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TOXIC SUBSTANCES

**EPA's Chemical Testing
Program Has Not Resolved
Safety Concerns**

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Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to continue our discussion with you on the Environmental Protection Agency's (EPA) actions to protect human health and the environment from the harmful effects of chemicals. In our previous reports and testimony,¹ we have pointed out that EPA has been slow in carrying out its responsibilities under the Toxic Substances Control Act (TSCA) to identify potentially harmful chemicals and to acquire from the chemical industry the health and environmental test data needed to decide which chemicals should be regulated. Our testimony today focuses on our June 1991 report on EPA's performance in reviewing and acting on chemical test data once the data are received from industry.² Specifically, we will discuss the basis for EPA's decisions on whether to take regulatory action under TSCA, the management controls over the chemical review process, and EPA's dissemination of information obtained through chemical testing. We will also discuss recent EPA actions to address the problems we identified in our report.

In summary, Mr. Chairman, we found the following:

¹See app. I for related reports and testimony.

²Toxic Substances: EPA's Chemical Testing Program Has Not Resolved Safety Concerns (GAO/RCED-91-136, June 19, 1991)

- EPA has not established criteria that define the levels of risk to health and the environment at which the agency will initiate regulatory actions to control chemicals shown through laboratory testing to be harmful. We believe that such criteria are necessary to guide agency officials in making critical and complex regulatory decisions and to provide accountability within the agency and to the public for these decisions.

- Serious management control weaknesses exist in EPA's process for reviewing test results. Years have been added to the assessment of chemical safety because EPA has not implemented an information system to track the process for individual chemicals. Nor has EPA made timely decisions on problems with chemical test data submitted by industry. Consequently, decisions on certain chemicals languished for years before receiving management attention.

- EPA has not done enough to make test results and its evaluations of these test results available to potential users by publishing such information in scientific journals and data bases.

We made a number of recommendations to improve EPA's performance in reviewing and acting on chemical test results. In response, EPA is developing an information system to track the

chemicals under review. In addition, EPA informed us that it is developing procedures to ensure that test data and evaluations will be published in a major data base administered by the National Library of Medicine. However, EPA has not yet begun to develop criteria that would build accountability into the chemical review process and that would provide assurance within the agency and to the public that chemicals are being regulated on the basis of the risks they impose.

Before I discuss our findings in more detail, I would like to provide you with some perspective on EPA's chemical testing responsibilities under TSCA.

BACKGROUND

The Congress enacted TSCA to provide a safeguard against the introduction of additional contaminants into the environment and to address the risks posed by existing chemicals. Under TSCA, EPA may require chemical manufacturers and processors to test potentially harmful chemicals for the purpose of assessing their health and environmental effects.

Several types of regulatory actions are available to EPA whenever testing shows that an existing chemical is harmful. These actions range from requiring warning labels on the chemical to banning its use. EPA can also make formal referrals to other

federal agencies having regulatory authorities related to the use of the chemical. For example, the Occupational Safety and Health Administration (OSHA) could receive a referral of a chemical shown to be dangerous to factory workers exposed to the chemical during a manufacturing process. The receiving agency must initiate action to regulate the chemical or publish a notice in the Federal Register explaining why no action is needed. In addition, EPA can issue advisories warning the public of chemical dangers or can informally send test results to other federal agencies having public safety responsibilities. However, such informal referrals do not require the agencies to take action.

Let me now elaborate on the problems we found in the chemical testing program.

EPA LACKS CRITERIA FOR DETERMINING
WHEN TO TAKE REGULATORY ACTIONS

While approximately 70,000 chemicals are used in commerce in the United States, the chemical industry has completed testing, at EPA's direction, on only 22 chemicals since TSCA was enacted in 1976. Of these 22 chemicals, EPA has completed its review on 16 and considered 3 of these to be particularly harmful and, therefore, candidates for regulatory action. (See app. II for a brief discussion on each of the three chemicals.) For example, EPA estimated that about 400 industry workers are exposed to 2-ethylhexanoic acid, a raw material used in oil-based paints. Tests

using laboratory animals showed that the chemical caused severe harm and fatalities to both pregnant mothers and fetuses; many of the surviving offspring had skeletal deformities.

Although EPA considered 2-ethylhexanoic acid and two other tested chemicals to be dangerous, it decided that the risk they impose did not warrant regulatory action. Nonetheless, as I mentioned earlier, EPA does not have criteria for making this determination. EPA told us that it does not believe that risk assessment is an exact science; it prefers to use professional judgment to determine whether the risk associated with a chemical is high enough to warrant its regulation. According to EPA officials, the agency has a high but undefined threshold for what it considers to be a risk warranting regulatory action.

Since our report was issued in June 1991, the U.S. Court of Appeals for the Fifth Circuit, in its ruling on EPA's ban on asbestos products, has expressed its concern about how EPA decided to impose the ban. EPA had issued a rule to prohibit the future manufacture, importation, processing, and distribution of asbestos in almost all products. Some of the manufacturers of the asbestos products in question filed suit against EPA, arguing that the rule was not promulgated on the basis of substantial evidence. In October 1991, the court agreed with the manufacturers and sent the rule back to EPA for further consideration.³

³Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

In our view, the court's ruling reflects the problem we identified in our work. Although EPA determined that asbestos presented an unreasonable risk to human health and that nothing short of a ban on asbestos products would be appropriate, EPA could not demonstrate to the court that it had evaluated the risks, costs, and benefits of intermediate levels of regulation before making its decision to impose a ban on asbestos products. The court pointed out that EPA had not demonstrated why a total ban on asbestos products was more appropriate than other actions, such as imposing manufacturing limits, use restrictions, and disposal limits and requiring warning labels.

Interestingly, EPA's lack of criteria for making regulatory decisions under TSCA contrasts with the method the agency uses in making certain regulatory decisions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Even though in the past we have criticized many aspects of EPA's implementation of FIFRA, EPA has established criteria for implementing certain regulatory actions--requirements concerning label warnings and restrictions on use--on the basis of the toxic effects shown through testing to be associated with a chemical pesticide.

The FIFRA label criteria (40 CFR 156.10) establish a framework that the agency can use to place the pesticide into a specific toxicity category on the basis of test results. Depending on the category, corresponding risk reduction actions are prescribed. The

FIFRA label requirements are constructed in such a way that the more severe the toxicity, the more restrictive the risk reduction actions stated on the mandated warnings. For restricted use requirements, FIFRA regulations establish toxicity criteria for restricting pesticides to use by certified applicators and identify a list of pesticides that are classified for restricted use on the basis of these criteria (40 CFR 152.70 and 40 CFR 152.175).

Let me now turn briefly to EPA's management controls for resolving chemical testing problems and for making test results available to others.

THE CHEMICAL TEST REVIEW
PROCESS IS NOT TIMELY

In our June 1991 report, we stated that EPA was not taking timely action in completing its assessment of industry's test data and in resolving chemical safety concerns. We pointed out that EPA's evaluation of industry's test data required an average of 2 years, while EPA's guidance indicates that such evaluations should be completed within 5 months.

For several chemicals, years were lost in taking action. For example, in May 1988 EPA received test data showing that cyclohexanone, a chemical used primarily in the production of nylon, may cause developmental problems in fetuses. EPA also received information that up to 839,000 workers might be exposed to

it. In May 1988, 4 years after these data were received, EPA concluded that cyclohexanone could be dangerous at levels seven times lower than the safety level established by OSHA. However, EPA did not send the summaries of its evaluation to OSHA for 3 additional years, largely because of inadequate management control over the review process. For example, EPA's referral to OSHA was delayed for 2 years because a memorandum directing the referral was inadvertently not issued.

EPA has responded to our findings and recommendations by acknowledging that management control problems exist in the chemical testing program and by initiating corrective actions. For example, EPA hired a contractor in March 1991 to establish a management information system capable of monitoring the status of the chemicals tested. EPA officials recently told us that the system will be operational by the summer of 1992.

TEST RESULTS ARE NOT AVAILABLE
TO POTENTIAL USERS

The chemical testing program generates a large volume of scientific information on chemical effects on human health and the environment. Various federal and state regulatory agencies and research organizations have used such information to identify hazardous chemicals and to protect people and the environment from their harmful effects. Information on chemical research can also

be useful in avoiding duplication of testing among the various regulatory agencies and research organizations.

In our June 1991 report, we pointed out that, while chemical testing information is available upon request from EPA, the agency does not publish the information to make it more readily available to a wide group of potential users. We recommended that EPA explore alternatives, such as publishing test results in scientific data bases, to facilitate the use of its test data and evaluations.

EPA told us that it is aware of the benefits of making test results more readily available and acknowledges that current procedures for making test results available are limited. Prompted by the recommendations in our June 1991 report, EPA is arranging to have test data and EPA evaluations published in a data base of the National Library of Medicine. EPA has not yet, however, implemented procedures to ensure that such data and evaluations are submitted to the Library for entry into the data base.

CONCLUSIONS

Mr. Chairman, EPA believes that risk management is not an exact science, and it prefers to rely on its managers' professional judgment in making risk management determinations. These managers are to use a high, but undefined, threshold for deciding when to take regulatory actions. While we recognize the value of

professional judgment, we believe that such criteria are needed now, not only to guide managers in making difficult assessments but also to build accountability into the risk management process. In our opinion, criteria clearly would provide EPA and the public with better assurance that EPA's decisions are based on the dangers presented by the chemicals.

We believe that EPA is now taking appropriate steps to achieve more timely reviews of existing chemicals by developing a management information system to monitor the status of each chemical being tested. Similarly, EPA's efforts to publish test data and evaluations in a data base of the National Library of Medicine should result in a broader dissemination of important information obtained through the chemical testing program.

Mr. Chairman, this concludes our testimony. We would be happy to answer any questions.

RELATED GAO PRODUCTS

Toxic Substances: Status of EPA's Reviews of Chemicals Under the Chemical Testing Program (GAO/RCED-92-31FS, Oct. 31, 1991)

Toxic Substances: EPA's Chemical Testing Program Has Not Resolved Safety Concerns (GAO/RCED-91-136, June 19, 1991)

Toxic Substances: EPA's Chemical Testing Program Has Made Little Progress (GAO/T-RCED-90-88, June 20, 1990)

Toxic Substances: EPA's Chemical Testing Program Has Made Little Progress (GAO/RCED-90-112, Apr. 25, 1990)

CHEMICALS FOUND TO BE HARMFUL IN
EPA'S EVALUATIONS OF TEST RESULTS

Cyclohexanone

Using statistics from the National Institute for Occupational Safety and Health (NIOSH), EPA estimated that about 839,000 workers might be exposed to cyclohexanone, a chemical used primarily in the manufacturing of nylon. EPA received test data in May 1984 showing that the chemical caused low weights in the embryos and fetuses of laboratory animals. In May 1988--4 years after the test results were received--EPA concluded from the test data that air concentrations of cyclohexanone of over 6.5 parts per million could be harmful, even though the existing Occupational Safety and Health Administration (OSHA) safety standard was 50 parts per million--over seven times higher than EPA's safe rate. Consequently, in March 1989, EPA managers decided to refer the test summaries to OSHA; however, according to the chemical's project manager, the referral was delayed for over 2 years. The project manager explained that the memorandum directing the referral was never issued, and no one followed up to ensure that action was taken. EPA finally sent the summaries in May 1991, 7 years after the test data were initially received.

2-Ethylhexanoic Acid

EPA estimates that about 400 industry workers are exposed to 2-ethylhexanoic acid as a raw material. Consumers do not encounter the chemical as a raw material but use oil-based paints in which it is contained. Tests on laboratory rats showed that 2-ethylhexanoic acid caused severe harm and fatalities to both pregnant mothers and fetuses, and many of the surviving offspring had skeletal deformities.

In November 1988 EPA managers agreed that an advisory should be issued to warn industry workers and that tests should be performed to determine the effects of the chemical on workers who may come into contact with paints containing the chemical. EPA's project manager for the chemical told us, however, that the November 1988 agreements were not carried out because they were lost in EPA's paperwork. In April 1991, 34 months after EPA received test results showing the chemical was dangerous, EPA forwarded the test results to OSHA for consideration for regulatory action. The test results were also sent to NIOSH.