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Serious Problems with EPA's Pesticide Reference Standards Program. CED-78-109; B-133192. April 26, 1978. 7 pp.

Report to Douglas M. Costle, Administrator, Environmental Protection Agency; by Henry Eschwege, Director, Community and Economic Development Div.

Issue Area: Environmental Protection Programs: Harmful Pesticides and Toxic Substances (2211).
Contact: Community and Economic Development Div.
Budget Function: Natural Resources, Environment, and Energy: Pollution Control and Abatement (304).
Organization Concerned: Food and Drug Administration.
Congressional Relevance: House Committee on Agriculture; Senate Committee on Agriculture, Nutrition, and Forestry.

The Environmental Protection Agency (EPA) has not effectively fulfilled its responsibility to provide reference standards (precisely defined samples) of pesticides for use by the Food and Drug Administration (FDA). As a result, the FDA is seriously hampered in monitoring pesticide residues in food and in enforcing pesticide tolerances. The Pesticide Reference Standards Section (PRSS), which provides regulatory agencies with samples of precisely defined composition for use in analysis of food for pesticide residues, was transferred from the FDA to EPA. After the transfer, the laboratory in which PRSS was located was closed. PRSS staff remained in administrative offices at the laboratory and continued to provide previously partitioned reference standards on request. The laboratory was moved and limited operations were resumed in February 1978. During its 18-month closure, PRSS exhausted its inventory of many standards and, therefore, was unable to provide some needed standards to FDA and provided some others that were either degraded or subpotent. The PRSS inability to provide pure, potent reference standards when needed seriously impairs the enforcement programs of other agencies. The Administrator of EPA should take whatever actions are necessary to: perform appropriate tests to assure that standards sent to enforcement agencies are of the proper quality; and enable PRSS to accomplish its other tasks, including data compiling and cataloging, indexing, synthesizing, and purifying standards materials. (RRS)

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

COMMUNITY AND ECONOMIC
DEVELOPMENT DIVISION

B-133192

April 26, 1978

The Honorable Douglas M. Costle
Administrator, Environmental
Protection Agency

Dear Mr. Costle:

Our ongoing reviews of Federal programs to regulate pesticides disclosed that the Environmental Protection Agency (EPA) has not effectively fulfilled its responsibility to provide reference standards--precisely defined samples--of pesticides for use by the Food and Drug Administration (FDA). As a result, FDA is seriously hampered in monitoring pesticide residues in food and in enforcing related tolerances. We are bringing this to your attention for corrective action because of its seriousness.

The Pesticide Reference Standards Section (PRSS) within the Office of Pesticide Programs (OPP) provides regulatory agencies (predominately FDA) with pesticide samples of precisely defined composition, called reference standards, 1/ for use in the analysis of food for pesticide residues. Reference standards enable FDA to confirm the identity and concentration of pesticide residues in food, which is necessary for the enforcement of pesticide residue tolerances under the Federal Food, Drug, and Cosmetic Act. Pesticide residues exceeding tolerances could cause a variety of consumer health problems including cancers, birth defects, and gene mutations.

1/ A reference standard is defined by the International Organization for Standardization as "a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus or for the verification of a measurement method."

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We made our review at EPA and FDA headquarters in Washington, D.C., and at FDA laboratories in Washington, D.C., Baltimore, New Orleans, and Dallas. We reviewed pertinent legislation, interagency agreements, records, budgets, and files relating to the detection, identification, and quantitation of pesticides.

PRSS FACILITIES AND STAFFING

In a memorandum of agreement, the Department of Health, Education, and Welfare and EPA agreed that, effective November 10, 1971, EPA should have primary responsibility for maintenance of an analytical reference standards repository and that, upon request, standards would be made available to FDA and local enforcement authorities for use in official analyses. FDA transferred its existing reference standards function to EPA as a result of the agreement. Under EPA the function continued with the following responsibilities:

--Secure and maintain a supply of reference standards for regulatory purposes.

--Catalogue and cross-index pesticide names.

--Compile data for identification.

--Monitor and physically measure characteristics of chemicals.

--Develop methods for partitioning pesticides (subdividing pesticide chemicals into appropriate samples for shipment) and for preserving in-storage purity.

--Synthesize and purify pesticides.

--Provide reference standards as well as descriptive data sheets to regulatory agencies.

After transfer to EPA, PRSS was moved to a laboratory in the South Agriculture Building in Washington, D.C. However, as a result of long standing basic safety and health deficiencies, EPA closed operations at the laboratory in June 1976. PRSS staff remained in administrative offices at the laboratory and continued to provide previously partitioned reference standards to regulatory agencies on request.

PRSS was moved to a Beltsville, Maryland, laboratory and resumed limited operation in February 1978. Although full PRSS operation requires five to seven chemists, the Beltsville laboratory provides adequate space for only four chemists. An OPP official described the laboratory facility situation as a "mix, match, and patch operation." At present, EPA does not have definitive plans for providing PRSS more suitable facilities, although EPA is considering moving PRSS to laboratory facilities in Research Triangle Park, North Carolina.

EPA also has had problems in adequately staffing PRSS. PRSS was staffed by five chemists under FDA, but only one was transferred to EPA. Additional chemists were hired to bring the staff level to four chemists. However, two chemists left after a short stay; therefore, PRSS has been staffed by only two chemists since August 1974. PRSS has repeatedly requested replacement personnel stating that "replacement of these people is imperative" and that "addition of at least three professional employees on a permanent assignment * * * is urgent."

Despite these requests, no additional chemists have been provided. The EPA Associate Deputy Assistant Administrator for Pesticide Programs stated that the program probably requires from five to seven chemists, but that additional staff have not been hired because of the 1976 laboratory closure and uncertainties in future program operations.

The overall problems associated with inadequate PRSS staffing and facilities were summarized in an April 1977 memorandum to OPP from the Chief of the OPP Chemistry Branch:

> "In view of the constraints under which * * * [this section] has been operating since the lab closure June 11, 1976, and the attrition of staff which has been permitted to occur in the standards function, any statement of plans for immediate improvement is largely rhetorical. It seems pointless to pursue the matter further with * * * [PRSS] unless we receive a concrete authorization from OPP to recruit chemists and unless the Agency provides safe laboratory facilities. * * *

> "This vital program has been allowed to flounder to the extent that it seriously compromises the FDA enforcement program, not to mention other regulatory and research laboratories which utilize the service."

The memorandum recommended that either PRSS be adequately staffed and housed to carry out its mission or that the PRSS function be transferred from OPP to another EPA program office or another Federal agency. Although PRSS has since been reactivated, the basic problems described in the memorandum remain uncorrected. No additional chemists have been provided, and the facilities at Beltsville are not adequate to house more than four of the five to seven chemists the OPP Associate Deputy Assistant Administrator believes are necessary to adequately fulfill the functions assigned PRSS.

PRSS EFFECT ON REGULATORY ACTIVITIES

The effect of the problems above on FDA operations has been important. During the 18-month period the laboratory was closed, PRSS exhausted over 100 of its supply of 650 pesticides--such as captan, chlordane, endrin, and carbaryl--that were packaged and ready for shipment to FDA. Additional standards could not be prepared for shipment, nor could any standards be tested to assure proper composition.

PRSS sent previously partitioned reference samples to FDA without performing necessary tests to assure that the standards were of desired purity and potency. PPSS has reference standards (chemicals) in its repository that are over 10 years old; an unknown number of these standards have degraded while in storage. FDA identified nine reference standards that EPA furnished to FDA field laboratories that were confirmed to be decomposed or subpotent. Examples include:

--Naled, a pesticide with approximately 50 tolerances, is characterized by PRSS as a clear, colorless liquid; the standard FDA obtained from PRSS was a red-brown, liquid-solid mixture.

--FDA received a standard for Monitor (a pesticide widely used in Mexico on U.S. imported vegetables) that was a colorless liquid, instead of the normal opaque, white solid.

--FDA was prepared to submit a seizure recommendation on a dog dewormer that was thought to be 200-percent superpotent. In rechecking, FDA determined that all of its PRSS-furnished reference standards were in fact 50-percent subpotent.

In the words of the FDA laboratory director, "We obviously cannot afford to continue using standards without some assurance that they are suitable."

In September 1977 FDA wrote EPA and explained that the FDA laboratories had experienced difficulties in obtaining standards or had received some decomposed or subpotent material. FDA requested that the standards service, including purity analysis, be resumed immediately.

By October 1977 the problem with obtaining reliable reference standards had become so acute that the FDA Commissioner wrote EPA that EPA has "* * * been unable to supply us with most of the pesticide standards we have been accustomed to getting from them" and that "* * * a number of residue analyses are quite impossible for us to carry out, because these involve * * * procedures that require freshly-made standards for comparison with the unknown." In the same letter the Commissioner offered assistance to the EPA stating, "I will be happy to put some money into this if you will; we've just got to fix this or people are going to die laughing at us." FDA has not received a written reply to this letter.

Although PRSS has reopened its laboratory since the FDA Commissioner wrote to EPA, its staff efforts are presently directed only to partitioning and distributing reference standards. PRSS does not have the resources necessary to accomplish other assigned tasks that are equally important.

CONCLUSIONS AND RECOMMENDATIONS

EPA has not provided PRSS sufficient staff or facilities for accomplishing the important tasks assigned to it. During its 18-month closure, PRSS exhausted its inventory of many standards and, therefore, (1) was unable to provide some needed standards to FDA and (2) provided others that were either degraded or subpotent. The PRSS inability to provide pure, potent reference standards when needed seriously impairs the enforcement programs of other agencies, such as the FDA program to assure that the U.S. food supply is not adulterated with illegal pesticide residues.

We therefore recommend that the Administrator, EPA, take whatever actions are necessary to:

--Perform appropriate tests to assure that the standards sent to enforcement agencies are of the proper quality.

--Enable PRSS to accomplish its other assigned tasks, including data compiling and cataloging, indexing, synthesizing, and purifying standards materials.

If EPA cannot or chooses not to accomplish the foregoing, it should initiate immediate efforts to transfer PRSS to another Federal agency--such as FDA or the National Bureau of Standards--that will accord PRSS the priority for staff and facilities necessary to accomplish assigned tasks.

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As you know, Section 236 of the Legislative Reorganization Act of 1970 requires the Head of a Federal agency to submit a written statement of actions taken on our recommendations to the House Committee on Government Operations and the Senate Committee on Governmental Affairs not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

Copies of this report are being sent to the Director, Office of Management and Budget; the Commissioner, Food and Drug Administration; and cognizant House and Senate committees.

Sincerely yours,

Henry Eschwege

Henry Eschwege
Director