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PESTICIDES

EPA's Information Systems Provide Inadequate Support for Reregistration

Statement of
JayEtta Z. Hecker, Director, Resources, Community, and Economic Development Information Systems
Information Management and Technology Division

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Mr. Chairman and Members of the Subcommittees:

I appreciate this opportunity to discuss EPA's information systems used for ensuring that data submissions from firms reregistering pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are properly identified, tracked, and reviewed. At your request, we are evaluating how EPA has planned and developed computer systems to support its FIFRA information management needs. We will be issuing a report in early 1992 that will discuss the results of this work in a more comprehensive manner. Today, I will focus on the work we have done to date as part of this ongoing review.

My colleague, Mr. Guerrero, talked about significant problems with EPA's section 6(a)(2) identification requirements which could allow unreasonable adverse effects data to escape the agency's review. Our review of EPA's information systems raises additional concerns about how effectively EPA manages, tracks, and controls information on adverse effects studies that it has identified as 6(a)(2) submissions.

Information on all data submissions made by registrants, including 6(a)(2) submissions, is repetitively entered and edited in several different information systems. EPA acknowledges that this duplication and lack of control has created data reliability and integrity problems. In addition, because information submitted by registrants may be scattered across different, non-integrated systems, EPA is unable to quickly compile a comprehensive and reliable picture of the review status of a particular pesticide. As such, these systems provide only limited support to EPA managers responsible for tracking reviews.

Your subcommittee has expressed longstanding concerns about EPA's management of pesticide reregistration information. Therefore, before discussing the specific systems that identify and track the receipt, review, and disposition of adverse effects studies submitted by registrants under section 6(a)(2), I would like to discuss how EPA has designed and implemented automated information systems to support its pesticide reregistration program.

EPA'S SYSTEMS DEVELOPMENT STRATEGY HAS FOCUSED ON QUICK SOLUTIONS

When amendments were made to FIFRA in 1988 accelerating the reregistration process, EPA used automated and manual processes to manage the information flows and decision making processes of its reregistration program. According to EPA, the automated systems that did exist were regarded by review managers as inaccessible, inaccurate, and of limited use. As a result, paper files and manual systems were created throughout the agency to manage information flows between registrants, review managers, and EPA's science divisions. Because of this mix of automated and manual systems, obtaining status or summary information for chemicals in

the review process was difficult, time-consuming, and labor intensive.

Since 1989, EPA's Office of Pesticide Programs (OPP) has been developing new information management systems to help track the voluminous paperwork and action items associated with reregistration. Currently, nine separate data-base management systems are used to track or manage information about chemicals pending reregistration.[1]

Seven of these nine systems are used to manage the submission and review of health and environmental studies conducted by manufacturers seeking to reregister their pesticide products. EPA says it has spent approximately $14.5 million between fiscal years 1989 and 1991 on systems development, operations and maintenance, and computer hardware and software acquisition to support FIFRA automation.

With the help of several contractors, EPA designed and developed these new systems in an incremental and independent fashion. According to EPA, information requirements and functional specifications for these systems were not analyzed in-depth prior to the start of systems development. Instead, EPA has focused on quickly bringing working systems on-line and refining them as users requirements and systems functions are more fully identified.

At the same time that individual systems were being designed, OPP acquired technology that allows its computers to be networked together. However, because each system has been designed and developed separately without a cross-functional emphasis, OPP cannot effectively use its computer networking. Basic information about a study--such as its unique identification number, date submitted, and special actions--is entered numerous times into different systems. This deficiency will persist until (1) EPA establishes standards for electronic data exchange and system interfaces, (2) data input and editing redundancies are identified and eliminated, and (3) remaining stand alone systems are put on OPP's local area network and consolidated.

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[1]Although not the subject of our ongoing review, still other automated systems exist in OPP's science divisions, which support scientists who evaluate the studies submitted by registrants, and in EPA's Office of Compliance Monitoring, which is responsible for administering product suspensions and cancellations and taking appropriate enforcement actions.

TRACKING SYSTEMS PROVIDE LIMITED INFORMATION ON 6(A)(2) STUDIES

Now, I would like to turn to specific information systems that EPA used at the time of the metam sodium spill in California to identify and track section 6(a)(2) studies. OPP's Reregistration Division has nearly 40 case review managers who act as intermediaries between the registrants, EPA's science divisions, and EPA management. Each review manager tracks a defined number of chemicals and manages information and deadlines pertaining to the submission, receipt, and review of studies supporting EPA's reregistration criteria.

The systems used by the review managers (1) record the status of studies supporting a chemical review, (2) provide information on the inventory of EPA registration standards for a chemical being reregistered, and (3) generate data submission forms for the registrants. As such, the systems function as support for specific operations rather than management decisions and make it difficult for EPA to respond to informational queries in a timely and reliable manner. (See attached chart.)

Four of these systems are specifically involved in indexing, inventorying, and routing studies submitted by registrants. Each contains information that could help identify a 6(a)(2) study submitted to EPA, describe its contents, and examine its review status. One of these systems indexes all studies when they are first received by EPA. At the time of the metam sodium incident, however, this system was not designed to distinguish 6(a)(2) studies from others submitted by registrants.

Two other automated systems are used directly by the case review managers to assist in their tracking responsibilities. The system being used by managers to track List A chemicals--primarily food use chemicals--was not designed to distinguish 6(a)(2) studies from others. Instead, a paper filing system is used to record information on any 6(a)(2) studies received by the Reregistration Division. The system used to track Lists B, C, and D chemicals--those with use patterns that generally have less human and environmental exposure--was designed to allow 6(a)(2) studies to be readily identified. Nevertheless, the system captures very limited information on the disposition of the study once it is processed within EPA.

Another system is primarily used by the Reregistration Division to generate an electronic routing slip that records dates as the adverse effects study moves through EPA's internal review. While the system has fields to indicate whether a study has been submitted under Section 6(a)(2), as well as its acceptance or rejection by OPP's science divisions, we learned that this system is not routinely used for tracking disposition in the science divisions.

These four 6(a)(2) systems are limited in how effectively they can track information. As an example, systems limitations made it difficult for EPA to respond to your requests for information on the number of 6(a)(2) studies submitted to EPA under FIFRA. The information generated by EPA for you is not from any existing database system; in fact, EPA's automated systems provided limited assistance in this effort. EPA is unable to obtain quickly a complete picture of the status of 6(a)(2) studies because (1) its inventory, tracking, and routing systems were not all designed to distinguish 6(a)(2) studies from others; (2) the lack of an integrated systems environment requires individual systems to be accessed, queried, and cross-checked for data reliability against other systems containing duplicate information; and (3) information pertinent to review status and actions remain in paper files or maintained by individual review managers in their own word processing files.

In response to criticisms stemming from the metam sodium incident, EPA has informed us that it is taking corrective actions to ensure that these systems provide better support in identifying adverse affects studies. For example, OPP's indexing system has been modified to separate 6(a)(2) studies identified by registrants from other studies. EPA is also designing a consolidated system that would eventually allow all 6(a)(2) studies to be identified and their review progress recorded. Until this is completed, EPA is considering developing a separate data base to specifically track 6(a)(2) studies apart from the normal reregistration process. However, by creating another data base, EPA may only compound its data integrity problems, particularly when such information should be available from systems already in place.

CONCLUSIONS

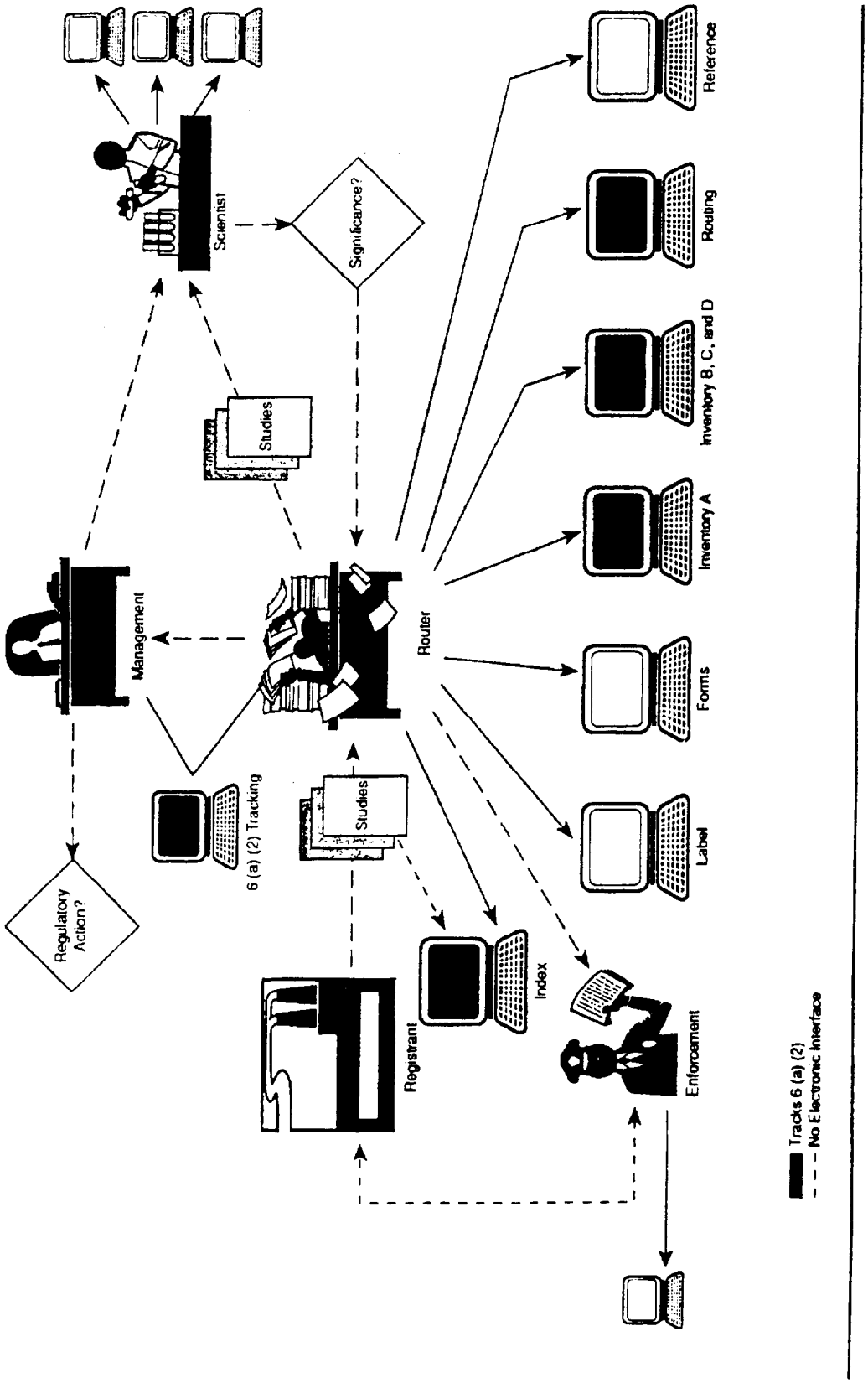
In summary Mr. Chairman, the process EPA used to obtain a complete inventory of 6(a)(2) studies raises concerns about the ability of its pesticide reregistration information systems to help assure that adverse effects studies are identified, reviewed, and acted upon appropriately and in a timely manner. The systems that exist now provide neither complete nor accessible information. Efforts to obtain a comprehensive view of 6(a)(2) studies received by the agency are stymied by the inability to access and retrieve information in an integrated fashion--an essential feature of any management information system. Additionally, some critical information about these studies is not kept in automated systems. Instead, manual records have to be compiled and verified. Rather than designing systems to provide timely and effective management support for a critical regulatory responsibility, EPA has narrowly focused on automating specific processes that simply track the movement of paper files.

Because our work is ongoing, we have not had sufficient time to analyze EPA's proposed solutions or corrective actions the agency has taken in response to these problems. This will require additional analysis that we will incorporate into our continuing review.

That concludes my statement, Mr. Chairman. I would be glad to answer any questions that you or Members of the Subcommittees may have about our work.

ATTACHMENT

GAO EPA's Reregistration Systems



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