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Report to Congressional Requesters

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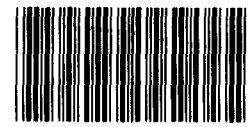
PESTICIDES

Information Systems Improvements Essential for EPA's Reregistration Efforts



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Information Management and
Technology Division

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November 23, 1992

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

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

Although pesticides have become an integral part of agricultural production in the United States, public concerns have risen about their toxic effects and risks to human health and environmental safety. The Environmental Protection Agency (EPA), under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), regulates the distribution, use, and sale of pesticides in the United States. EPA reviews all pesticides to ensure that if used properly, they present no unreasonable health or environmental risks.

Concerned that EPA may not be meeting its pesticide reregistration responsibilities under FIFRA, the Chairmen, Senate Committee on Agriculture, Nutrition, and Forestry, and the House Committee on Government Operations, Subcommittee on Environment, Energy, and Natural Resources, asked us to review the information systems EPA uses in its reregistration of pesticides. Specifically, we (1) examined how EPA is using automated information systems to provide information tracking and analysis for pesticide reregistration, and (2) determined if any changes are needed to better support its pesticide reregistration information needs. Our report expands on issues presented in testimony before you in October 1991.[1] Details of our objectives, scope, and methodology are contained in appendix I.

Results in Brief

After more than 3 years of effort and systems investments costing more than $14 million, EPA cannot easily assemble accurate, reliable, and complete information on chemicals in the reregistration process. This has

[1]Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration (GAO/T-IMTEC-92-3, Oct. 30, 1991).

compounded the already difficult task facing the agency in meeting pesticide reregistration deadlines imposed by the Congress.

EPA's information management problems are traceable to inadequate systems planning and poor data management. EPA adopted a rapid development strategy for developing its new reregistration systems because of an overload of reregistration information and short time constraints. However, EPA developed new systems before it had adequately established program management requirements and defined systems requirements.

Furthermore, the consistency, accuracy, and completeness of information within the new systems is also jeopardized because EPA has not implemented data management procedures to ensure data consistency and quality. Information from existing EPA databases with known accuracy and completeness problems was used to populate new information systems. In addition, because EPA does not have standard data definitions, integrating and sharing information between the systems will continue to be difficult. As a result, the new systems fall short in meeting users' needs for automated pesticide information monitoring functions; compiling information about pesticides undergoing reregistration remains difficult, labor-intensive, and time-consuming.

Background

Registering pesticides in the United States is no small task. Over 50,000 pesticide products have been registered since FIFRA was enacted in 1947. Most of these pesticides were registered before their long-term health and environmental effects were fully understood. In 1972, the Congress amended FIFRA to require EPA to reevaluate registered pesticides under more current scientific and regulatory criteria. In 1988, the Congress again amended FIFRA to accelerate EPA's reregistration review process by imposing time frames that would result in the completion of most pesticide reregistration decisions by 1997. As of July 1992, EPA had reached final decisions on only 2 of the 17,000 products subject to reregistration.

EPA regulates pesticide products primarily on the basis of their pesticidal active ingredients—that chemical component of a pesticide product that acts on the pest. Approximately 676 pesticide active ingredients are currently subject to reregistration as of April 1992. In addition, pesticides can be composed of several active ingredients and must be reregistered for all intended uses. As a result, EPA can require over a hundred different kinds of tests to support one pesticide reregistration. For example, the

reregistration of a food-use pesticide may require between 60 and 100 different studies covering the pesticide's chemistry, toxicology, and environmental effects. EPA estimates that it receives between 500 and 600 analytical studies—of varying complexity and volume—each month in response to reregistration requirements.

Once a set of scientific data on the active ingredient in a product is assessed, EPA may (1) grant full reregistration of the product and its uses; (2) request changes in the product's label (e.g., changes in usage, dosage, or application methods); (3) change the pesticide tolerances (i.e., residue level of a pesticide in food); or (4) restrict use of the pesticide.

EPA's Office of Pesticide Programs (OPP) is responsible for managing EPA's pesticide programs under FIFRA. Within OPP, there are three primary sets of users who are involved with pesticide reregistration information—case review managers (CRM), scientists,[2] and program managers.

CRMs are the principal liaison between EPA and registrants (the pesticide manufacturers).[3] They manage the extensive flow of paperwork between EPA and registrants, address registrants' questions or problems, and initiate actions when registrants do not comply with EPA's requirements or response deadlines. CRMs must track EPA's request, receipt, and review actions on test studies to ensure that registrants are properly notified of any outstanding test data submission requirements and keep program managers apprised of a chemical's review status. Scientists working in OPP's two science divisions review the test data submitted by registrants and advise the CRMs and program management on regulatory actions. They may need to consult EPA's historical information about a chemical, product labeling information on the intended use and application, pesticide residue chemistry results from field crop test sites or food monitoring reports, and survey data collected on food consumption patterns. Program managers are responsible for overall administration of the reregistration effort, and they use summary and aggregate information on the status of pesticides undergoing reregistration to report to the Director of OPP and key congressional oversight committees on the status and progress of reregistration. In addition, program managers plan for the resources

[2]The term scientists includes chemists, toxicologists, biologists, ecologists, and other related disciplines represented by staff in OPP's science divisions.

[3]OPP currently utilizes about 40 case review managers. Each CRM is responsible for a specific set of chemicals undergoing reregistration. CRM work loads vary depending on the complexity of the individual chemical reviews.

needed to complete the reregistration process based on reports made by CRMs on the progress of specific chemicals undergoing review.

Before 1989, pesticide registration information was primarily maintained at EPA's National Computer Center in North Carolina. However, because this information was often not accurate and was not easily accessible, users maintained their own personal paper file systems to keep track of information. In 1989, concerned about the data integration problems of the paper file systems and the large influx of studies that was inundating the CRMs, OPP began acquiring hardware and software as part of an effort to develop new officewide reregistration information systems.

Because of the vast amount of information that was coming into the CRMs, and because of the short time frames for meeting the 1988 FIFRA requirements, OPP decided to stress the quick development of these officewide systems. OPP developed a strategy that hinged on the following premises: (1) speed of system delivery was more important than data quality and reliability, (2) systems would be built and modified while new or revised work processes were being developed, and (3) data integration efforts would be undertaken only after the individual reregistration systems were developed and refined.

OPP chose to develop its systems in two stages. During the first stage OPP planned to quickly develop several systems that would assist in entering and tracking specific information needs, such as registrant compliance with data requirements or the status of a study within the review process. While these systems would contain reregistration information, the information would be fragmented across several systems, and some information would be duplicated. OPP planned to integrate and consolidate the systems during the second stage of development. Appendix II provides a list of the primary databases now used by OPP to support the pesticide reregistration program.

To finance its two-stage automation approach, OPP estimated it needed approximately $27 million between fiscal years 1989 and 1995. These funds would come from EPA's general budget and fees paid by registrants as part of the reregistration program. In support of the first stage of its automation approach, OPP spent over $14 million between fiscal years 1989 and 1991 on hardware and software acquisition and systems development and maintenance. OPP expects to integrate the new systems and data in support of the second phase of its approach by March 1993.

Inadequate Planning Is Jeopardizing EPA's Systems Development

Before developing an automated system, an agency should analyze its business processes, determine users' needs, and evaluate different software and hardware options. OPP management, however, did not establish procedures for managing new reregistration requirements and processes, define users' information needs associated with these processes, or consider different software applications that could be used to best accommodate these needs prior to developing their systems. Instead, OPP chose a rapid development methodology without first fully evaluating its long-term automated systems requirements.

While rapid development methodology is a viable option for developing a system, its success, like any development methodology, hinges on whether adequate planning has been done and a firm foundation laid out. As part of this foundation, agencies should perform functional requirements analyses, feasibility studies, and cost/benefit analyses. Functional requirements—including a description of the proposed system, summary of improvements sought, functions and performance required of the new system, data sources, and data characteristics—are used to provide a mutual understanding of information needs and system capabilities between users and designers of the system. Feasibility studies provide an analysis of the system objectives, requirements, and system concepts; an evaluation of alternatives for reasonably achieving objectives; and an identification of proposed approaches. Cost/benefit analyses provide managers, users, and designers with cost and benefit information to evaluate alternative approaches to developing systems.

These analyses and studies should be done at the beginning of any system development project, regardless of the methodology, because they are critical to making informed decisions about whether proposed systems are worth their cost, and determining what users want and need and if the most appropriate and cost-effective approach for developing systems has been identified. Proceeding without these analyses increases the risk that the system developed will not perform as required and will exceed expected costs and schedules.

OPP, however, did not perform any of these analyses or studies before it began developing its systems. OPP's System Branch Chief told us OPP did not have the time to complete analyses and also ensure that the new automated systems would be in place to handle the thousands of documents coming into the agency.

OPP's primary purpose in developing its automated systems was to help CRMs manage their work loads and facilitate the reregistration process by providing a means for CRMs to query and track registrants' compliance with FIFRA requirements and deadlines. OPP's decision to implement single-purpose standalone systems has limited users' abilities to efficiently monitor the status of pesticides undergoing review. CRMs cannot query studies by due date to determine registrants' compliance and cannot effectively aggregate and integrate information from the systems to produce status and progress reports. For instance, information describing a study is in one system, a separate system tracks where the study is in the review process, and yet another system contains results of EPA's review. Integrating all this information into a complete picture remains largely a manual process, as the CRMs must go into each system, retrieve the specific information, and then piece these different bits together.

EPA Proceeded Without Addressing Data Management Problems

Stable data management policies and procedures are critical to successfully developing good information systems. Elements of a strong data management program include a well-defined quality assurance process, a data dictionary that contains data-naming conventions and standards, and data-flow models explaining systems linkages. These elements are critical foundations for protecting the integrity of organizational information. They also help enhance data integration capabilities and assist an organization in meeting future systems interoperability requirements.

OPP, despite knowing that its existing data had integrity problems, made a conscious choice that systems development take priority over resolving data accuracy and integration problems. As a result, OPP did not establish a data management program or develop plans for data integration and sharing. Consequently, OPP now has numerous data consistency, accuracy, and completeness problems in its new reregistration information systems.

OPP designed each reregistration system to support a specific tracking function, and thus, each system was designed with its own data files. However, information in these files is often duplicated in other systems' data files. In order for OPP to ensure that all information in the systems remains accurate and up-to-date, all data changes made in one system must be synchronized across every other system. At the time of our review, however, there were no procedures in place to ensure that this synchronization occurred. OPP System Branch officials agreed that data consistency problems exist.

Another of OPP's goals when developing its reregistration systems was to take information from its National Computing Center and integrate it into files in the new reregistration systems. However, some of this information was known to be incorrect or incomplete. For instance, in 1990 we reported that as much as 60 percent of the data in a disinfectant (antimicrobial pesticides) database at the computing center was inaccurate or incomplete.[4] In September 1991, EPA's Office of Inspector General also reported problems with data accuracy and completeness in one of the databases at the computing center.[5] Despite knowing about these data integrity problems, OPP still used this information to populate records in many of its new reregistration systems. Consequently, OPP continued the data integrity problems that in the past had led users to abandon other automated systems in favor of personal paper files.

Planning documents from OPP's systems branch discuss the need for a central data dictionary, standard definitions across systems, and a full-time data administrator. However, because of the priority OPP placed on getting systems up and functioning, these matters were not addressed while developing the new reregistration systems and they are still not fully resolved. As a result, data integrity is a continuing concern across separate systems.

At the conclusion of our review, OPP had not taken steps to implement quality assurance measures for data entry and was just beginning to run software to perform cross-system data consistency checks. Unless redundant data in OPP's separate systems are identified and inconsistencies resolved, future system integration efforts could encounter unnecessary delays and problems.

Conclusions

OPP's pesticide information is still not being managed in a manner that facilitates efficient, reliable assessments of reregistration progress. Information about the status of pesticides in reregistration may not be current or accurate and substantial effort is still required to assemble information on a single chemical. Moreover, because pesticide reregistration information is not uniform across systems, data often remain suspect and users often manually verify information for accuracy by manually checking paper files.

[4]Disinfectants: Concerns Over the Integrity of EPA's Data Bases (GAO/RCED-90-232, Sept. 21, 1990).

[5]Inert Ingredients in Pesticides, Office of Inspector General, Environmental Protection Agency, Audit Report No. E1EFF1-05-0117-1100378, Sept. 27, 1991.

The fragmented nature of OPP's new reregistration information systems, combined with the continuing data integrity problems, leaves formidable tasks to be addressed under the FIFRA deadlines. While the systems were planned to facilitate the reregistration process, additional resources—staff, time, and effort—are still required to assemble and then validate aggregate information derived from automated systems on the status of pesticides undergoing reregistration.

Recommendations

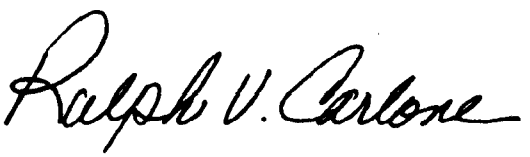
Given the central role that information management plays in ensuring the effective and efficient reregistration of pesticides, we recommend that the Administrator, EPA, direct the Assistant Administrator of the Office of Prevention, Pesticides, and Toxic Substances to:

- Strengthen OPP's conformance with federal guidance and generally accepted practices for automated systems development so that OPP's information systems are consistently planned, developed, and enhanced. As part of this effort, OPP should ensure that the pesticide information needs of all users involved in administering and managing EPA's pesticide reregistration process are defined and linked to an overall program management plan;
- Establish data management policies and implement a plan with milestones for resolving OPP systems' data integrity problems; and
- As OPP moves towards systems integration activities, ensure that requirements analyses, feasibility studies, and cost/benefit analyses are conducted to support OPP's automated systems solutions.

As requested by your office, we did not seek written agency comments on this report, but discussed its contents with EPA officials and included their comments where appropriate. We conducted our review between June 1991 and September 1992 in accordance with generally accepted government auditing standards.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution 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 upon request.

This report was prepared under the direction of JayEtta Z. Hecker, Director, Resources, Community, and Economic Development Information Systems, who can be reached at (202) 512-6416 if you or your staff have any questions. Other major contributors are listed in appendix III.



Ralph V. Carlone
Assistant Comptroller General

Objectives, Scope, and Methodology

Our review focused on computer systems development efforts within the Office of Pesticide Program's (OPP) Special Review and Reregistration Division since 1989. Specifically, our objectives were to (1) examine how EPA is using automated information systems to provide information tracking and analysis for pesticide reregistration, and (2) determine if any changes are needed to better support EPA's pesticide reregistration information needs.

To address these objectives, we reviewed federal and agency information resources management regulations, policies, and guidelines. We evaluated system development and design plans and documentation and discussed them with officials at OPP. We interviewed systems users at OPP's Special Review and Reregistration Division, Registration Division, Health Effects Division, Environmental Fate and Effects Division, and Biological and Economic Analysis Division. We also interviewed officials responsible for designing and managing the reregistration support systems at OPP's Program Management and Support Division.

To gain insights into users' needs, we observed case review managers from the Special Review and Reregistration Division using the reregistration systems. We met with these users to obtain their views on the reliability of the systems and data contained in them, the usefulness of the systems and reports, and their general reaction as to how these systems facilitate their management of reregistration information.

We met with OPP System Branch officials to discuss their systems development approach and reviewed internal automated systems plans. We reviewed and analyzed available systems development documentation to determine OPP's adherence to federal guidance. We also analyzed available documentation on OPP's data management practices with OPP's System Branch Chief and senior analysts to determine how past data reliability problems have been addressed.

We also interviewed contractors used by EPA to program the local area network database applications, reviewed their statements of work and general contract requirements, and discussed their overall project involvement.

Characteristics of Automated Database Systems Supporting OPP's Pesticide Reregistration Program

Category	System	Function	Hardware[a]	Software[b]	Operational[c]
Mainframe Database Systems	Pesticide Document Management System (PDMS)	Cross-indexed catalog of pesticide studies and summaries	IBM Mainframe	ADABAS/ Natural	1978
	Pesticide Product Information System (PPIS)	Central storage of pesticide product data	IBM Mainframe	ADABAS/ Natural	1972
LAN-based Database Systems	A-List Inventory Support System (ALISS)	Record of registrants' compliance with reregistration requirements for list A chemicals[d]	Desktop PC	Clipper/ dBase III+	1989
	Accelerated Reregistration Tracking System (ARTS)	Record of registrants' compliance with reregistration requirements for list B, C, and D chemicals[e]	Workstation File Server (LAN)	Clipper/ dBase III+	1989
	Data Call-In system (DCI)	Form generator and record of registrants' responses to EPA's requests for additional study data	Workstation File Server (LAN)	Clipper/ dBase III+	1990
	Pesticide Regulatory Action Tracking System (PRATS)	Record of document flow between CRMs and OPP scientists	Workstation File Server (LAN)	Clipper/ dBase III+	1990
	Reference File System (REFS)	Read-only subset of PPIS pesticide product data	Workstation File Server (LAN)	Clipper/ dBase III+	1989
Off-site Database System	Label Use Information System (LUIS)	Catalog of pesticide label and use information	Workstation File Server (LAN)	Advanced Revelation	1990

[a]The reregistration support systems can reside in (1) the case review mangers' desktop computers as standalone, (2) file servers in OPP's local area network (LAN), or (3) in the IBM mainframe at the National Computing Center in Research Triangle Park, NC. An exception is LUIS, which resides in a LAN at a contractor site. For the most part, these systems were designed by OPP's systems analysts and developed by contractors.

[b]The software used to develop the reregistration support systems include (1) Clipper/dBase III+ and Advanced Revelation for microcomputer applications development and (2) ADABAS/Natural for mainframe database management applications development.

[c]The dates shown for the systems residing on OPP's LAN and in desktop PCs represents the first time the systems were put into production. Different versions of these systems have been introduced over time.

[d]List A pesticides have the highest potential for human and environmental exposure and risk; they are typically high-volume and food-use chemicals.

[e]Following List A, List B pesticides have the highest potential for exposure and risk, followed by pesticides on Lists C and D.

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