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PESTICIDES

EPA Lacks Assurance That All Adverse Effects Data Have Been Reviewed

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Mr. Chairmen and Members of the Subcommittees:

Ms. Hecker and I are pleased to be here today to discuss the Environmental Protection Agency's (EPA) process for identifying, reviewing, and tracking studies on pesticides' adverse health and environmental effects. The agency receives these studies from pesticide registrants under section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Your interest in this area stemmed from the Subcommittees' becoming aware that EPA had not reviewed information in its files on metam-sodium, the pesticide that recently spilled into the Sacramento River.[1] This information indicated that metam-sodium can cause birth defects. What is disturbing about this incident is that EPA received this information from the registrant over 4 years ago and had not reviewed the studies until after the spill occurred. As a result, EPA was not in a position to warn pregnant women and workers in the area of the spill of the pesticide's hazards. More importantly, the metam-sodium spill raises questions about whether EPA adequately protects consumers and the environment from the effects of potentially dangerous pesticides.

As you requested, our testimony presents the results of our work regarding three questions: (1) Does EPA know the universe of studies that it has received from registrants under section 6(a)(2); (2) will EPA's recent initiatives to improve the processing of these studies ensure that all will be identified and reviewed in a timely manner; and (3) does EPA have a tracking system to ensure that these studies are appropriately identified and reviewed?

My testimony today presents the results of our work regarding your first two questions. With regard to your third question, Ms. JayEtta Hecker, a director with our Information Management and Technology Division, will discuss EPA's management information systems.

Our short answer to all three of the Subcommittees' questions is "no." The results of our work suggest that EPA may not have identified all unreasonable adverse effects studies that it has received from registrants; that recent procedural changes will not ensure that all studies submitted to EPA will be reviewed; and that its tracking system will not provide the level of assurance EPA managers need to be confident that the job is being done right.

Before I discuss EPA's management of unreasonable adverse health and environmental effects data submitted under section

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[1]Recently, we testified on the transportation safety issues and circumstances surrounding the metam-sodium spill: Hazardous Materials: Chemical Spill in the Sacramento River (GAO/T-RCED-91-87, July 31, 1991).

6(a)(2), let me provide some background information on the legislative requirements.

BACKGROUND

Federal regulation of pesticides is governed by FIFRA, which was first enacted in 1947. The Congress added section 6(a)(2) to FIFRA in 1972 to require the following:

> "If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator."

According to EPA, section 6(a)(2) was enacted to ensure that the agency promptly receives any data possibly leading it to conclude that the use of a pesticide may pose unreasonable health and environmental risks. EPA has stated that receiving such information early is important because doing so permits the agency to take prompt regulatory action to minimize human exposure to potentially dangerous pesticides.

This safeguard is especially important because most pesticides used today were initially registered before current scientific standards were imposed. EPA evaluates the risks and benefits of pesticides before they are registered (licensed) for use. Although EPA was required by the 1972 FIFRA amendments to reassess these older pesticides by 1976, this task remains far from complete and EPA's deadline has been extended several times. By the 1976 deadline, no pesticide had been fully tested to determine its potential for causing long-term health effects such as cancer and reproductive disorders, birth defects, and adverse ecological and environmental effects.

The Congress subsequently extended the 1976 deadline 1 year because of EPA's inadequate resources and delays in the agency's development of a reregistration program. In 1978, the Congress reaffirmed the need for the expeditious reregistration of all pesticides but rescinded the deadline because of the uncertainty in predicting how many years this complicated task would require.

In 1988, the Congress amended FIFRA and set a deadline of 1997 for completing the reregistration program in five phases.[2] In

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[2]During phase 1, EPA published four lists of pesticides subject to reregistration. Phase 2 required registrants to identify the studies needed for reregistration and then commit to submitting new studies or replacing inadequate existing studies. During phase 3, registrants summarized, reformatted, and resubmitted

(continued...)

September 1991, EPA reported to the Subcommittees' staff that reregistration will not be completed by 1997, but will extend into 1999 and beyond due to, among other things, the volume of inadequate studies that registrants will need to repeat. In the interim, previously registered pesticide products may be sold and distributed under their existing registrations with incomplete knowledge of their long-term health and environmental effects.

Mr. Chairmen, the pace at which EPA is progressing toward reregistering pesticides, identifying those pesticides that pose unreasonable health and environmental risks, and removing those pesticides from the marketplace has come under considerable criticism. In response to this criticism, EPA has taken the position that until the reregistration program is completed, section 6(a)(2) will act as the safety net for identifying and removing potentially dangerous pesticides from the marketplace. Yet as we are testifying today, there are questions about whether EPA has adequately implemented this important provision to protect consumers and the environment from the effects of potentially dangerous pesticides.

While the short time available precluded us from comprehensively reviewing the agency's files and records, our work nonetheless raises questions about EPA's current process for identifying and reviewing section 6(a)(2) studies.

EPA DOES NOT KNOW IF IT HAS REVIEWED ALL SECTION 6(a)(2) SUBMISSIONS

I would like now to elaborate on the questions you have raised about whether EPA has identified and reviewed all unreasonable adverse health and environmental effects data submitted by pesticide registrants under section 6(a)(2). From what we know of this program, it is possible that studies--like the metam-sodium studies--have slipped through the section 6(a)(2) safety net. Although the Congress added section 6(a)(2) to FIFRA in 1972, it was not until 1988--some 16 years later--that EPA required pesticide registrants to identify data submissions as for 6(a)(2). Even these requirements contain gaps that allow registrants to avoid identifying unreasonable adverse effects data.

Over the years, EPA has received voluminous information on the health and environmental effects of the pesticides it registers.

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[2](...continued)
existing studies for EPA's review. In phase 4, EPA must review registrants' submissions under phases 2 and 3, identify missing and inadequate studies, and require the submission of studies to fill remaining reregistration requirements. During phase 5, EPA must conduct a comprehensive review of all studies submitted and decide whether each pesticide is eligible for reregistration.

Some of this information may demonstrate unreasonable adverse effects, but because, prior to 1988, EPA did not require registrants to specifically identify such information as section 6(a)(2) data and because gaps in the requirements remain, registrants may not have always identified information on unreasonable adverse effects. This information may be overlooked or not receive EPA's immediate attention and consequently may lie unreviewed for years in EPA's files. A review of EPA's actions since 1972 to implement section 6(a)(2) will illustrate how this can happen.

Between 1972 and 1988, EPA had no enforceable regulations requiring registrants to specifically identify section 6(a)(2) data submissions. That is, during this 16-year period, it was sufficient for a registrant to submit to EPA a study demonstrating unreasonable adverse effects in a plain brown wrapper to comply with section 6(a)(2).

EPA first issued regulations implementing section 6(a)(2) in 1975. These regulations, according to EPA, were immediately challenged by the chemical industry, revoked, and replaced by a 1978 interpretive rule, in the form of a memorandum, that broadly defined the reach of 6(a)(2). Industry also challenged EPA's 1978 interpretive rule, but the U.S. District Court for the District of Columbia upheld the rule in a 1980 decision that said registrants must submit all new data showing a pesticide's unreasonable adverse effects.[3] In 1979, EPA also issued an enforcement policy notice defining which types of unreasonable health and environmental adverse effects information it wanted registrants to submit and when registrants were to submit the information.

In 1985, EPA published both its 1978 interpretation of section 6(a)(2) and its 1979 enforcement policy in a final interpretive rule and statement of policy (40 C.F.R. part 153, subpart D). EPA, however, never announced an effective date for the rule because of unresolved issues that commenters raised with it. In any event, since EPA used an interpretive rule rather than a notice and comment rulemaking, the 1985 rule is not enforceable. The 1985 rule stated it is EPA's policy that most data must be received within 15 working days of a registrant's first possessing or knowing of the data and added an address for submitting the data. It also stated that submissions should, not must, bear a notation (identify) that the data are 6(a)(2) submissions.

Although not requiring "flagging" (a registrant's written statement that certain studies--of long-term health effects, ecological effects, and pesticides' behavior in the environment--do or do not meet or exceed any applicable criteria), the 1985 rule

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[3]Chemical Specialties Manufacturers Association v. EPA, 484 F. Supp. 513 (D.D.C. 1980).

requested that submitters voluntarily do so.[4] In a separate 1985 action, EPA issued a proposed rule to revise its registration requirements. The proposal contained a flagging requirement for data submitted to EPA to support new or amended pesticide registrations or to maintain existing registrations (FIFRA section 3).

In 1986, EPA issued guidance to registrants applying for any regulatory action to include a separate transmittal document in their data packages identifying, among other things, the regulatory action for which the package is being submitted--that is, to identify whether it is a registration application, data received in response to an EPA requirement, a 6(a)(2) submission, or a submission for some other action. The guidance calls for the transmittal document to identify 6(a)(2) submissions but does not require the submissions themselves to be identified. The 1986 guidance also advises registrants that statements flagging 6(a)(2) submissions would be required once the flagging requirement was finalized.

In May 1988, EPA issued a final regulation containing the requirement to flag unreasonable adverse effects data (40 C.F.R. 158.34), but the requirement does not apply to all data reportable under section 6(a)(2). It applies only to data that EPA calls for to support new or amended registrations or to maintain existing registrations. For example, if EPA called for a registrant to perform a reproductive effects study and the registrant on his own also performed a cancer study, the registrant is required to report any data on unreasonable adverse effects in the cancer study, but he is not required to flag these data. The registrant, however, is required to report and flag any such data in the required reproductive effects study, if the data meet or exceed applicable criteria for flagging. In addition, in response to industry comments, EPA decided not to promulgate the criteria it established for studies of pesticides' ecological effects and environmental fate. Consequently, while required to report these studies under section 6(a)(2), registrants are not required to flag or specifically identify them as 6(a)(2) submissions.

The 1988 FIFRA amendments required registrants of List B, C, and D pesticides to identify data reportable under section 6(a)(2)

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[4]EPA provided criteria to flag any unreasonable adverse effects uncovered in the three general types of studies. This was to facilitate the prompt review of the section 6(a)(2) information with the most significant consequences to health and the environment.

as part of reregistration.[5] The statute also required EPA to issue guidance on what constitutes "unreasonable adverse effects information." In December 1989, in compliance with the statute, EPA issued guidance requiring these registrants to specifically identify and submit all information reportable under section 6(a)(2) regardless of whether the information had been previously submitted or not.

In April 1990, in response to industry comments, EPA modified its guidance for identifying section 6(a)(2) data. The revised guidance required registrants to identify long-term health effects studies if the effects met the flagging criteria defined in the 1988 regulation. The revised guidance, however, was unclear about whether registrants were required to identify unreasonable adverse health effects data that did not meet the flagging criteria. An official in EPA's reregistration division told us that he, too, was uncertain about this requirement when we sought clarification from EPA. This guidance applied to registrants of List B, C, and D pesticides. Guidance for all other required data submissions, such as studies supporting reregistration of List A pesticides (which are most of the major food-use pesticides), continues to be the 1986 guidance that now (since 1988) requires statements flagging information in certain studies.

Mr. Chairmen, the agency's failure to issue enforceable regulations for identifying 6(a)(2) submissions compounded the metam-sodium incident. As we have seen, prior to 1988, registrants were not required to identify any studies containing unreasonable adverse effects data. When the 1987 metam-sodium studies arrived at EPA in response to the agency's request for data to support the pesticide's reregistration, the studies were not identified as section 6(a)(2) submissions. Consequently, the agency missed the significance of the data and did not give the studies the immediate attention they deserved. In 1990, when the registrant resubmitted summaries of the metam-sodium studies in compliance with the agency's guidance implementing the 1988 FIFRA amendments, EPA again missed the significance of the data because the registrant's summary said the studies were not statistically significant.

EPA'S RECENT INITIATIVES TO IMPROVE THE SECTION 6(a)(2) PROCESS WILL NOT ENSURE THAT ALL STUDIES ARE IDENTIFIED AND REVIEWED

Since the metam-sodium spill, EPA, to its credit, has been taking steps to change the way it processes and reviews section 6(a)(2) submissions. Your question to us was whether these steps

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[5]The 1988 FIFRA amendments created four lists of pesticides according to their priority for reregistration: A, B, C, and D. List A pesticides had a large part of reregistration work already done and were not subject to phased data submissions.

are adequate for ensuring that all section 6(a)(2) studies will be identified and reviewed in a timely manner.

As a first step, EPA has conducted an inventory of all section 6(a)(2) studies identified and submitted by registrants since the 1988 FIFRA amendments. The inventory showed that as of September 1, 1991, EPA had received 185 such studies and reviewed 150 of them. Review of the remaining 35 studies will be completed by December 1, 1991, according to EPA's Office of Pesticide Programs officials. However, because registrants were not required to identify section 6(a)(2) submissions prior to 1988 and because, since 1988, only certain 6(a)(2) studies are required to be flagged or specifically identified, we believe EPA's inventory may not represent the universe of studies the agency has received under section 6(a)(2).

In addition to conducting this inventory and reviewing all post-1988 section 6(a)(2) submissions, EPA has taken other steps it believes will ensure that these studies are reviewed and acted upon expeditiously. Among these, EPA is establishing a special team of scientific reviewers and program managers that will be responsible for the cradle-to-grave tracking of section 6(a)(2) submissions. We question whether this approach will ensure that all earlier submissions not identified as reportable under section 6(a)(2)--such as the 1987 metam-sodium studies--will be identified and promptly reviewed by EPA.

OBSERVATIONS

While registrants may have complied with FIFRA section 6(a)(2) in submitting data on pesticides' unreasonable adverse effects, prior to 1988 EPA had no means of readily identifying all of the data as section 6(a)(2) submissions. This is because EPA did not require registrants to specifically identify data reportable under section 6(a)(2). Consequently, in EPA's files there may be section 6(a)(2) studies, such as the studies submitted for metam-sodium, that registrants have not identified and that EPA may not review for years. Although not a simple task, EPA needs to identify all unreasonable adverse health and environmental effects data that have been submitted to the agency. To do this, EPA could explore several options such as requiring registrants to identify past submissions to assist in locating unreviewed section 6(a)(2) information in EPA's files or requiring registrants to add to an inventory that EPA conducts of all previously identified section 6(a)(2) submissions currently in its files.

In addition, we believe there are a number of limitations in EPA's current requirements to identify section 6(a)(2) submissions. These limitations could allow data on unreasonable adverse effects to "slip through the cracks" and escape EPA's review. For example, registrants are currently required to flag studies as containing unreasonable adverse effects information only when specific types

of long-term health effects data meet or exceed certain criteria defined by EPA in the 1988 regulation. As we have stated, the criteria apply only when registrants submit these studies for regulatory action by EPA. The criteria do not apply when these studies are submitted solely in compliance with section 6(a)(2). In addition, EPA did not promulgate criteria for flagging unreasonable adverse effects uncovered in studies of ecological effects and environmental fate. This problem would be solved if EPA issued final regulations for implementing section 6(a)(2) that will close the gaps permitting registrants to submit, but not specifically identify, unreasonable adverse effects data.

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Mr. Chairmen, this concludes my prepared statement. After Ms. Hecker has presented her statement on how EPA tracks section 6(a)(2) submissions, we would be pleased to respond to questions from you or Members of the Subcommittees.