater studies can take from 40 to 160 hours; reviewing protocols for certain residue chemistry and human exposure

studies can take from 20 to 56 hours. According to data EPA provided, since 1988 over 200 test protocols have been submitted for review.

As part of the process, EPA also reassesses pesticide tolerances—the maximum amounts of pesticide residues that lawfully may remain in food or animal feed. Lowering a pesticide's tolerance level may reduce human exposure to the pesticide, so this measure may be used to eliminate any unreasonable risks. According to EPA, 62 tolerances have been reassessed for pesticides undergoing reregistration.

Reregistering Specific Products

Once EPA determines that a pesticide poses no unreasonable risk to humans and the environment when used according to directions, the agency issues a RED, summarizing the data reviewed and the conclusions reached. Through the RED, EPA requests the registrants to submit product-specific studies and revised labeling for each product. If changes in labeling and/or tolerances are likely to eliminate unreasonable risks, EPA is likely to propose such changes before taking other regulatory action. In these situations, products containing the pesticide will be declared eligible for reregistration on condition that the label or tolerance is changed. If the changes are not made, EPA will then consider taking more formal regulatory action against the registrants, such as permanently revoking (canceling) their products' registrations.

Generally, once EPA has received and accepted the studies and labeling revisions and determined all uses to be eligible, it reregisters the individual pesticide products. For products formulated with more than one active ingredient, the reregistration process may proceed only after REDs have been issued for all active ingredients contained in the products. Moreover, products containing inert ingredients—components used to dissolve, dilute, deliver, or stabilize a pesticide—that are of toxicological concern will not be reregistered until the inert ingredients are removed or EPA receives data indicating that they will not cause unreasonable risks.

According to EPA, the agency does not intend reregistration to eliminate the need for continual reassessment of pesticides. Pesticides reregistered for use will be reassessed as new data are received or new concerns are identified. New information EPA receives may trigger a special review or cancellation action at any time.

Responding to Factors That Complicate the Process

The complexity of the reregistration process is compounded by a number of factors. For example, EPA must follow up on data it has requested from the registrants to ensure timely compliance with the requirements. In doing so, EPA must, among other actions, resolve registrants' responses that range from challenging the data requirements to requesting data waivers and deadline extensions. According to EPA's figures, from 1989 to 1993 the agency responded to 453 requests for data waivers and 99 requests for deadline extensions. Each request can take up to 8 hours to review. If additional information or a policy decision is needed, the responding to the request can take even more time.

EPA's follow-up also includes initiating suspension actions against product registrations that are not in compliance with reregistration data requirements. Suspending product registrations because the registrants did not submit data and other information requested for reregistration can take from 60 to 90 days to complete. Additional time is required if the registrants request a hearing. According to EPA's figures, as of February 1993 the agency had initiated 563 actions that resulted in the suspension of 135 product registrations; 19 of these cases had proceeded to hearings.

Requirements imposed on EPA by the Office of Management and Budget (OMB) under the Paperwork Reduction Act also complicate the reregistration process. Using its authority under that act, in December 1989 OMB required that EPA submit for prior approval such things as quarterly reports on all data requests the agency planned to issue to the registrants of list-A pesticides. Furthermore, if OMB required it, EPA had to submit justification for certain individual requests. EPA also had to conduct and submit to OMB "value of information" analyses before requesting certain groundwater studies.

Concerned that these requirements could seriously compromise its ability to meet its reregistration deadlines, in August 1990 EPA requested that OMB modify the requirements. In addition to expressing concern about meeting the deadlines, EPA pointed out that OMB had not formally cleared the first data requests it had submitted 4 months earlier despite expectations that OMB's review would take no longer than 15 days to complete.

In May 1991, EPA and OMB reached an agreement that eliminated the need for OMB to approve routine data requests before EPA issues them. However, EPA must still, among other things, submit quarterly reports that identify all data requested in the previous 3 months and justifications for individual

data requests when and if OMB requires them. Our case study on chlorothalonil illustrates the effect of OMB's involvement on the pace of reregistration. (See app. I.)

Providing Guidance and Information

In an effort to provide clearer guidance to both EPA staff and the registrants on what studies are required for reregistration, in May 1992 EPA provided a definition of "reregistration" and established a fixed target data base for the program. The definition specifies the criteria that EPA will use in making reregistration decisions. In establishing the target data base, EPA acknowledged that a fixed set of data requirements may become outdated as scientific knowledge increases or regulatory requirements change. However, EPA believes that its target data base for reregistration includes the data needed to bring older pesticides up to a level that closely reflects the standards it currently applies for registering new products.

EPA is also making efforts to provide information on the reregistration program's progress to the general public and to pesticide producers, users, and other groups that are most directly affected by pesticide reregistration decisions. For example, the agency publishes quarterly progress reports that provide regular updates on the program, fact sheets that summarize reregistration eligibility determinations, and an annual report—known as the "Rainbow Report"—that provides comprehensive lists and summaries of the regulatory status of all pesticides undergoing reregistration and special review. Also, EPA provides opportunities for conveying information and answering questions about the program through annual reregistration workshops and other public meetings.

Objectives, Scope, and Methodology

The Chairman of the Senate Committee on Agriculture, Nutrition, and Forestry and the Chairman of the Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, asked GAO to review what steps EPA has taken to comply with the reregistration provisions of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988 (FIFRA '88). Specifically, our objectives were to (1) examine the progress EPA has made in meeting the deadlines of FIFRA '88 and (2) identify factors impeding EPA's ability to complete reregistration as expected.

To accomplish these objectives, we examined EPA's pesticide reregistration plans, policies, guidance, and status reports. We reviewed EPA's cost and revenue estimates and projections for completing reregistration. To assess EPA's progress in meeting program objectives, we obtained program accomplishment data from EPA's automated information systems and compared these data with EPA's plans and projections.

We interviewed officials in EPA's Office of Pesticide Programs (OPP), including scientists in OPP's Health Effects Division and Environmental Fate and Effects Division, pesticide case review managers in OPP's Special Review and Reregistration Division, product reregistration officials in OPP's Registration Division, and budget officials in OPP's Program Management and Support Division. In addition, we attended EPA's internal and external workshops designed to enhance participants' understanding of the reregistration process and help resolve major program difficulties.

To examine the complexity and potential obstacles involved in reregistration, we performed case studies on two major pesticides undergoing reregistration. We selected these pesticides on the basis of their large-scale use on food products and their classification as possible human carcinogens and potential groundwater contaminants. For each case study, we obtained information on the pesticide's regulatory history, reviewed major requirements and concerns identified during the reregistration process, and examined reasons for delays in the process.

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.	Peter F. Guerrero, Associate Director J. Kevin Donohue, Assistant Director Robert Tice, Assignment Manager Carol Ruchala, Evaluator-in-Charge Cheryl Goodman, Senior Evaluator Jennifer Clayborne, Staff Evaluator Mark Trapani, Staff Evaluator Phyllis Turner, Reports Analyst
Office of the General Counsel	Doreen Stolzenberg Feldman, Senior Attorney

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