



B-266002

October 26, 1995

The Honorable Pat Roberts
Chairman
The Honorable E. Kika de la Garza
Ranking Minority Member
Committee on Agriculture
House of Representatives

As agreed with your offices, this letter provides suggested amendments to H.R. 1627, the Food Quality Protection Act of 1995, that would improve the Environmental Protection Agency's (EPA) accountability to the Congress for funds spent for reregistration and expedited registration of pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).¹ Specifically, you requested our suggestions for improved accountability for the reregistration program through annual financial reporting, performance information, and audits.

Adoption of our suggestions would annually provide the Congress with reasonable assurance about the accuracy of reported FIFRA program fee receipts, appropriations, and expenses. In addition, EPA would be required to annually report key performance information on its progress in completing the reregistration process. Preparation and audit of annual financial and performance information would provide timely information on EPA's progress in meeting FIFRA goals.

PROGRAM HISTORY

Federal efforts to reassess pesticide safety began with the 1972 amendments to FIFRA. Under these amendments, the Congress directed EPA to reassess older pesticide

¹H.R. 1627 would also, among other things, amend certain pesticide regulatory procedures under FIFRA, as well as alter EPA's authority to establish allowable pesticide residue levels in foods under the Federal Food, Drug, and Cosmetics Act.

registrations against modern health and environmental testing standards and to complete the task within 4 years. Primarily because of insufficient resources, EPA's early attempts to develop a reregistration program were unsuccessful, and EPA did not meet the deadline. In 1978, due to the uncertainty in predicting how many years reregistration would require, the Congress amended the act to require that EPA reregister all pesticides as expeditiously as possible but did not impose a specific deadline.

In 1986, we reported that at its current pace, EPA's reassessment and reregistration efforts would extend beyond 2000 because of the magnitude and complexity of the tasks involved.² We provided options for the Congress to consider, including setting deadlines for EPA's reregistration and providing EPA with additional resources from pesticide user fees. In 1988, the Congress again amended FIFRA to, among other things, set a statutory timetable requiring EPA to establish an expedited process to complete pesticide product reregistrations by 1998 and give priority to pesticides used on food. It also authorized EPA to collect fees from pesticide registrants to provide resources for accomplishing reregistration.

In 1993 we reported that EPA would not meet the 1998 deadline because reregistration had proved lengthy and complex.³ Further, EPA underestimated the resources needed for the program and the rejection rate for studies submitted by pesticide registrants.⁴

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

³Pesticides: Pesticide Reregistration May Not Be Completed Until 2006 (GAO/RCED-93-94, May 21, 1993).

⁴While EPA's rejection rate has been as high as 45 percent, the rate has dropped significantly for studies recently submitted to EPA. EPA believes the lower rejection rate is a result of the agency's efforts to work with registrants to identify causes of rejected studies and to identify steps to improve the rates. Redoing unacceptable studies adds years of additional work to the reregistration process, both for the registrant that must do them and EPA that must rereview them.

Reregistration of pesticide products begins after EPA issues a reregistration eligibility decision (RED), which presents EPA's conclusion about whether a pesticide's uses are eligible for reregistration. Under the accelerated program EPA established in response to the 1988 FIFRA amendments, before the agency reregisters a pesticide, a RED is issued on the active ingredient(s). 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 in accordance with the terms and conditions EPA has established. The registrant then submits information on the acute health effects and chemistry of a specific product containing the pesticide. After reviewing the information, EPA can reregister the product.

A RED is issued for each chemical case, which consists of one or more related pesticide active ingredients.⁵ Currently, registrants--usually chemical producers--are supporting 405 chemical cases for reregistration.⁶ Although a registrant may choose at any time not to continue to support the registration of a particular pesticide's use, these chemical cases currently cover about 18,200 pesticide products. Through the end of August 1995, EPA had reassessed 105 of the 405 supported chemical cases, comprising 152 of the 590 supported active ingredients used in pesticides, and had made

⁵Active ingredients are the components contained in the product that destroy or control the targeted pest.

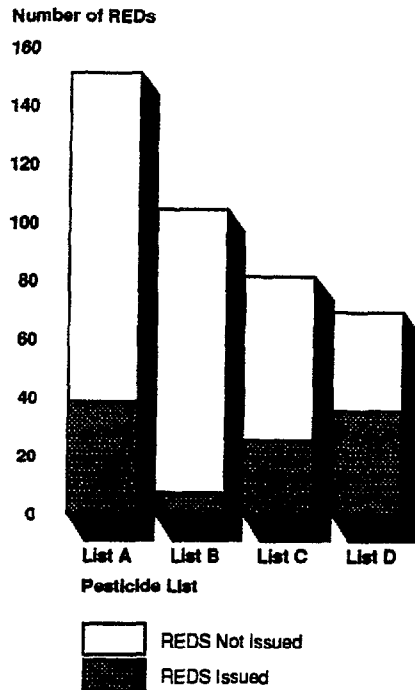
⁶Supported means that the producer(s) of the pesticide has made commitments to conduct the studies and pay the reregistration fees, and is meeting those commitments promptly.

reregistration decisions for 2,087⁷ of the 3,968 products using those active ingredients.

As directed by the 1988 amendments to FIFRA, EPA divided the universe of chemical cases into four lists--A, B, C, and D--ranked according to their potential for human exposure and risk. Generally, pesticides on list A, which includes most pesticides with food-related uses, have the greatest potential for exposure and risk, while those on list D have the least. Figure 1 shows supported chemical cases and the completed REDs through the end of August 1995.

⁷These decisions pertain to 688 products reregistered, 22 registrations amended, 1,024 voluntarily canceled, and 353 suspensions. Action is pending on the remaining 1,881 products, including those REDs which have been approved but not yet mailed out to the registrants, those awaiting a registrant response, and those awaiting an EPA decision on the registrant response. According to FIFRA, EPA should reach a reregistration decision on each product 14 months after issuance of a RED, provided that the registrant submits acceptable data on time. EPA's Office of Pesticide Programs (OPP) reports that pesticide products generally are registered about 14 to 24 months after a RED is issued. OPP's experience shows, however, that reregistration of many products will take longer than 2 years for the following reasons: (1) many product registrations are suspended because registrants do not respond to OPP's initial call for supporting data, but decide to respond later, (2) time extensions are normally granted when product-specific data are found to be deficient and must be regenerated, (3) the smaller registrants that are often involved in product reregistration frequently make errors or do not submit complete applications, resulting in two or more resubmissions to EPA before a reregistration decision can be made, (4) many registrants request time extensions and/or data waivers for product-specific data requirements, (5) REDs that cover many products cause an "overload" for certain parts of OPP and cannot all be processed according to the desired schedule, and (6) backlogs of product reregistration decisions build up due to inadequate resources or "overload."

Figure 1: Status of REDs by Pesticide List (August 31, 1995)



Based on the number of chemical cases currently supported by registrants, EPA expects to issue a total of 405 REDs.

EPA's Office of Pesticide Programs (OPP) estimates that if the current user fee level remains unchanged, the reregistration of all pesticide products could be completed by 2005.⁸ Pending reregistration, most of these pesticides may continue to be sold and distributed even though knowledge of their health and environmental effects is incomplete. OPP officials stated that the reregistration program progress is

⁸EPA's estimate assumes that (1) \$112 million in user fees will be available to the reregistration program at \$14 million a year from fiscal year 1996 through fiscal year 2003 and (2) reregistration of all products covered by a RED will be completed within 2 years after the RED is issued.

directly dependent upon resources available to review studies submitted by registrants⁹ and that a large backlog of studies was awaiting review as of March 1995. At that time, OPP reported a backlog of 7,694 studies, including 2,204 studies for list A pesticides, 3,671 studies for list B pesticides, 1,146 for list C pesticides, and 673 for list D pesticides.¹⁰ Furthermore, EPA officials projected that the program will cost substantially more than originally estimated and that receipts from registrant fees will be less than planned.

As a result of historical program delays, cost overruns, and other concerns (such as how efficiently EPA uses the fees it collects), pesticide manufacturers have called for more program accountability.

CURRENT FINANCIAL AND
PERFORMANCE REPORTING
REQUIREMENTS

Under the Chief Financial Officers (CFO) Act of 1990, agencies are required to prepare audited financial statements for commercial, revolving, and trust funds through fiscal year 1995. All FIFRA reregistration and expedited processing activities are reported as part of the FIFRA Revolving Fund, which is subject to audit under the CFO Act. Starting with fiscal year 1992, the FIFRA Fund financial statements¹¹ have been audited by the EPA Inspector General (IG). The FIFRA Fund 1994 financial statements showed \$41 million of total expenses, consisting primarily of \$16 million in program expenses and \$25 million in expenses from an overhead allocation. These expenses were financed

⁹For example, OPP officials estimate that the reregistration program could be completed by 2004--with all REDs being completed by 2002--if user fees totaling \$135 million from fiscal year 1996 through fiscal year 2004 were made available to the program. This means that for an additional \$23 million, the program could be completed 1 year earlier.

¹⁰Pesticide Program Progress Report (EPA 738-R-95-020), April 1995.

¹¹The FIFRA Fund financial statements are included in the Fiscal Year 1994 Annual Financial Statements for the U.S. Environmental Protection Agency (CFO Annual Report).

primarily by appropriations of \$25 million and fees of \$16 million.¹²

For 1994, the IG issued a qualified opinion¹³ on the FIFRA Fund for the Statements of Financial Position and Cash Flows because property and accounting systems were not integrated, resulting in EPA's failure to identify all property and equipment that should have been capitalized. The IG issued a disclaimer of opinion¹⁴ on the Statements of Operations and Changes in Net Position because of property and equipment deficiencies and because the IG did not audit the nearly \$25 million overhead allocation. Also, the IG reported weaknesses in internal controls relating to property and equipment recordkeeping and indirect cost allocation.

The Congress passed the Government Management Reform Act of 1994 (GMRA) to expand the benefits resulting from the CFO Act's requirements for audited financial statements. Thus, beginning with fiscal year 1996 operations, EPA will be required by 31 U.S.C. 3515(a) to prepare, have audited, and submit to the Office of Management and Budget (OMB) by March 1, 1997, consolidated financial statements. These statements are to reflect the overall financial position and results of operations for all EPA activities, including FIFRA. Separate commercial, revolving, and trust fund financial statements are generally not required under GMRA unless the fund is designated by OMB as an agency component under 31 U.S.C. 3515(c).¹⁵ Thus, EPA will not be required to prepare and have audited separate financial statements for the FIFRA Fund for fiscal year 1996 unless OMB designates

¹²According to EPA, total current annual pesticide sales at the user level are \$8.5 billion. Annual user fees are currently less than 0.2 percent of total sales.

¹³A qualified opinion states that "except for" the effects of the matter to which the qualification relates, the financial statements are fairly stated.

¹⁴A disclaimer of opinion states that the auditor does not express an opinion on the financial statements. It is appropriate when the auditor has not performed an audit sufficient in scope to enable expression of an opinion.

¹⁵Under 31 U.S.C. 3515(c), OMB is authorized to identify components of executive agencies that will be required to have audited financial statements.

FIFRA as an EPA component. EPA told us that it plans to continue to produce financial statements for the FIFRA Fund.

The Government Performance and Results Act of 1993 (GPRA) expands on the CFO Act by requiring agencies to develop strategic plans, reach a reasonable degree of consensus on desired goals with key stakeholders, and measure and report progress toward achieving those goals. One of the key purposes of GPRA is to improve congressional decision-making by providing objective information on program performance.

OPP currently prepares annual and quarterly reports¹⁶ that include FIFRA program performance information. In 1992, we reported that OPP had many problems with data accuracy, consistency, and completeness in its information systems and that information was often duplicated in other systems' data files.¹⁷ We recommended that EPA implement a plan with milestones for resolving OPP systems' data integrity problems; however, EPA has no data quality assurance efforts planned or under way. An OPP official stated that data quality efforts have not been funded because of resource constraints. This official also stated that as EPA moves towards a more integrated systems environment, stronger data ownership will help improve data quality.

In addition, the 1994 overview to the FIFRA Fund financial statements¹⁸ prepared in accordance with the CFO Act included two performance measures that EPA said support program strategic goals. According to EPA, these efforts are related to the agency implementation of GPRA. The FIFRA program will be included in EPA's strategic plan, which is required to be completed by September 30, 1997. The first report required under GPRA is for fiscal year 1999 and is due March 31, 2000.

¹⁶The annual report for 1994 is called Office of Pesticide Programs Annual Report for 1994 and the quarterly report is called Pesticide Program Progress Report.

¹⁷Pesticides: Information Systems Improvements Essential for EPA's Reregistration Efforts (GAO/IMTEC-93-5, November 23, 1992).

¹⁸The overview to the financial statements is a narrative prepared by the agency that is intended to include the strategic goals of the agency or programs and what was done during the year to achieve those goals. Agencies typically report performance information in the overview.

FINANCIAL REPORTING

It has been established over the past several years that the preparation and audit of financial statements provides needed accountability for federal programs. As a result of GMRA, agency financial statements will be on a consolidated basis beginning in fiscal year 1996, supplemented by the financial statements of the agency components designated by OMB under 31 U.S.C. 3515(c). If the Congress decides that audited financial statements for the FIFRA Fund are critical to EPA's accountability for the FIFRA program, it could ensure that EPA has such statements after fiscal year 1995 by designating in H.R. 1627 that the FIFRA Fund is an EPA component for purposes of 31 U.S.C. 3515(c).

If FIFRA Fund audited financial statements are required, including them in the same document as EPA's future consolidated financial statements would help streamline reporting efforts. While other options for auditing the FIFRA Fund might be more efficient, they would provide less accountability. For example, EPA could continue to show separate FIFRA Fund activity in notes to the consolidated financial statements. This option would provide some overall assurance on FIFRA Fund activity and would require fewer audit resources. No separate opinion or reports on internal controls and compliance with laws and regulations would be required.

Under the law (31 U.S.C. 3521(e)), the EPA IG, or an independent external auditor approved by the IG, is required to perform the audit. If the FIFRA Fund audit requirement is added, the auditor would be required to continue preparing a separate audit opinion on the financial statements and reports on internal controls and compliance with laws and regulations. If H.R. 1627 or other legislation does not designate another source of payment, the cost of the audit would be borne by the EPA IG. Alternatively, H.R. 1627 could provide for the FIFRA Fund to reimburse the IG for the costs of the audit. According to the EPA IG, its resources are decreasing; thus, we believe that providing funding for the audit would ensure its completion. The IG did not have an estimate of the annual audit cost.

Because of the IG's disclaimer of opinion for fiscal year 1994 on the Statement of Operations, there was no assurance that the FIFRA Fund fee receipts, appropriations, and expenses were fairly stated. The primary reason for the disclaimer of opinion was that the IG did not audit the

\$25 million overhead allocation to the FIFRA Fund. We discussed the reasons for not auditing this allocation with representatives of EPA's IG and Financial Management Division (FMD) offices. We found that the allocation to the FIFRA Fund is based on a formula rather than specific transactions. Indirect costs for EPA as a whole are allocated to various programs/funds, some of which are currently not required to be audited. The IG representative stated that, as a result, the entire agency would need to be audited to review this allocation.

Because of the overhead allocation's significance to the FIFRA program--it represents 60 percent of the cost--the allocation would have to be audited in order to express an opinion on the Fund's financial statements. The IG does not plan to audit the overhead allocation for fiscal year 1995. However, when the IG does its required audit of EPA's consolidated financial statements for fiscal year 1996, an audit of all expenses, including those in the allocation, would be necessary. Thus, if H.R. 1627 designates FIFRA as an EPA component, a full scope audit of the FIFRA Fund could be attempted for fiscal year 1996. H.R. 1627 could also require that this audit include a review of the reasonableness of the overhead allocation and the adequacy of disclosures of direct and indirect costs.

PERFORMANCE REPORTING

In its 1994 CFO Annual Report, EPA included two measures that it stated support the program's strategic goals. The first measure is the number of REDs completed versus the EPA target and compared to the prior year. For 1994, EPA reported that 34 REDs were completed versus a target of 38 and compared to 19 in 1993. The second measure is the number of products reregistered, canceled, or amended. For 1994, EPA reported that 351 products were reregistered and 338 were canceled. The combined 689 actions were achieved versus a target of 903 actions and compared to 665 actions in 1993.

Some reregistration program performance information was also published in the OPP Annual Report for 1994. Examples of this information include the

- number of REDs by fiscal year and cumulative to date;
- number of active ingredients, pesticide products, and tolerances covered by completed REDs;

- aggregate status of reregistration cases;
- pesticide volume used by category (for example, fungicides) and sector (for example, homeowner) covered by completed REDs;
- risk reductions achieved for REDs completed in fiscal year 1994;¹⁹
- number and significance of data call-in requests issued to registrants for studies to support pesticide reregistration;
- study review status for list A pesticides and for lists A, B, C, and D pesticides combined;²⁰
- status of product reregistration; and
- aggregate status of tolerances reassessed.

OPP's efforts in developing performance information and its annual report are related to implementation of GPRA, which requires, among other things, program outcome and output measures. While OPP's current performance information is useful in assessing EPA's progress during 1 year compared to a target, it does not tell when the program will be completed or how fiscal year 1994's performance impacts the program completion date. This concern will be addressed, in part, by OPP's plan to add "Future REDs Schedule" as a new performance measure. This measure will be included in the annual report to show anticipated RED completions for future years with and without an increase in user fees. The future REDs schedule

¹⁹Each RED document issued in 1994 involved changes to reduce the potential risks of the pesticide being evaluated. Risks can be reduced by canceling products, declaring uses ineligible for reregistration, strengthening the requirements on product labeling, or limiting the amount of pesticide residues that may remain in food by establishing, reducing, or revoking the tolerances, which are the maximum residue limits.

²⁰Studies are categorized as reviewed or awaiting review. OPP reported that as of the end of March 1995, registrants had submitted 20,116 studies in support of reregistration. Review of the studies is critical for making reregistration decisions.

should provide a means of establishing baseline performance goals against which progress toward completion of the reregistration process can be measured.

However, we believe the schedule's usefulness could be strengthened by linking it to a performance schedule showing which chemical cases will be completed each year. OPP officials stated that they can reasonably estimate the number of REDs that can be completed each year but that they are less certain of their predictions of which REDs will be issued in specific years. For example, at current resource levels, OPP's goal is to complete about 40 REDs each year. However, to complete 40 REDs, OPP identifies about 60 RED candidates with substantially complete databases. During a given year, the completion of risk assessment decisions on a number of RED candidates may be delayed for various reasons, such as late or rejected studies. As a result, while OPP may meet its production goal for the year, it will not know with certainty which REDs will be completed.

Because this uncertainty is related to a number of factors, some of which are beyond EPA's control, EPA has generally resisted calls to develop schedules by RED to the end of the program. However, OPP officials stated that they could develop a list of potential REDs to be issued for the current fiscal year plus 1 out-year on a rolling basis to the end of the program. Further, they stated that the program's performance for each RED on that 2-year rolling schedule could be measured.

We believe that the key performance measures should address various aspects of program performance. A schedule containing the number of REDs to be issued each year until the end of the program, with annual reporting of the program's output, could provide an important measure of program performance against interim and final goals and show progress or slippage from year to year. A related schedule showing which REDs are to be issued by year on a 2-year rolling schedule would highlight whether EPA is meeting its annual production goal for the numbers of REDs by substituting REDs from the lower risk lists B, C, and D for those scheduled from the higher risk list A pesticides. The information would help the Congress assess whether EPA is appropriately prioritizing its reregistration efforts and whether it is meeting its goals for completing the program.

Accordingly, H.R. 1627 could require EPA to report key performance measures for the FIFRA program in the same

document as its 1996 consolidated financial statements. This reporting would be consistent with EPA's GPRA implementation efforts and could be included in the FIFRA Fund overview to the financial statements. Further, H.R. 1627 could require the EPA IG (or an independent external auditor) to examine the key performance measures, as agreed to by the Congress and EPA, and include an opinion on the reported performance data as part of its report on the FIFRA Fund financial statements.

AGENCY COMMENTS

We requested comments on a draft of this letter from the EPA Administrator or her designee. On September 27, 1995, the Director of EPA's Financial Management Division; the Assistant Inspector General for Audit, Office of Inspector General; and the Deputy Director, Policy and Special Projects Staff, Office of Pesticide Programs provided us with oral comments. These officials generally agreed that there needs to be strong accountability for the FIFRA Fund. However, they stated that they would prefer to meet congressional needs through a more flexible alternative than a legislative requirement to prepare and audit separate FIFRA Fund financial statements. The IG and OPP representatives expressed concern about the level of resources needed to meet the proposed legislative requirement for audited financial statements. In addition, the IG representative stated that continuing to audit the FIFRA Fund financial statements individually will neither speed up reregistration of pesticides nor address the pesticide industry's other concerns.

Assuming that the Congress desires more accountability for the FIFRA Fund than the overall financial audit of EPA would offer, a legislative requirement to prepare and audit Fund financial statements would be the best way of achieving that added assurance. Recognizing the IG's resource constraints, our letter indicates that the audit could be financed from Fund resources. While we agree with the IG that financial audits will not speed up the reregistration process or improve program efficiency, we believe that full scope financial audits of the FIFRA Fund would improve the program's overall financial accountability.

The Deputy Director, Policy and Special Projects Staff of OPP, agreed in principle with our suggestions for improved reporting of reregistration performance measures. However, he cautioned that the relative risks of pesticides, based

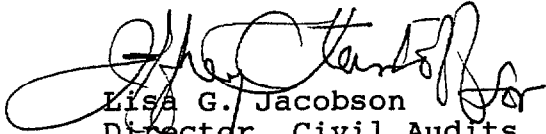
solely on their placement on list A, B, C, or D, should not be oversimplified. He stated that EPA consistently places a higher priority on RED production for higher risk pesticides from any list--taking food uses and other high-risk exposures into consideration--from the pesticides with substantially complete datasets. While this may be true, the pesticides with substantially complete datasets may not be the pesticides that pose the highest risk. Accordingly, we believe it is important that EPA focus its efforts on obtaining and reviewing the datasets for the list A pesticides before those for pesticides from lists B, C, and D, except in those circumstances where EPA can demonstrate that pesticides from lists B, C, or D pose a higher risk than those on list A.

SCOPE AND METHODOLOGY

In preparing our suggestions, we contacted officials from the offices of EPA's Financial Management Division, Inspector General, and Office of Pesticide Programs. In addition, we contacted officials from OMB. We did not evaluate the results of the IG's 1994 audit of the FIFRA Fund or the reasonableness of the IG's opinion or reports on internal controls and compliance with laws and regulations. We conducted our work in August and September 1995, in accordance with generally accepted government auditing standards.

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If you have any questions about this letter, please contact Lisa Jacobson at (202) 512-9508 or Peter Guerrero at (202) 512-6111.



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