

Chapter 7

Programs for Detecting Pesticides in Food

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Federal Methods Development Programs for Detecting Pesticides in Food

Successful monitoring of pesticide residues depends upon the existence of cost-effective analytical methods for their identification and quantification. A number of Federal agencies are interested in improving methods to test for pesticide residues, but only EPA, FDA, and FSIS programs will be discussed here because

their research most directly affects the methods used for analyzing pesticide residues in food. Nevertheless, increased coordination, or at least communication, between all Federal agencies involved in such work would help improve use of research resources.

ENVIRONMENTAL PROTECTION AGENCY

Although EPA currently does not have a significant research program on analytical methods development for pesticide residues in food, EPA supports development of such methods through three activities:

1. Requiring the submission of a pesticide residue method as part of the tolerance-setting process for a pesticide to be used on food or feed and performing a single-laboratory evaluation of many of the submitted methods.
2. Performing a small amount of pesticide methods research that might be applicable to the analysis of food.
3. Administering several programs that support the ability of Federal and State laboratories to conduct pesticide methods research.

Methods Submitted for a Pesticide Tolerance

All pesticides for use in the United States must be first registered with EPA. If a pesticide is to be registered *for use* on food or feed, or if its use will result in residues on food or feed, a tolerance must be first established for each commodity in which the residue will occur. EPA requires the person or company peti-

tioning for a tolerance to submit an analytical method able to detect and quantify the pesticide residue in every commodity for which a tolerance is to be established. The person or organization petitioning for a tolerance is known as a petitioner or maybe called a registrant if the registration and tolerance-setting process occur simultaneously.

EPA's guidelines allow the submission of either a single or a multiresidue method to fulfill this requirement (see EPA, "Pesticide Assessment Guidelines, Subdivision O," October 1982). The petitioner usually submits a single residue method (SRM), which is usually less expensive to develop and more sensitive than a multiresidue method (MRM) (13).

Once a method is submitted, it undergoes a paper review by EPA's Office of Pesticides and Toxic Substances, and then if considered necessary and if resources permit, it is evaluated by an EPA laboratory. The first one or two analytical methods for a specific pesticide in plant commodities and one method for that pesticide in animal commodities normally receive such an evaluation (24). EPA has two laboratories—one in Beltsville, MD and one in Bay St. Louis, MS—that test submitted methods. Methods are initially reviewed on paper at these laboratories.



Photo credit: Contractor for the National Aeronautics and Space Administration

EPA has two laboratories that test analytical methods as part of the tolerance-setting process. Here, an analyst at the Environmental Chemistry Laboratory in Bay St. Louis, MS, performs the extraction step of a method.

If deemed unacceptable, the method is returned to the petitioner. If the method is acceptable, an EPA chemist then tests it and makes a recommendation regarding its suitability for enforcing the pesticide tolerance. This process usually takes 3 months. Where necessary, petitioners will make modifications and resubmit the method to the Office of Pesticides and Toxic Substances (16). Once approved, the method is submitted to FDA for inclusion in FDA's *Pesticide Analytical Manual, Volume II: Methods for Individual Residues* (also known as PAM II). Copies of the method can also be obtained from EPA once the tolerance is approved.

The number of methods tested by EPA's laboratories has been increasing over time and outstripping EPA's capabilities, resulting in a backlog of methods to be tested and delays in the registration of some pesticides. For example, in FY 1986, EPA had 25 methods to test but was only able to test 19, carrying the rest over to FY 1987. In FY 1987, EPA was only able to evaluate 24 of 47 methods that needed testing; the rest were carried over to the next year. By

March 1988, EPA had 52 methods to test, had evaluated 17, and expected to receive up to 18 more methods for testing in 1988. In FY 1987, EPA had assigned 7.5 full-time equivalents (FTEs) to testing and expected to assign 10 FTEs in FY 1988, but the backlog still exists (15, 16).

Some SRMs submitted to EPA can be a source of concern for Federal and State pesticide regulatory agencies, because these methods may not be practical for use in Federal and State food monitoring programs for several reasons. First, these SRMs often involve complex and time-consuming analytical manipulations. Regulatory agencies prefer to use the more cost-effective MRMs for routine monitoring and to use SRMs only when intelligence data show that a pesticide residue maybe present or when data on the residue level are needed (20). Second, SRMs submitted to EPA need be effective only for the commodities for which tolerances are established and may not be applicable to other commodities (20). Third, some of these SRMs maybe analytically flawed, poorly documented, or incapable of analyzing significant metabolizes, making them difficult or unusable for regulatory work (5,17).

EPA has taken several recent steps to improve the quality and usefulness of submitted SRMs (25). It is now mandatory for EPA to test all methods for new pesticides used on foods. User forms have been included in PAM II to alert EPA and others of specific problems with a method. EPA will be requiring an independent evaluation of each method before its submission to EPA beginning August 1, 1989. Also, EPA now requires petitioners to test whether their pesticide can be successfully analyzed through official FDA MRMs, and the test results are sent to FDA. In addition, EPA is considering how to incorporate FDA and USDA input on the regulatory usefulness of submitted methods in the tolerance-setting process.

EPA Research

Methods development at EPA is carried out primarily by EPA's Office of Research and Development (ORD). Although EPA has identified pesticide residues in food as a significant source

of human exposure to pesticides, ORD does not have a specific program on methods to detect these residues because regulation of food is outside EPA's mandate.

EPA conducts pesticide analysis and some methods development work at its field laboratories primarily for nonfood matrices. Because of the different matrices involved, the applicability of EPA research on conventional analytical methods for use on food may be limited, especially for extraction and cleanup steps. On the other hand, since EPA uses detection equipment similar to that used in food analysis, EPA advances in the detection step maybe applicable to food analysis (3, 18).

EPA's immunoassay work for detecting chemicals may be applicable to food analysis. The Environmental Monitoring Systems Laboratory in Las Vegas, NV, houses a 2-year-old program designed to assess the usefulness of immunoassay for analyzing toxic chemicals, including pesticides. The program's budget for FY 1988 is \$450,000 and the program's objectives are to: develop immunoassays, develop criteria for evaluating immunoassays, develop a list of chemicals for which immunoassay can and should be made, and evaluate commercially available immunoassay (28). Although none of this work is aimed at food, immunoassay developed for analyzing soil and water can be adapted for use on food. Further EPA research and the development of an evaluation protocol for immunoassay could be used by FDA and USDA. The Las Vegas laboratory has an inter-agency agreement with USDA to cooperate on developing antibodies of mutual interest.

Supporting Programs

EPA has several programs that support development of pesticide residue methods at Federal, State, and other laboratories. These programs include the Pesticide and Industrial Chemicals Repository and a training program for State laboratories under contract with EPA.

The Pesticide and Industrial Chemicals Repository provides samples of approximately 1,600 pesticides (foreign and domestic) free of

charge to Federal, State, private, and foreign laboratories. Having a chemical of known concentration and purity, known as a standard, is necessary to develop new methods and to check that existing methods used in regulatory work are correctly identifying pesticides. Standards are provided by chemical manufacturers, stored at the repository, and distributed one sample per chemical per year to a requesting laboratory, although greater quantities will be supplied to Federal laboratories upon request (12).

The repository is funded by three EPA programs: Superfund, Solid Wastes, and Pesticides. For FY 1988, the repository had a budget of about \$3 million and 22 full-time employees. The pesticide part of the repository costs about \$630,000 a year to operate. Because the EPA pesticide program wants to reduce its contribution to the repository's budget, the repository has recently restricted its distribution of pesticide standards. As of July 15, 1988, pesticide standards will no longer be provided to university, private, and foreign laboratories (3, 11).

To further defray costs, EPA is interested in having recipients such as FDA and USDA, who are the largest users of pesticide standards, provide additional support for this activity. FDA is interested in expanding the repository to include an additional 150 foreign pesticides not registered in the United States but that might exist on imported foods (12).

In addition to supplying analytical standards, EPA provides a quality assurance and training program for State laboratories to improve analysis of pesticides in the environment. Currently, EPA has contracts with 52 State laboratories and Puerto Rico, some of which also analyze for residues in foods as part of their own program. EPA helps maintain the quality of analysis of these laboratories through two means. First, EPA performs laboratory quality assurance tests by sending out samples containing known quantities of pesticide residues for the laboratories to analyze. Second, EPA's Denver Regional Office provides weeklong hands-on training workshops for State personnel on the use of specific methods. On average, three

workshops are held a year with a limit of 12 participants for each. Demand for the workshop often exceeds available space (10). States have expressed the need for more such training

courses (2), including training in the area of analyzing for residues in foods, but this is outside EPA's training goals.

FOOD AND DRUG ADMINISTRATION

Because of FDA's mandate to monitor and enforce pesticide tolerances in food, it is the lead Federal agency for the development of pesticide analytical methods specifically for food. FDA's research concentrates on MRMs as a result of FDA's need to determine the presence or absence of many pesticides in food commodities for which little information exists on pesticides application.

In general, FDA's methods development research can be divided into two broad types: 1) that which deals with immediate program needs, and 2) that which is directed to future goals of greater scope to solve particular problems or to improve overall effectiveness or efficiency. Most of FDA's effort is the first type (7).

Pesticide methods research is primarily conducted in-house at three levels within the agency: in the 16 field laboratories, in two special research centers, and at the Center for Food Safety and Applied Nutrition (CFSAN) in Washington, DC. The CFSAN and two research centers conduct the bulk of methods research because field laboratories normally spend at least 90 percent of their time on regulatory work. FDA does little outside contracting of methods research, although in late 1987 it awarded a contract for immunoassay development because of a lack of in-house expertise.

FDA's pesticide methods research agendas are planned on a year by year basis. These agendas are open to interruption as emergencies arise, e.g., the recent EDB problem.¹ Formal planning sessions with headquarters and field participation are held each year, research projects are printed in the annual technical plan, and their progress reported quarterly.

Research priorities are influenced by factors such as the Surveillance Index, Pesttrak,² domestic and foreign pesticide use data, new toxicological information, gaps in monitoring coverage, and pesticide registration cancellations. Mechanisms for setting research priorities are currently informal, and detailed listings of long-range priorities have not been prepared (14). No formal list of priority pesticides requiring research action exists. However, an informal list of pesticides requiring methods research in 1988 was developed at the annual planning meeting for the research centers in 1987. Responsibility for the work was divided among the research centers and the Los Angeles field laboratory. The list was a combination of pesticides identified by CFSAN and ongoing work at the research centers (1). Currently, CFSAN is developing a long-term research plan to be completed in 1988. The level of field and outside input into the draft plan is not clear.

CFSAN has the largest concentration of pesticide analytical expertise in one place in the FDA system, with six FTEs carrying out pesticide methods research for food in its laboratory. CFSAN develops a separate annual technical plan containing its own research projects. Current research ranges from expanding MRMs to cover additional pesticides, their metabolites, and additional food commodities to evaluating new technologies and attempting to fit them into existing methods. CFSAN also develops new MRMs on pesticides that cannot be tested with existing MRMs. As the focal point, CFSAN also provides research direction and advice to the research centers and field laboratories. Representatives from CFSAN sit on the committees that approve field laboratory research projects.

¹Improved analytical techniques, in 1984, led to the identification of a large number of illegal EDB residues in grain products.

²Pesttrak is a computerized data base used to track whether pesticides can be analyzed using one of FDA's five routinely used MRMs.

CFSAN has been a leader in the development of MRMs. Its work has led to the development of four of the five MRMs routinely used by FDA. Based on OTA's observations, however, field laboratories may not consider the bulk of CFSAN's current work to be addressing their analytical methods needs. In addition, CFSAN's research activities do not seem to be meeting the regulatory needs of field laboratories in a timely fashion, and because of the lack of a long-term research plan, CFSAN may not be effectively addressing future monitoring needs.

FDA has two research centers developing methods for analyzing pesticides and other industrial contaminants in foods. Headquarters and research center staff meet annually to set the centers' research agendas, and the centers request research suggestions from the field laboratories. These two centers—the Total Diet Research Center (TDRC) in Kansas City, MO and the Pesticide and Industrial Chemicals Research Center (PICRC) in Detroit, MI—were established in 1980 to meet the analytical needs of field regulatory laboratories. Combined they have six FTEs doing research and one FTE for management.

The TDRC's work primarily supports the Total Diet Study (TDS) carried out by the Total Diet laboratory in Kansas City, MO. The Total Diet Study is not under the same time constraints as many of the field laboratories and requires more sensitive methods than those used by the field laboratories. Thus, some of TDRC's methods development work done for the Total Diet laboratory may not be appropriate for field laboratories' needs.

In several cases, TDRC's work has benefitted specific field laboratories; for example, the use of gel permeation chromatography and wide-bore capillary chromatography, and the development and expansion of two newer MRMs that detect a small number of chlorophenoxy acids or phenylurea herbicides (19). TDRC has also conducted research assigned by CFSAN that addresses field laboratories' specific regulatory needs. For example, TDRC tested a method for ETU (a breakdown product of EBDC fungicides) and found it applicable to only a

few commodities (19). TDRC also has a project that uses mass spectrometry to identify or characterize pesticide residues that cannot be analyzed by conventional chromatographic approaches. This project, however, does not seem to be well linked with similar efforts at FDA's Los Angeles and New York laboratories.

PICRC is the center with primary responsibility for supporting FDA field laboratories' analytical methods needs for pesticide residue detection. Much of its work has focused on developing methods for detecting important non-pesticide chemical contaminants in foods, such as dioxin and PCBs. In the area of pesticides, PICRC focuses on classes of pesticides not determinable by existing MRMs.

PICRC has developed methods for the detection of captan, folpet, and captafol using wide-bore capillary gas chromatography and for the benzimidazole-related fungicides (benomyl, carbendazin, thiophanate-methyl, and thiabendazole) using high performance liquid chromatography. The latter work was in support of an assigned field laboratory monitoring program in 1987 and a compliance program in 1988. In response to a contamination problem in dairy products caused by heptachlor epoxide-contaminated feed, PICRC developed a method that allowed the Minneapolis District in 1986 to analyze fatty samples more rapidly than by using the existing official method (27). PICRC has also worked on applying capillary column technology to the analysis of pesticide residues in food and has been instrumental in the Detroit field laboratory's adoption of capillary columns (21). Ongoing research addresses methods for the detection of the "quats" (paraquat, diquat, and difenzoquat) and triphenyltin and its metabolites.

As noted, PICRC's work has supported specific method needs of individual field laboratories. However, OTA observed that several field laboratories do not find the majority of PICRC's work as relevant to their regulatory needs. In part, PICRC was viewed as not having strong enough ties to the field laboratories, especially when compared with its ties to CFSAN. To some extent, the field laboratories



Photo credit: Pesticide and Industrial Chemicals Research Center, FDA, Detroit, MI

FDA's Pesticide and Industrial Chemicals Research Center is responsible for addressing pesticide analytical methods needs of the field laboratories.

contribute to this problem by not working more closely with PICRC on the type of research PICRC could conduct. For example, only four of sixteen field laboratories responded to PICRC's request for research proposals for FY 1988 (27).

A total of about seven FTEs carry out pesticide methods research at the field laboratories through short-, medium-, and long-term work (6). In the past, medium- and long-term research were approved by separate committees, but starting in FY 1989, a single committee composed of laboratory directors, science advisers, and personnel from CFSAN and the Office of Regulatory Affairs (ORA) will approve this work. This committee also will oversee the work of the two research centers. Much of the field laboratory research work focuses on evaluating whether additional pesticides can be ana-

lyzed through existing MRMs. But field laboratory research can make more significant contributions. The most widely used MRM, the Luke method—which was used in 80 percent of FDA's 1987 pesticide residue analyses—was developed at FDA's Los Angeles laboratory (20).

For short-term research, FDA provides 50 hours of "discretionary research" per operating laboratory analyst. The laboratory director normally determines how the time will be divided among analysts and priority topics. "Discretionary research" is used as the need arises for short-term projects and is often, in the area of pesticides, aimed at extending an existing MRM to a new commodity.

With regard to medium-term research at the field laboratories, a pool of research time made up of 150 hours per operating analyst is set aside

for research projects. Projects usually require 300 hours and might address expanding a known method to several commodities or developing a new method for a class of pesticides. Project proposals from field laboratories, the two research centers, and CFSAN are ranked by a research committee, reviewed by the director and deputy-director of the ORA (which has line authority over the field laboratories), and final approval rests with the Associate Commissioner for Regulatory Affairs.

Long-term research at the field laboratories takes place through the Science Adviser Research Associate Program (SARAP). Field laboratories may contract with one to two persons from the academic community who then work with laboratory personnel. Field analysts in conjunction with the science adviser may propose long-term research projects (6 to 12 months), often to be done outside the laboratory at the adviser's academic institution sometimes with additional training for the analyst. Approval must be received from the laboratory, the district, the research committee, the ORA, and the Associate Commissioner for Regulatory Affairs. Normally five SARAPs exist at one time, and they may be for any of the methods areas in which FDA works (e.g., microbiology), not only for pesticide residues in food.

A significant amount of resources are used for pesticide methods research being conducted

by different groups at FDA. However, based on OTA observations, much of the work conducted by CFSAN and the two research centers is not adequately supporting the needs of regulatory laboratories for fast, practical methods for analyzing pesticide residues in food,

This situation could be addressed by existing groups taking the research responsibilities for which they seem best suited. Normally free from regulatory "fire-fighting" work and away from the "front lines," CFSAN could use its nucleus of expertise to focus primarily on long-term, future-oriented research. To increase the regulatory relevancy of the research centers' work, their research could be more responsive to field needs as identified by the field laboratories rather than by CFSAN. In support of this, field laboratories could expend increased effort in communicating their needs to the research centers, especially to PICRC. Although field laboratories are usually too busy analyzing samples to conduct research, whatever research does take place is perhaps the most immediately relevant for regulatory action. Perhaps more time should be allocated to field laboratory analysts to conduct research, but this would require additional resources to allow laboratories to keep up with their regulatory workload.

UNITED STATES DEPARTMENT OF AGRICULTURE

Development of residue analytical methods by USDA comes under the purview of the FSIS, and pesticide residue research is currently conducted by the Chemistry Division and Field Service Laboratories Division in the Science Program. FSIS's pesticide methods development program currently emphasizes the expansion of existing MRMs complemented by the development of faster methods, many of which are based on immunoassay techniques. These faster methods will allow the weeding out of a large percentage of samples that do not have violative residues without having to analyze them with the more expensive conventional

method. This emphasis is, in part, a response to recommendations by a 1985 National Academy of Sciences report and a 1987 General Accounting Office study (9, 23).

FSIS monitors food solely with MRMs and does not depend on SRMs because generally it considers SRMs as too time-consuming and expensive to be practical in a large-scale monitoring program. Therefore, FSIS works primarily to incorporate additional pesticides under its MRMs rather than to improve SRMs. All methods used by USDA in its monitoring programs are subjected to in-house validation,

which includes at least three analysts at two laboratories with a minimum of 12 to 18 analyses per analyst for each pesticide-meat tissue combination (4).

In 1985, FSIS closed down its central laboratory at Beltsville, MD (a counterpart of FDA's CFSAN laboratory), which conducted research on analytical methods for detecting pesticide residues in food. Methods research has since been conducted by FSIS field laboratories, through contracts with private organizations, through the Agricultural Research Service (ARS) of USDA, and through interagency agreements. In addition, the Chemistry Division in Washington, DC, is also seeking commercially available rapid test kits.

FSIS has three field laboratories, two of which are currently working on pesticide residue methods (located at Athens, GA, and Alameda, CA). Each laboratory has a methods division unit, and regulatory personnel may also conduct methods work. In-house work on pesticides totals approximately \$200,000 per year and 5.5 FTEs (8), with the majority of the work conducted at the Athens, GA, laboratory. Examples of current work include the following:

- Setting up a new, conventional analytical method for four triazines for regulatory

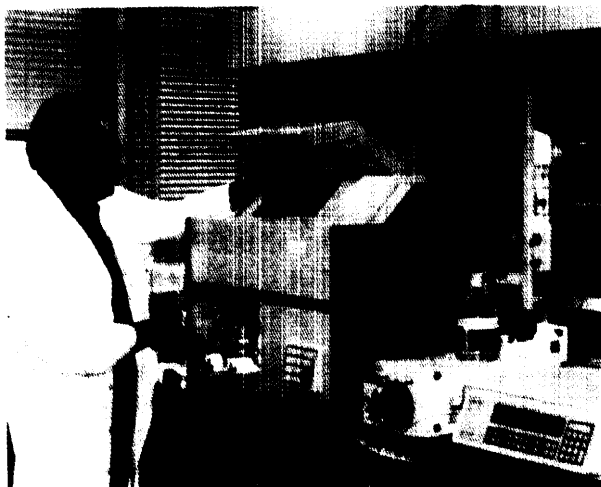


Photo credit: Food Safety and Inspection Service Laboratory, Athens, GA

Much of FSIS' pesticide methods research takes place at the field laboratories. Here, a new methodology using high performance liquid chromatography is being evaluated.

work and testing a commercial rapid immunoassay kit to detect triazines in order to weed out the large percentage of samples that are not violative.

- Expanding an existing MRM for organophosphates, and evaluating a commercial, rapid cholinesterase enzyme kit that tests for organophosphates.
- Setting up a quick semiquantitative immunoassay method for five synthetic pyrethrin insecticides that makes use of solid phase extraction for cleanup.
- Expanding the number of Pesticides that gel permeation chromatography can be used for cleanup of meat products.

FSIS also contracts out research with private organizations and other Federal agencies. Current contracts for pesticide residue methods total approximately \$285,000 and include the following:

- The Department of Energy's Lawrence Livermore Laboratory's work on an immunoassay for heptachlor-related chlorinated pesticides. This laboratory also developed the pyrethrin immunoassay now being implemented at the Athens laboratory.
- The Colorado School of Mines is investigating supercritical fluid chromatography for aniline-based pesticides.
- The University of Washington is working on the use of thin layer chromatography as part of a quantitative assay.

In addition to outside contracts, ARS also does work for FSIS on pesticide residue methodologies. Currently, ARS in Peoria, IL, is working on the use of supercritical fluid extraction and chromatography in low-fat meat products, and ARS in Beltsville, MD, is researching a quantitative method using gas chromatography for the detection of synthetic pyrethroids (26).

The Cooperative State Research Service of USDA provides funds to four land-grant university laboratories that support the registration of pesticides for use on minor crops. These laboratories may develop SRMs as part of their application for tolerances for the pesticide residue on minor crops (22).

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*These reference papers are contained in appendix B.