United States General Accounting Office

GAO

Report to the Chairman, Government Information, Justice, and Agriculture Subcommittee, Committee on Government Operations, House of Representatives

January 1992

FOOD SAFETY

USDA Data Program Not Supporting Critical Pesticide Decisions

GAO/IMTEC-92-11

GAO

United States
General Accounting Office
Washington, D.C. 20548

Information Management and
Technology Division

B-245645

January 31, 1992

The Honorable Robert E. Wise, Jr.
Chairman, Government Information,
Justice, and Agriculture Subcommittee
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

Ensuring the safety of the nation's food supply is a key responsibility of the federal government. To assist the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) in reaching decisions on the safe use of pesticides, as well as helping carry out its own responsibilities, the United States Department of Agriculture (USDA) in 1990 began the Coordinated Pesticide Data Program. Under this program, USDA is surveying farmers in 13 states to determine the types and quantities of chemical pesticides being used on selected fruit, vegetable, and nut crops. In addition, USDA is collecting data on the amount of pesticide residues remaining on selected crops once they enter wholesale and retail food distribution centers.

Food safety scares relating to pesticides—such as the use of alar on apples—have elevated uncertainties about the risks to consumers and the environment created by the use of pesticides in agricultural production. To evaluate pesticide safety, the government requires reliable data to weigh the health risks and economic benefits of pesticides. Data on usage are an important input in considering possible pesticide restrictions. In addition, pesticide residue data can help form the foundation for setting safe, legal limits for residue levels.

Because of concerns about how agencies share reliable pesticide data, you asked us to review USDA's program and determine (1) whether it is producing the data needed for making improved pesticide regulatory decisions, and (2) whether USDA has a strategy for managing the data resulting from the program. Appendix I provides additional details of our objectives, scope, and methodology.

Results in Brief

The Pesticide Data Program is not providing pesticide residue data needed to make key regulatory decisions to help ensure food safety. Although the program's ongoing pesticide usage surveys are generally satisfying interagency users, residue data collection has had major problems. USDA originally intended to start providing residue data to EPA and FDA on 22 food commodities and 16 pesticides in July 1991. However, as of January 1992, USDA had not provided any data because it had only assembled partial results on seven commodities and eight pesticides. More importantly, USDA's data are not statistically reliable, as originally planned, and will therefore be of limited use to EPA in making upcoming decisions on pesticide safety in food products.

Although USDA has not developed a statistically reliable sampling approach, it plans to spend $24 million to collect residue data in fiscal years 1991 and 1992. However, because USDA does not have agreements with EPA and FDA on the direction of the program, USDA risks expending resources without knowing whether the program is improving food safety. At the conclusion of our review, USDA officials stated they were attempting to obtain signed agreements with EPA and FDA.

The program's problems are magnified by the absence of an information management strategy. Data collection activities, which will result in thousands of residue data records from state food analysis laboratories, commenced without determining the requirements for supporting the processing and dissemination of these data. As such, USDA has not determined the information resources required to accommodate users' needs.

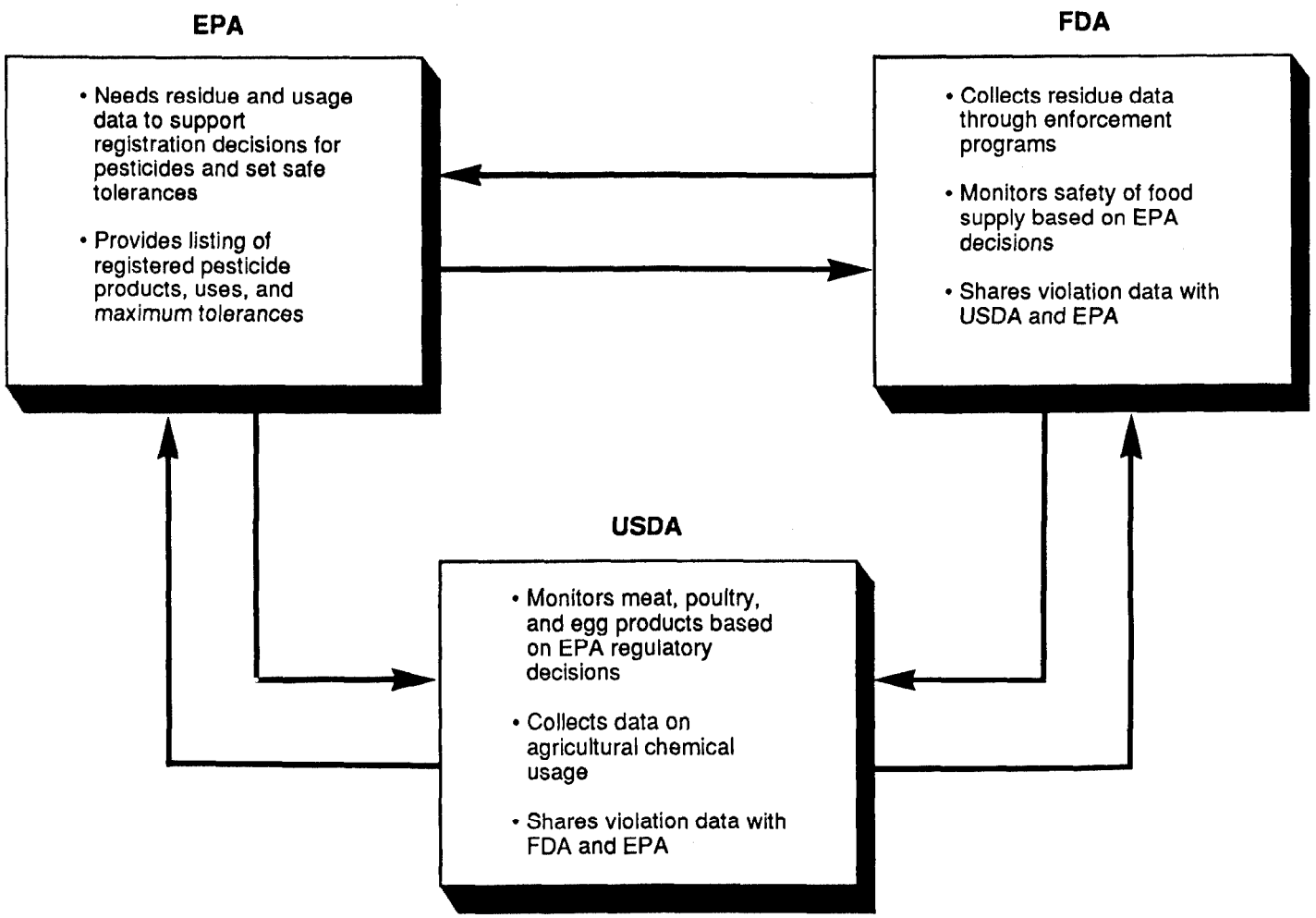
Background

EPA, FDA, and USDA each play a role in regulating the safety of agricultural pesticides. EPA registers pesticides for commercial and consumer use under the Federal Insecticide, Fungicide, and Rodenticide Act, and sets maximum tolerances[1] for pesticide residues allowed in food commodities under authority of the Federal Food, Drug, and Cosmetic Act. FDA enforces these tolerances and monitors the food supply through sampling and testing of fresh and processed commodities, such as fruits and vegetables. USDA monitors pesticide residues through its meat, poultry, and egg product inspection responsibilities, and conducts studies on the economic benefits of pesticide use on the agricultural industry. These fragmented responsibilities require extensive program coordination and information

[1]A tolerance is the legal limit of pesticide residue allowed to remain in or on raw agricultural commodities, processed foods, or animal feed. It represents an amount that is considered to impose no health hazard over a lifetime of daily exposure.

exchange between the agencies to avert wasteful duplication of effort, prevent gaps in commodity coverage, and avoid conflicting reports on food safety.[2] Figure 1 shows the pesticide information shared among USDA, EPA, and FDA.

Figure 1: Pesticide Information Shared Among EPA, USDA, and FDA



Data on pesticide residues are particularly important to EPA in assessing the safety of pesticide products, as required by the Federal Insecticide, Fungicide, and Rodenticide Act. To further ensure the continuing safety of

[2]Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19B, Dec. 1, 1990) provides an overview of specific federal agencies' responsibilities for food safety and quality.

pesticides, the Act requires EPA to reregister all pesticides that were previously registered before November 1984 using more stringent standards. EPA's reregistration of these pesticides, to be based on current standards, will require reliable residue data to reassess the safety of approximately 400 pesticides and thousands of products containing these pesticides as active ingredients.[3]

Historically, pesticide usage and residue data used by EPA to support pesticide product registrations have often been incomplete, statistically unreliable, or not readily accessible. For example, in carrying out its enforcement mission, FDA collects data based on its selective targeting of pesticide samples where the probability of violation is greatest. Although FDA routinely provides these data to EPA, EPA is limited in using these data to make accurate projections about the relative safety of the food supply because the data are not statistically reliable. In the absence of scientifically collected data on actual pesticide residue levels, EPA can only apply a theoretical maximum residue concentration when calculating the possible risk posed by the proposed tolerance level.[4]

We have previously reported on FDA's limited coverage and its inability to make broader conclusions about the safety of the larger food supply.[5] FDA has subsequently begun examining ways to conduct more statistically based residue sampling.[6]

USDA Implemented Pesticide Data Program to Improve Regulatory Decisions

Because of continued concerns about food safety, the President's 1989 Food Safety Plan called for further changes in pesticide regulation. This initiative pressed for streamlining the government's ability to remove potentially hazardous pesticides from the market. EPA, FDA, and USDA consider reliable pesticide usage and residue data to be of paramount importance in achieving these goals.

[3]An active ingredient is defined as the component in a pesticide product that is intended to specifically control or destroy a pest.

[4]EPA assumes that (1) the entire crop has been treated with the pesticide, (2) the residues resulting from the application are at the maximum level (i.e., the proposed tolerance), and (3) all consumers eat a certain fixed percent of the commodity in their diet.

[5]Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues (GAO/RCED-87-7, Oct. 27, 1986); Federal Regulation of Pesticide Residues in Food (GAO/T-RCED-87-21, Apr. 30, 1987).

[6]In fiscal year 1990, FDA contracted with Research Triangle Institute, Incorporated, to produce a more statistically valid residue sampling model that the agency could use for its surveillance activities. A final report was issued to FDA in March 1991 and the agency is planning a pilot test for tomatoes and pears using two district offices.

In response to the President's 1989 initiative, USDA launched the Coordinated Pesticide Data Program to provide better pesticide data beneficial to all three federal agencies. This program is focused on collecting pesticide usage and residue data on fresh fruits and vegetables. It was expected to provide reliable data to improve government decisions on food safety, assist in the analysis of alternative pesticide policies, and inform the public of the safety of the nation's food supply. As detailed in USDA's May 1990 program plan, key objectives were to (1) collect comprehensive, statistically valid, and scientifically based pesticide usage and residue data during 1991 and 1992; and (2) provide EPA with pesticide residue data that it could use in making pesticide reregistration decisions.

To meet these objectives, in fiscal year 1991, USDA's National Agricultural Statistical Service collected usage data from farmers in five states—Arizona, California, Florida, Michigan, and Texas—on items such as pesticide used, target crop, acres treated, and application rates. In fiscal year 1992, pesticide usage data are being collected on fruit and nut crops in eight additional states.

Concurrently, USDA's Agricultural Marketing Service planned to collect pesticide residue data on fresh fruit and vegetables from food distribution centers in six states—California, Florida, Michigan, New York, Texas, and Washington. Sample collection and laboratory analysis for residues were to be conducted by state government laboratories with USDA providing funding through cooperative agreements signed with each state's agriculture departments. USDA originally planned to analyze 22 types of fresh fruits and vegetables and 16 pesticide residues, and report these initial results to EPA, FDA, and within USDA by July 1991. USDA planned to expand the program in fiscal years 1992 and 1993 by analyzing additional commodities and pesticides.

For fiscal years 1991 and 1992, USDA plans to spend about $33 million to cover program costs. Over 70 percent of this funding, or approximately $24 million, is being spent on residue data collection. USDA intends to spend approximately $7 million of the total funding on the pesticide usage surveys.[7] USDA has not yet disclosed estimated costs beyond 1992.

USDA's program represents a significant increase in the amount of federal funds being spent to collect pesticide data. For example, FDA estimates that

[7]USDA's Economic Research Service and Human Nutrition Information Service also received $1.1 million for fiscal year 1991 and $1.1 million for fiscal year 1992 to conduct economic and health risk analyses using the residue and usage data.

it spends approximately $24 million annually for the nation's primary nationwide pesticide surveillance and compliance program that monitors fresh fruits and vegetables for unsafe residue levels.

Residue Collection Proceeding Slowly and Not Meeting Requirements

Although its usage surveys are proceeding on schedule and meeting needs, USDA's pesticide residue data collection effort has faced continuing problems. This portion of the program is behind schedule, proceeding with a reduced scope, and not producing statistically reliable data—a key program objective. These problems have occurred because USDA underestimated the complexities of implementing the program and did not reach agreements with EPA and FDA on specific program direction.

Usage Data Meeting Needs, but Residue Data Collection Encountering Problems

USDA's ongoing pesticide usage surveys are proceeding on schedule and EPA and FDA officials have expressed satisfaction with the initial data published in June 1991. USDA completed its initial surveys in the fall of 1990 and published the results, as scheduled, in June 1991. Because a different reporting approach was used for California, these data were provided as a supplement in November 1991.

By contrast, USDA's residue data collection has encountered numerous unanticipated difficulties. Residue collection efforts started later than originally planned and are subsequently behind schedule. As of December 1991, USDA still had not provided initial data sets to FDA or EPA, even though this was expected to occur by July 1991.

Further, USDA's first-year data collection was also significantly reduced in scope. In July 1990, USDA's plans were to collect data on 22 fruit and vegetable commodities and 16 pesticides. By January 1992, however, USDA officials had only assembled partial data on seven commodities being analyzed for eight pesticide residues.[8]

In addition, all seven of these commodities are already routinely monitored for pesticide residues by FDA as part of its pesticide safety surveillance and enforcement activities. Although FDA's program focuses on detecting

[8]State labs have collected pesticide residue data for lettuce, grapes, potatoes, apples, bananas, grapefruit, and oranges. Specific pesticides being tested are chlorpyrifos, dicloran, hexachlorobenzene, iprodione, lindane, methoxychlor, permethrin, and quintozene. In January 1992, USDA stated that it had started testing acephate, methamidophos, and dicofol, but data had not been assembled on these.

residue levels exceeding legal limits, it uses similar extraction procedures, sampling methods, and established laboratory quality control measures.[9] EPA chemists stated that they often request FDA's residue data and consider the data useful in conducting health risk assessments or evaluating adjustments in residue tolerances.

USDA's residue data collection effort will also not yield statistically reliable results, as originally planned. Instead, USDA started collecting residue data using interim sampling procedures that will not produce statistically reliable conclusions. Further, despite the notable costs associated with data collection, USDA officials are unable to specifically say when the program will produce statistically valid data. At the conclusion of our review, USDA officials said that they are now beginning to determine the requirements and feasibility of using a statistically defensible sampling methodology.

Because of these limitations, EPA does not have immediate plans to use USDA's initial residue data, even though the program was intended to meet EPA's priority needs. Further, according to the head of EPA's Office of Pesticide Programs, the first-year data from USDA do not cover the chemicals expected to be the subject of pesticide reregistration decisions in the near future.

Unrecognized Program Complexities and Absence of Agreements Have Impeded Progress

These problems have occurred in part because of USDA's underestimation of the complexities in planning and implementing such a program. Specifically, USDA underestimated the effort involved in evaluating and establishing requirements for commodity sampling methods, laboratory testing procedures, and quality assurance practices. According to program officials, residue data quality hinged on statistically valid sampling methods, uniform state laboratory procedures, and an effective quality assurance program. Attempting to coordinate and agree on these issues with the involved USDA components, EPA, FDA, and the participating states has taken longer than USDA expected.

Soon after program initiation in 1990, USDA officials recognized that these issues could not be resolved quickly. They therefore proceeded to implement the program with interim sampling and laboratory procedures in order to collect data during fiscal year 1991. For example, officials determined that states' existing laboratory equipment and procedures were

[9]Differences will exist between USDA's initial data and existing FDA data sets on the same commodities. The USDA data use larger, more randomly selected samples; reflect more sensitive detection levels for pesticide concentrations; and analyze only the edible portion of the commodities.

not sufficient to ensure reliable results for all pesticides. Because of this, USDA officials decided to collect less data and use pesticide and commodity combinations that could be best accommodated using the states' existing laboratory equipment and residue testing procedures.

The problems encountered to date are also due in part to the lack of agreement between USDA, FDA, and EPA on program direction. Before initiating the residue monitoring portion of the program, USDA held working group meetings with EPA and FDA officials on the key issues discussed above. However, key issues requiring interagency input, such as how the progress or data results of the program would be assessed, were never agreed upon. Neither EPA or USDA could provide documents on how USDA's residue data collection would correspond to EPA's schedule of pesticide regulatory reviews. Additionally, it was not resolved how USDA and FDA would coordinate to ensure that present and future efforts under USDA's program and FDA's plans to do more statistically based residue enforcement sampling would not overlap.

USDA, FDA, and EPA officials now believe that the first full year of data collection can be best used to assess the logistical requirements of the program, rather than to address original program objectives. EPA, in particular, views the residue collection project as a pilot venture to establish a laboratory infrastructure for pesticide residue data collection in the states, which can then become more focused on meeting specific pesticide data needs.

USDA plans to continue collecting pesticide residue data after the first-year effort is complete. However, no agreements have been reached with EPA or FDA on how to best accommodate immediate and future pesticide data needs, and statistically valid sampling plans have yet to be finalized. At the conclusion of our review, USDA officials stated that they planned to obtain documented agreements with EPA and FDA on future program direction.

Data Collection Proceeding With Minimal Information System Planning

To be useful to the agencies involved, automated systems must process and disseminate large volumes of pesticide information in a timely fashion to support the Pesticide Data Program. To ensure that available computer resources can do that, USDA's regulations require that responsible organizations determine the resources required to manage data before they are collected. However, even though the program has been approved and data collection is underway, USDA has not developed a strategy to determine whether available computer resources can adequately process

or disseminate the data, or whether new systems will be necessary. As a result, USDA risks not meeting program objectives because the agency does not know if its information systems can provide the collected data to USDA, EPA, and FDA in a timely and cost-effective manner to best meet users' needs.

New Data Base for Pesticide Usage Survey Has Been Delayed

To manage the data generated from the pesticide usage surveys, USDA is relying on its existing information resources. USDA formed an internal committee to study the requirements for new pesticide-related data bases, including data contents, security requirements, software options, user needs, and other essential development steps. To date, no conclusions have been reached regarding these issues, and no firm target dates have been established for their resolution. According to USDA officials overseeing the committee, disagreements among program officials within the Department over the scope and intended uses of the data bases have impeded the committee's progress in addressing these issues.

In the interim, USDA is using its mainframe computer to manage the data and publish summaries of the survey results annually. However, this solution may not adequately address users' needs for access to more detailed usage data than that aggregated at a statewide level. EPA officials, who have traditionally relied on USDA pesticide usage reports, said that obtaining data from USDA publications has not always been timely or detailed enough to meet their information needs. USDA's proposed plans to publish the data within 6 months of collection is a significant improvement over past annual reports. However, agreements with EPA on access to more specific survey results have not been resolved because of confidentiality and privacy protections granted to farmers participating in the surveys.

USDA Has Not Adequately Assessed Residue Information System's Requirements

The Pesticide Data Program will eventually collect thousands of residue data records annually from laboratories in participating states. This requires a well-defined process for collecting, organizing, maintaining, and disseminating the data. Despite this, USDA has not determined the information resources necessary to manage this data in accordance with program objectives.

USDA officials stated that since 1990 they have been addressing sampling and laboratory procedures, and therefore decided to set aside information management issues until later. In the interim, USDA plans to manage pesticide residue data using a commercial off-the-shelf data base system

implemented in December 1991. This system will manage the residue information received from the state labs on paper forms and be used in conjunction with a formal system requirements analysis to help define additional system needs. Additionally, USDA has made little progress in systematically assessing or addressing state laboratory information management systems and technology needs that could assist in integrating, monitoring, and supporting quality assurance processes.

In September 1991, USDA hired a contractor to begin the initial system design and development phases for a residue information system. The contractor is expected to analyze user needs—including those of FDA and EPA—and create a plan for developing and implementing an operational residue information system. Even without the contractor's results, USDA estimates that it will have a new residue information system operational by the end of 1992. This new system is expected to be an expansion of the system now in place, and will include additional user and system requirements designed to enhance data accessibility, retrieval, and management reporting capabilities. USDA believes that the expanded system can be met with existing computer resources or minor hardware additions. Yet, because system requirements remain largely undefined at this point, the data collection and reporting may be subjected to further changes that could jeopardize the value of the data now being collected.

Conclusions

USDA's pesticide usage surveys are providing more comprehensive data on selected patterns of statewide pesticide use. However, despite considerable start-up costs for the study of a limited number of pesticides and commodities, USDA's pesticide residue data collection is not yet producing statistically reliable results and will be of limited use to EPA's near-term decisions on pesticide reregistration. Accordingly, continued residue collection without agreement on how the program best fits into an interagency data strategy is questionable. Without complete interagency agreement on the scope and anticipated benefits of the program, USDA cannot be assured that the resources it is spending today will meet program objectives in the future.

Concurrently conducting, managing, and directing data collection and systems planning is a formidable exercise. However, USDA has proceeded with data collection without fully analyzing information system requirements and thus risks limiting the future quality, usefulness, and availability of the data—all key elements of program success.

Collectively, these problems jeopardize USDA's ability to provide highly reliable, statistically defensible, and timely data to support EPA's pesticide registration program and to build public confidence in government data used to support the safety of the nation's food supply. Without adequate coordination with more statistically based residue data collection activities at FDA, USDA also risks duplicating similar FDA efforts.

Recommendations

To help establish a better foundation for the success of USDA's Coordinated Pesticide Data Program, we recommend that, after completing the current data collection effort with the existing six states, seven commodities, and eleven pesticides, the Secretary of Agriculture not proceed with further residue data collection activities until the Administrator of the Agricultural Marketing Service

- evaluates, in conjunction with EPA and FDA officials, the results of current data collection efforts;
- reaches agreement with EPA and FDA on how the Pesticide Data Program can most efficiently provide statistically reliable data, meet users' needs, and support interagency pesticide responsibilities; and
- documents these agreements with EPA and FDA.

We also recommend that the Secretary of Agriculture direct the Department's Office of Information Resources Management, working with the USDA components involved in the program, to develop and implement an information technology strategy, plan, and implementation schedule that details how the Department will manage, process, and disseminate all pesticide data being compiled under the Pesticide Data Program.

Agency Comments and Our Evaluation

USDA's Agricultural Marketing Service disagreed with all of our conclusions. USDA stated that the Pesticide Data Program can produce data that will benefit EPA's pesticide risk assessments, that information systems supporting data management for the program are being addressed, and that the program has been coordinated with other interested federal agencies. We reviewed USDA's comments and see no reason to change our conclusions. USDA agreed that our recommendations are appropriate and stated that it is addressing them as part of its ongoing evaluation of the program. USDA's comments are reprinted in appendix II. Except for enclosure 3 on information management, we did not reprint the enclosures to USDA's comments because these materials had been previously supplied to us and are reflected in our report as appropriate.

Pesticide Data Program Plan and Objectives

USDA states that the problems we cite with residue data collection are based largely on comparisons with a preliminary planning document that was dependent on funding, agreements with states, and agreement with EPA on data needs. USDA also indicated that the program is in its early stages and has not generated enough data to clearly measure its benefits. USDA agrees that the program is not yet producing statistically reliable residue data. However, USDA maintains that the data being collected will be more reliable than that of pesticide enforcement programs administered by other state and federal agencies. Moreover, USDA states that the data being collected during the first year of the program are meeting EPA's requirements and will be used by EPA for health risk assessments.

Regarding program planning, significant preparation for USDA's Pesticide Data Program transpired during 1990. USDA prepared three publications containing program background, goals, objectives, and schedules for both pesticide usage and residue data collection activities.[10] The first of these was published in May 1990 and subsequently updated in December 1990 and again in February 1991. The updates revised the completion schedules for certain program activities for residue data collection; as such, they reflect slippage from USDA's original plan.

By February 1991—the date of the last program overview document—funding had been established, a data listing had been discussed jointly with EPA, state lab contacts had been established, and sampling site visits had been made. Using the schedule of activities in the February 1991 program document as opposed to earlier planning documents, USDA remains behind schedule in reporting residue testing results to EPA. According to the February 1991 document, USDA expected to deliver its first residue data set by July 1991. However, as of December 1991, USDA had not delivered these data.

Rather than using these schedules, USDA states that it is following a plan outlined in an October 1990 document. However, this document is a draft internal memorandum that does not discuss nor update schedules.

Although USDA agrees that the program is not producing statistically valid residue sampling data—a key program objective—it maintains that the data will still be valuable to EPA. However, the interim sampling plans, using simple random selection techniques, will not produce data representative

[10]"USDA Agricultural Marketing Service Food Safety Data Initiative," May 1990; "USDA's Coordinated Pesticide Data Program," December 1990; and "USDA's Coordinated Pesticide Data Program," February 1991.

at the national or state levels. Devising statistically valid sampling plans for a multi-commodity residue testing program is a complex undertaking, particularly since the marketing structure for fresh fruit and vegetables varies widely from state to state. Further, USDA has not determined the costs of conducting its residue testing program with statistically valid sampling techniques. Instead, it has chosen to use its interim sampling plans to gain more knowledge of fresh fruit and vegetable market distribution patterns, which can help refine future sampling techniques. Compared to the data collected through pesticide safety enforcement activities in other agencies, this approach jeopardizes a fundamental benefit of the program.

Although USDA states that data currently being collected will meet EPA's data needs, EPA officials told us they prefer to view the USDA program as a pilot that can provide supplemental pesticide residue data until it can be determined whether USDA can accommodate more specific requirements.

Interagency Cooperation and Agreements

USDA states that it has reached an understanding with EPA and FDA on program direction and has signed cooperative agreements with the involved states. USDA believes that the program is meeting EPA's needs and does not duplicate existing data. However, USDA agrees that it needs to reach documented agreements with EPA and FDA on the program's direction.

Coordination meetings have occurred regularly, however, written agreements between the three agencies on the program do not exist. The lack of documented interagency agreements for a program of this proposed magnitude, importance, and cost constitutes an alarming weakness in overall program management and jeopardizes accountability for the program's intended objectives. To illustrate, the arrangements between USDA and EPA on specific commodity and pesticide pairings to be tested—and the rationale for the choices made—are not supported by documentation or evidence of review and approval by senior agency officials. Further, unless agreement is reached between FDA and USDA on avoiding data duplication, similarities between USDA's and FDA's residue sampling efforts may become more apparent as FDA moves toward more statistically valid enforcement data. Therefore, our recommendations are aimed at ensuring that an interagency consensus on program direction is achieved among the three involved federal agencies.

Information Systems Planning and Data Management Concerns

USDA states that before June 1991, most of its efforts on the residue program had concentrated on sampling procedures and laboratory methodology. Since that time, USDA believes an information management strategy has been constructed and that steps are being taken to ensure that data collected under its program are being effectively managed with automated systems. In particular, USDA notes that it has designed a data base system capable of handling data management needs until the end of 1992. In addition, a contractor has been hired to develop the mission analysis, concept definition, and automation plan for the residue portion of the program.

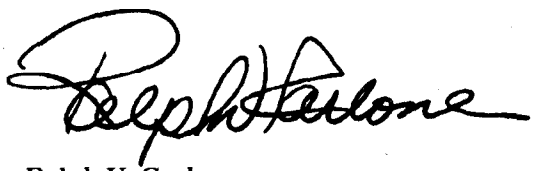
As our report states, the absence of a plan that addresses the information management and technology needs associated with the program poses unnecessary risks for effective data management support. For most of fiscal year 1991, USDA's Agricultural Marketing Service did not actively involve its Information Resources Management Division in determining systems requirements necessary to accommodate inter- and intra-agency data needs. In September 1991, USDA hired a contractor to perform these analyses and this work is now underway.

USDA now believes that it can have a new information system for its residue program implemented by the end of 1992. Based on its review of program scope, USDA believes that program requirements can be satisfied with existing computer resources or minor hardware additions. Yet, with system requirements still largely undefined at this point, the data collection and reporting may be subjected to further changes that could jeopardize the value of the data now being collected.

We conducted our review between November 1990 and January 1992, in accordance with generally accepted government auditing standards. We are sending copies of this report to the Secretary of Agriculture; the Administrator, EPA; the Commissioner, FDA; the Director, Office of Management and Budget; and other interested congressional committees. Copies will also be made available to others upon request.

This report was prepared under the direction of JayEtta Z. Hecker, Director, Resources, Community, and Economic Development Information Systems, who can be reached at (202) 336-6416 if you or your staff have any questions. Other major contributors are listed in appendix III.

Sincerely yours,



Ralph V. Carlone
Assistant Comptroller General

Contents

Abbreviations

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
GAO	General Accounting Office
IMTEC	Information Management and Technology Division
RCED	Resources, Community, and Economic Development Division
USDA	U. S. Department of Agriculture

Objectives, Scope, and Methodology

Our objectives were to determine whether (1) USDA's program is producing the data needed for making improved pesticide regulatory decisions, and (2) USDA has a strategy for managing the data resulting from the program.

To do this, we analyzed program plans and documentation and discussed them with USDA program officials. We interviewed data users at EPA's Office of Pesticide Programs, FDA, and USDA's Economic Research Service and Human Nutrition Information Service. We also interviewed USDA, EPA, and FDA officials who regularly participated in interagency working group sessions that addressed program implementation issues. Additionally, we interviewed officials from the state agriculture departments of Arizona, California, Florida, Michigan, New York, Texas, and Washington to determine each state's ability to provide the requested information.

We identified and examined other sources of pesticide data used by USDA, EPA, and FDA. We met with EPA and FDA officials to discuss EPA's reliance on FDA residue data generated from its surveillance and compliance activities. In addition, we reviewed FDA's most current pesticide residue monitoring plan and compared it with data-collection activities planned for the Coordinated Pesticide Data Program.

To evaluate the adequacy of USDA's information system planning, we examined preliminary system planning and budget documentation at USDA. In the absence of explicit documents outlining USDA's automation strategy, we discussed plans for information systems with USDA program officials and information resources management staff.

USDA's Agricultural Marketing Service provided written comments on a draft of this report. These comments are presented and evaluated in our report.

Comments From the Department of Agriculture

United States Department of Agriculture
Agricultural Marketing Service
P.O. Box 96456
Washington, DC
20090-6456

December 13, 1991

Mr. Ralph V. Carlone
Assistant Comptroller General
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Carlone:

On December 6, 1991, representatives from the General Accounting Office (GAO) met with representatives from the Department of Agriculture (USDA) agencies involved in the Pesticide Data Program (PDP). The representatives from USDA included the Office of Information Resources Management (OIRM), Office of Budget and Program Analysis (OBPA), Agricultural Marketing Service (AMS), National Agricultural Statistics Service (NASS), Economic Research Service (ERS), and Human Nutrition Information Service (HNIS).

At the meeting on December 6, 1991, we provided extensive oral comments on the GAO draft report, and promised to provide written comments as a follow up. This letter and its enclosures constitute our official response to the draft. We urge you to include these comments as an exhibit in your final report.

The GAO draft report is directed at the review of a program for the production of data needed to make improved pesticide decisions, and the USDA strategy for managing the data produced from this program. Additionally, GAO also commented on communications within USDA, and with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) as they relate to this endeavor.

GAO acknowledged in the exit interview that the audit from November 1990 until mid-1991 was conducted when PDP was in its formative stages, and when many of the policy issues and operational procedures were being finalized.

GAO states that the program is not providing improvements in residue data to ensure food safety, and that residue data collection is behind schedule, narrow in scope, and duplicates existing data. GAO concludes that this occurred because of the underestimation of the complexity of the program, and that agreements with EPA and FDA were not reached prior to program implementation. Further, GAO states that problems with the program are magnified by the absence of an information management strategy.

Mr. Ralph V. Carlone 2

The GAO report is replete with inaccurate statements, assesses current and future data requirements incorrectly, and leads readers of the report away from the intent of the program and its many accomplishments. Inquiries for material used in this report began shortly after the program received funding. Conclusions were made about the results of the program long before the 2-year data collection cycle for each commodity-pesticide pairing could be assembled. USDA, on numerous occasions, interacted with GAO investigators and provided detailed records and explanations of program direction and implementation. Materials and explanations of technical and program areas did not get included into this report, nor were they presented in the proper context. Information was included that could focus the report toward an inaccurate conclusion.

The recommendations that GAO has made are appropriate, notwithstanding USDA has and is continually evaluating current data collection activities with EPA and FDA officials, has reached agreement with EPA on the current and future statistical considerations necessary to make any data reliable for EPA's risk assessment needs within the realm of practicality, and is in the process of finalizing a Memorandum of Understanding (MOU) for USDA, EPA, and FDA to formalize a steering committee for future program direction.

This written response is directed at three areas found deficient in the GAO report.

Program Plan

In our exit interview, GAO stated that the source for some of the deficiencies was from an early planning document. AMS pointed out that this was a preliminary document and was dependent upon funding, agreements by the States, and data production as agreed to by EPA. The AMS program implementation in May 1991 was on schedule. AMS is following the plan initially outlined in the October 2, 1990, document and provided this plan to FDA and EPA. (Enclosure 1) PDP is committed by design to meet the data collection needs of EPA for pesticide reregistration.

Sampling

This is the first program where primary sampling is near the consumer level while retaining the identification of product origin. Other programs generally use farm gate, packing houses, ports of entry and occasionally supermarkets for sampling commodities. The AMS initial plan emphasizes random sampling. The proportion of samples to be collected by the States is based on the population. These sampling criteria satisfy EPA's requirements. This is the first program where distribution centers and terminal produce markets are used to provide valuable information on the marketing and origin of produce. As the program develops, this information will be used to further refine the sampling system, using additional statistical considerations. (Enclosure 2)

Cooperation

This is the first time where the efforts and planning of three Federal Agencies (USDA, EPA, and FDA) and six major agricultural production States have been harmonized. From the onset of PDP the Agencies discussed issues and implemented decisions on sampling systems, analytical methods, and data information systems. PDP will provide EPA with national uniform residue data for risk assessment. PDP also enhances interchange with FDA on newer testing technologies, uniform data reporting, and residue issues. AMS is drafting a MOU with EPA and FDA to provide oversight for PDP and the establishment of a "steering committee" for planning.

Title (Page 1)

The title of the response states a conclusion before discussing the individual subject areas. GAO should change the title to a more objective phrase, e.g., "Review of the USDA Pesticide Data Program."

Results in Brief (Pages 1-3)

The report uses terms such as: "overly optimistic," "underestimated," and "complexity." None of these divergent terms accurately portrays AMS' planning or implementation of this program. On the contrary, AMS clearly stated in its program of meetings with other organizations, which were made available to GAO, all of the issues needing to be addressed before implementing sample collection. Sampling was initiated in May 1991, just after the last State cooperative agreement was signed. Terms such as "data which already exists" and "narrow range of crops" are misleading. PDP is designed to generate high quality data. All detected pesticide residues are verified and meet very

sensitive detection requirements. PDP is designed to, and has, reported pesticide concentrations in commodities at levels where other programs cannot detect the pesticide. PDP also provides data on the edible portion of a product and at the distribution level near the consumer. This does not duplicate existing data. PDP has a clearly defined quality assurance system and provides uniform data from the six States.

PDP's mission is to provide actual residue data. Residue data, coupled with toxicology and food consumption data, are then evaluated as part of the risk assessment equation. The quality of the residue data generated by PDP will provide substantive improvements in information for risk assessments decisions.

On the bottom of page 3, "thousands" is incorrect. As of early December 1991, PDP has about 1,300 data records. The information requirements were incorporated into PDP in April, as was part of the sample and laboratory forms currently being used by the States. These forms were reviewed by FDA for compatibility with their nomenclature and forwarded to EPA for their use. In reference to computer resources, the AMS Information Resources Management Division is assessing short-term needs and contracted for design of a system compatible with long-range requirements. Actual data needs will be known after 1 year of data collection. To purchase both hardware and software, prior to data generation, which may not be needed, would not be a prudent expenditure of resources. (Enclosure 3)

Background (Pages 4-9)

On page 4, AMS has responsibility for egg products inspection.

On page 6, we find a conflict in statements made for the inception of PDP. GAO acknowledges that FDA does not produce data commensurate with EPA's needs for risk assessment data. Yet, on page 2 and page 11, the report states that PDP produces the same type of data which is already available. An understanding of the foundation and operation procedures on PDP clearly shows that the data are different between the programs.

On page 9 and again on page 11, the GAO report references an AMS commitment to analyze for 30 commodities and 16 pesticides. Program introduction was developed by phases and was outlined in an October 1990 memorandum. It was never planned or possible to implement the entire EPA request at once, since the resources did not exist in the State laboratories at that time to meet such a massive commitment.

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A list of pesticides (multiresidue and single analyte methodology) was provided by EPA in July 1990. (Enclosure 4) This list referenced only 22 commodities. The 16 pesticides listed by EPA included 9 different analytical methods and at least 6 different extraction systems. (Enclosure 5) AMS introduced 7 chlorinated pesticides in May 1991, and added another chlorinated pesticide in October 1991, making a total of 8. Organophosphates were added in November 1991. The 10 pesticide pairs initially representing 3 commodities were expanded to 7 commodities and 24 pairs.

The GAO report indicated that AMS had planned to issue a report in October 1991 for EPA decision-making concerning risk assessment. Residue data is designed to be collected on a yearly cycle to accommodate all sources of commodities which may be in the marketing chain. These data could be received by AMS weeks after collection. Therefore, an October report date would only be feasible if an entire year's residue data were collected.

Residue Collection Proceeding Slowly and Data Collection Encountering Problems (Pages 10-12)

Although all the correspondence generated by PDP was made available to GAO, the chronology of program events was not accurately presented in the report.

- The GAO report stated that AMS began testing procedures

  5 months late (January 1991 vs. May 1991). An AMS publication entitled, "USDA's Coordinated Pesticide Data Program," dated February 1991, and commonly known as the "Gray Book," references March 1991 for the initial sample collection date.

- Congressional funding including the sequester was not done until January 1991. AMS was using existing resources to plan the program.

- Cooperative agreements were required with the States, which required funding. The cooperative agreements were signed by the respective State Agencies between March 20 and May 16, 1991. Each of the States had to process the agreements through their own administrative offices, which in some States required legislative approval. AMS could not circumvent this process. Therefore, the May 1991 PDP initiation date for testing produce was the earliest date possible, as evidenced by the enclosed sampling report. (Enclosure 6)

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Unrecognized Program Complexities

The 24 commodities/pesticide-pairs being analyzed at present are from the EPA list provided to AMS in July. (Enclosure 4) We expect that these data will be used in EPA's reregistration process sometime in the future. AMS can redirect program resources to test for any specific pesticides/commodities of interest to EPA with appropriate planning and lead time for the participating States to comply. AMS cannot unilaterally change the emphasis of the program.

Unrecognized Program Complexities and Absence of Agreements (Pages 13-15)

The statement in the GAO report regarding underestimation of complexity is incorrect. By May 1991, all PDP operational issues addressing commodity sampling, laboratory testing procedures, and quality assurance were completed. The need for a uniform extraction method for pesticides was overcome by a common detection system and comprehensive quality control requirements to assure data equivalency among the participating States.

Using the chlorinated pesticides as the initial testing basis was the correct decision to maximize the program's data collection efforts, since it covered half of the compounds of interest to EPA.

Interagency cooperation with EPA and FDA has been fundamental in developing PDP and is the primary reason implementation was effectively accomplished. Cooperative efforts for sampling systems, commodity preparation, analytical methods, data compatibility, sensitivity requirements, and other issues to define program policy began in early October 1990 and concluded in May 1991 for the first seven commodities. (Enclosure 7) This process also involved input from the States, since they will be the organizations conducting pesticide residue analysis. The requirements of a testing system specifically for risk assessment versus some programs designed for enforcement are described on Enclosure 8.

AMS also reached a mutual understanding with EPA and FDA on program direction, testing requirements, and minimizing any overlap of program objectives. To reiterate, PDP is predicated on collecting pesticide residue data on commodities at the lowest verifiable concentrations targeting specific pairs. Some other testing programs are designed for enforcing tolerances and collecting surveillance data. In some of these programs, sensitivity for specific compounds may be compromised for the ability to detect a wider array of compounds with limited quality control to determine data integrity.

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A copy of the GAO draft report with revisions from OBPA is included. (Enclosure 9)

Conclusion (Page 19-20)

Based on the information presented in the GAO report, the conclusions are not valid. PDP can produce residue data which will benefit EPA's risk assessment work. The information systems for data management are being addressed, and the program is being coordinated with other interested Federal Agencies.

Recommendations (Page 20)

We accept GAO's clarification at the exit interview not to suspend the present testing effort. We have already acted prior to GAO's recommendation on the need to improve interagency cooperation for a program of this magnitude. In response, we are finalizing an MOU for future program direction and to formalize a steering committee between the three Agencies. The emphasis of this cooperative effort should reflect regulatory missions of both FDA and EPA. The primary use of the residue data produced by PDP is for EPA's risk assessment process in the special review and reregistration of pesticides. The program will cooperate with both Agencies in providing information on violations for enforcement, in introducing new analytical technologies, and in planning testing programs and common data nomenclature systems.

We believe that PDP was designed to develop a data base for risk assessment to meet the needs of EPA for the special review and reregistration of pesticides. PDP by design meets the data quality and random sampling design required for risk assessment studies. All of the program components required to conduct the program were agreed to by the interested Federal Agencies and participating States and have been implemented. We are confident that this program is needed by the Federal Government for making decisions on food safety issues and addressing public perceptions concerning the safety of the Nation's food supply.

I am grateful for the opportunity to provide these comments on your draft report, and I urge you to include them in your final report.

Sincerely,

Daniel D. Haley
Administrator

Enclosures

ENCLOSURE 3

Data Management Concerns

FOOD SAFETY: USDA Program Not Supporting Critical Pesticide Decisions (Page 3)

"The program's problems are further magnified by the absence of an information management strategy. Data collection activities involving thousands of residue data records from laboratories in six States commenced without determining the requirements for supporting the processing and dissemination of this data. As such, USDA does not know if its existing computer resources can meet users' needs."

AMS Response: An information management strategy has been developed over the past 6 months and is currently being implemented. Prior to the summer of 1991, efforts on the PDP had concentrated on sampling procedures and laboratory methodology. Since June, AMS' Information Resources Management Division has been working with the Science Division to address data handling requirements of the program.

A prototype system has been developed which will allow the entry of sample data to begin in December 1991. The system, as designed, will accept data on samples, such as what type of commodity, where in the distribution chain it was collected, and sample weight. This information is matched up with data reflecting the laboratory results from which various reports will be produced. To ensure maximum flexibility, the system has been developed as an ORACLE data base and is designed to run on either a stand-alone microcomputer, or on a network accessed by multiple users. Various levels of security are being developed to allow users access to the data.

Simultaneously with this effort, the Science Division and the Information Resources Management Division of AMS are working with a contractor to develop and document the mission analysis, concept definition, and ADP plan for PDP. These two efforts are not proceeding in a disjointed fashion, the difference between the two is that the contractor-supported effort will address longer term requirements and will expand on the prototype system. Even the expanded system will be met with existing computer resources, or with some minor additions in hardware within the current file server architecture.

"Data Collection Proceeding with Minimal Information System Planning" (Page 15)

"To be useful to the agencies involved, automated systems must process and disseminate large volumes of pesticide information in a timely fashion to support the Pesticide Data Program. To ensure that available computer resources can do that, USDA's regulations require that responsible organizations determine the resources required to manage data before they are collected. However, even though data collection is underway, USDA has not developed a strategy to determine whether available computer resources can adequately process or disseminate the data, or whether new systems will be necessary. As a result, USDA risks not meeting program objectives because the agency does not know if its information systems can provide the collected data to USDA, EPA, and FDA in a timely and cost-effective manner to best meet users' needs."

AMS Response: AMS information systems will provide data to other USDA agencies and to EPA and FDA in a timely and cost-effective manner. The file servers being implemented in the AMS Science Division will have the ability to transmit data via telecommunications, provide ASCII data on diskettes, and produce hard copy reports. Details regarding the content of the data are being considered as part of the contractor study being performed, and the physical ability to exchange data has been accounted for. Since the system will process sample data, even an expansion in the number of States, commodities, and pesticides measured will not exceed the capacity of the file server architecture being planned.

"USDA Has Not Adequately Assessed Residue Information System's Requirements" (Page 17)

"USDA officials are in the midst of receiving thousands of residue data records from laboratories in the six participating states. This requires a well-defined process for collecting, organizing, maintaining, and disseminating the data. Despite this, USDA has not determined whether it currently has the information management resources necessary to manage this data in accordance with program objectives. Instead, it has decided to purchase microcomputers and use off-the-shelf data-base software to manage the information until a formal system requirements analysis is performed. USDA officials stated that for the past year they have been preoccupied with addressing sampling and laboratory procedures, and therefore decided to set aside information management issues until later."

AMS Response: It is true that prior to the summer of 1991 efforts on PDP concentrated on sampling procedures and laboratory methodology. The criticism as stated in the draft report may have been valid in June 1991, but the efforts of the past 6 months are virtually ignored in the report. The selection of an ORACLE data base on a file server in a network environment is not considered merely a stop-gap measure, but a viable architecture

for PDP's future needs. While the data base software is a commercial product, significant custom development has been and will be required, therefore, it is incorrect to identify present software as an off-the-shelf system. A viable system is being implemented which will be expanded over the next year.

"USDA officials do not expect a new system to become operational until 1993. Because USDA does not intend to implement a system to collect, organize, and disseminate the data until 1993, it places the value of the data now being collected unnecessarily at risk." (Page 18)

AMS Response: Preliminary estimates were made projecting a 1993 implementation before the size of the system was known. This was based on a worst-case scenario which assumed that major hardware purchases would be required which would involve various levels of technical approval, delegation of procurement authority, a request for proposals, and a fully competitive procurement. Since the objectives of the system can be achieved with sample data, the volume will never be such that a large hardware procurement will be necessary. This effectively reduces the time estimates by about 1 year. Entry of sample data will begin in the first quarter of FY 1992, preliminary reports will be produced in the second quarter of FY 1992, and machine readable data will be available to other Agencies in the third quarter of FY 1992.

Recommendations (Page 20)

"...suspend residue data collection activities beyond the current efforts to determine data collection capabilities and logistical requirements...."

AMS Response: If this means that new States, commodities, and pesticides should not be added until analysis of the effectiveness of the original data is performed, that would be prudent and make sense. If it means that current efforts at collection of data be suspended, there would be inadequate information available to asses the value of the system.

(Page 21)

"...the Department's Office of Information Resources Management... develop and implement an information technology strategy, plan, and implementation schedule...."

AMS Response: AMS has kept the Department informed of our efforts in PDP through of our annual IRM plans and all budget submissions. The effort was, in fact, highlighted in our IRM plan submission under the heading "Cross-Cutting or Interagency Program Supported." It was also included in our report to the Department for inclusion in the "Secretary's Annual Report to the President 1991." We have contacted OIRM and are not adverse to additional OIRM involvement.

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