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Report to the Secretary of Agriculture

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U.S. DEPARTMENT OF AGRICULTURE

Improving Management of Cross- Cutting Agricultural Issues



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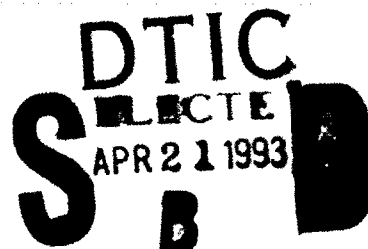


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Resources, Community, and
Economic Development Division

B-238361

March 12, 1991

The Honorable Clayton Yeutter
The Secretary of Agriculture

Dear Mr. Secretary:

This is one of several reports on the management of the U.S. Department of Agriculture (USDA). These reports are part of a series of GAO management reviews of major departments and agencies. In October 1989 we reported our interim findings on USDA to you.¹ As you know, USDA is composed of 36 agencies, under the leadership of two under and seven assistant secretaries. Traditionally, policies are established and implemented by the agencies responsible for a particular area. However, a growing number of issues, which we call cross-cutting issues, must be dealt with by more than one agency. These issues not only cut across agencies, but also across areas for which individual under and assistant secretaries are responsible.

We assessed the Department's effectiveness in managing cross-cutting issues and identified ways for improving its management of these issues. We chose to review three of these emerging issues—food safety, agricultural biotechnology, and water quality—because they are representative of concerns requiring senior management attention.²

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Results in Brief

USDA has not developed an approach for managing cross-cutting issues that gives it a cohesive departmentwide strategy in any given area. Rather, management generally relies on ad hoc groups or individual agencies to develop policies and plans. These agencies implement and monitor their specific responsibilities in a cross-cutting issue. However, uncoordinated agency efforts cannot achieve an integrated, departmental perspective.

For the three cross-cutting issues we reviewed, these agency efforts have led to narrowly focused or insufficiently defined policies and fragmented planning and monitoring efforts. As a result, USDA is missing opportunities to deal with pressing national needs, duplicating efforts to

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¹U.S. Department of Agriculture: Interim Report on Ways to Enhance Management (GAO/RCED-90-19, Oct. 26, 1989).

²We also reported on USDA's water quality activities in Agriculture: USDA Needs to Better Focus Its Water Quality Responsibilities (GAO/RCED-90-162, July 23, 1990).

meet specific concerns, and delaying overall departmental progress because differences among agencies are not quickly resolved

Recognizing that USDA can better manage its multi-agency efforts, you have instituted the Secretary's Policy Coordination Council to formulate departmental policy on issues requiring coordination across two or more under or assistant secretaries. You have also implemented the President's management-by-objectives (MBO) system at USDA. However, in part because staff support for the Council has been limited and the Department has faced difficulties in defining the roles of the Council, MBO system, and other coordinating mechanisms, departmental management has not fully developed these initiatives into an integrated, comprehensive approach for managing multi-agency issues.

As a result, the Department has not developed clear, comprehensive goals and policies for cross-cutting issues and has not established a comprehensive capability for monitoring and evaluating progress from a departmental perspective. We believe that with some modifications, the Council and MBO system could be used to develop a comprehensive and integrated approach to assist USDA in overcoming its agency-specific orientation to multi-agency issues and enhance its ability to provide effective policy leadership in these areas.

Background

USDA has traditionally encouraged U.S. agriculture to provide an abundant supply of reasonably priced food by improving and stimulating production. This approach has been successful, but recently it has begun to conflict with issues involving public health, safety, and the environment. As a result, USDA must manage for farm productivity while considering the effect of farm production on these emerging issues.

Each of these issues cuts across numerous USDA agencies and involves other federal departments and agencies, as well as state governments. Within USDA, they involve multiple under and assistant secretaries and from 8 to 12 agencies. We looked in general at the management of these issues from a departmental perspective to identify common problems.

USDA Needs an Effective Approach for Cross-Cutting Issues

USDA must marshal its agencies' considerable experience and resources into cohesive departmentwide strategies if it is to address cross-cutting issues successfully. To develop such strategies consistently, USDA needs a management approach that defines and links the basic management functions—policy-setting, planning, implementing, and monitoring. Clear departmental policies establish a foundation for effective planning and program implementation. Monitoring systems enable senior Department officials to evaluate USDA's overall progress in achieving policy goals. However, the Department has yet to develop such a systematic management approach.

In the food safety, biotechnology, and water quality areas, policies are either narrowly focused or insufficiently defined because USDA lacks an effective management approach. In addition, plans and monitoring efforts target narrowly focused agency activities and do not comprehensively address all the major components of each cross-cutting issue.

Narrowly Focused Food Safety Efforts Mean Missed Opportunities and Duplication

USDA does not have a comprehensive food safety policy and plan. Instead, in response to legislative mandates, agencies develop independent policies to achieve specific aspects of food safety. Consequently, the departmentwide concern for ensuring a safe food supply is expressed through narrowly focused and sometimes duplicative efforts. A comprehensive policy establishing goals and objectives and a plan detailing how to achieve these goals could help to ensure the Department's effective integration of agencies' activities.

Lacking a comprehensive policy, USDA misses opportunities to address food safety concerns. For example, the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) each have legislatively mandated responsibilities—APHIS focuses on animal health, FSIS on human health. The Department has not addressed the relationship between the two agencies' responsibilities by recognizing the link between animal production practices, animal disease and human health. For example, salmonella enteritidis, an organism transmitted through poultry to eggs, has little impact on animal health but causes food poisoning in humans. Because salmonella is a human health concern, APHIS did not until recently have the authority to implement controls that would detect the disease in the animals and restrict its transmission to humans. Upon determining that this organism does affect animal health, APHIS did institute stronger controls to restrict its spread among animals; however, the agency still has no direct authority to restrict its spread among humans.

With a departmental food safety policy, APHIS officials told us, the agency could expand its role in the food safety area. For example, APHIS animal and plant specialists could analyze the causes of animal and plant diseases and examine their impact on food safety and human health. Without such a departmentwide policy, however, APHIS is reluctant to devote the resources needed to collect and analyze such data.

In addition, duplication can occur without a departmentwide plan. For example, FSIS and the Extension Service (ES) provide similar services to answer consumers' inquiries. FSIS operates a hotline, which receives about 50,000 calls a year, to answer the public's meat and poultry questions. ES, with its vast network of county agents, answers over 3 million calls a year on food safety. Each agency brings different strengths and expertise to bear on the issue. With the increasing focus on food safety, FSIS and ES are beginning to discuss coordinating their efforts but are still operating independently. A departmentwide plan would address agency policy and procedures needed to deal with public inquiries about food safety. With such guidance in place, FSIS and ES could better decide how to integrate their separate systems.

Insufficiently Defined Policies Delay Biotechnology Guidelines

USDA has a major leadership role in safely harnessing the agricultural promise of biotechnology, an area of science that could revolutionize the production of food and fiber by allowing scientists to transfer genes between related or unrelated organisms to improve plants or animals. USDA's challenge is to improve the nation's international agricultural competitiveness by applying biotechnology so as to balance its benefits to humanity and risks to the environment.

In March 1986 we reported on USDA's early efforts to develop a biotechnology regulatory system and observed that the Department's success in the area depends on all parties working together toward common goals.³ We also expressed concern that USDA researchers and regulators were struggling over who would be given prime responsibility for biotechnology and recommended that the Secretary provide the Department's biotechnology coordinating committee with the authority to resolve differences among USDA's agencies.

Since our March 1986 report, USDA has refined its organizational systems and structure for managing biotechnology-related activities. For

³For further information, see our report *Biotechnology: Agriculture's Regulatory System Needs Clarification* (GAO/RCED-86-59, Mar. 25, 1986).

example, it has established broad biotechnology policies; delegated research and regulatory responsibilities to specific agencies; and established three coordinating groups—an assistant secretary-/agency administrator-level committee (the Committee on Biotechnology in Agriculture), a small staff office supporting the committee (the Office of Agricultural Biotechnology), and a program manager-level council (the Biotechnology Council). However, USDA has not developed a goal-oriented, departmentwide approach to biotechnology. Specifically, the Department has not sufficiently defined its biotechnology policies, developed USDA-wide biotechnology goals, or provided its coordinating organizations with enough authority to implement a departmentwide program.

As a result, USDA has not successfully dealt with differences among research and regulatory agencies concerning how each group should oversee proposed field tests of genetically altered organisms. Researchers who must field test genetically improved plants and animals before the public will accept these improvements generally believe that they should have some latitude to review and approve low-risk projects. In contrast, USDA regulators believe that their legislative responsibility to protect the nation's agriculture gives them the authority to review and approve researchers' test plans for outdoor biotechnology experiments.

Without departmental guidance clarifying how agencies can balance researchers' and regulators' biotechnology views, USDA has experienced difficulties and delays in developing administrative research guidelines for conducting safe outdoor biotechnology experiments. In 1986, APHIS issued regulations requiring researchers to obtain agency permits to field test plants that have been genetically altered using genes from either known or suspected plant pests. But separate USDA administrative guidelines for conducting field tests, which would cover projects not regulated by APHIS, have only recently been drafted for public comment by USDA's biotechnology staff office and biotechnology research advisory committee—4 years later. These draft guidelines addressed researchers' perceptions that APHIS regulations overly restrict biotechnology progress by proposing an alternative, decentralized approach to expedite USDA approval of outdoor research projects. However, APHIS does not agree that its regulations are impeding research and has reservations about the guidelines' approach to project approval.

We continue to believe that, given appropriate authority and accountability, USDA's biotechnology committee could potentially resolve such differences and develop departmentwide biotechnology goals and plans. However, USDA management has not given the committee such authority and responsibility. Without these, the committee has not addressed interagency differences or developed departmentwide goals and plans to guide agencies' activities. Instead, it has generally focused on coordinating administrative matters and exchanging information among its members.

USDA's management has also not assigned clear responsibility to the biotechnology committee or supporting staff office for monitoring the Department's overall biotechnology progress. Without a specific mandate for monitoring from the Secretary, the committee and office have not examined whether, from a departmental perspective, USDA's regulatory, research, and education programs are moving biotechnology ahead while balancing the competing goals of international competitiveness and environmental protection.

USDA groups have repeatedly disagreed about the supporting staff office's precise role and responsibilities. Although departmental management has twice affirmed that the office is responsible for coordinating all USDA biotechnology activities, the Department has not clarified how far the office's responsibility extends. According to APHIS, the Department's 1986 delegations of biotechnology authority gave APHIS exclusive authority for such coordination. This difference of opinion has frustrated office personnel and increased tensions between regulators and researchers.

Broad Water Quality Policy Does Not Ensure Agency Actions

In response to increased concern that agricultural production practices can adversely affect water quality, USDA has expanded and attempted to refocus its water quality programs. In 1986 and 1987, it developed policies on nonpoint source pollution and groundwater quality, respectively.⁴ In fiscal year 1990, USDA began its Water Quality Initiative to expand ongoing water quality programs and start new ones. It also established an interagency working group to coordinate the Department's water quality activities. In September 1990, following our July

⁴Nonpoint pollution originates from diffuse sources, such as farm fields, as opposed to a point source, such as an outflow pipe or production facility. Studies show that agriculture is one of the main contributors to water degradation.

1990 water quality report, the Department issued a single, broad water quality policy.

In our July 1990 report we recommended that USDA establish a single, comprehensive water quality policy to effectively guide its activities. At that time, the Department's policies were incomplete and uncoordinated. Its 1986 and 1987 policies did not address point source contamination of surface water.⁵ In addition, these policies could work at cross-purposes because they did not recognize that practices used to protect some types of water sources could harm others. For example, ridge tilling farming practices, aimed at reducing the runoff of agricultural chemicals from the land into surface water in compliance with the nonpoint source pollution policy, could contribute to groundwater pollution when water percolates through the soil to groundwater supplies and takes chemical contaminants with it. Similar problems could occur when, to achieve the high yields encouraged by USDA commodity programs, farmers use agricultural chemicals that have been associated with long-term damage to soil and water quality.⁶

USDA's new water quality policy, which states that the Department will foster agricultural and forestry practices that protect and enhance ground and surface water resources, is a step in the right direction. However, the policy does not specifically state how the Department plans to address the concerns raised in our July 1990 report. In addition, it does not provide guidance or interpretation for achieving its objectives. Finally, the policy does not consider the feasibility of using penalties and/or incentives in commodity programs to improve water quality, as we recommended. Without more detailed guidance, we believe that the agencies responsible for achieving water quality objectives will have difficulty focusing on a common departmental objective.

We also reported in July 1990 that USDA did not have an effective management structure for planning, coordinating, and evaluating its water quality activities. Although USDA considers its new water quality working group responsible for these activities, the group, consisting of representatives from the Department's agencies with water quality activities, has only one essentially full-time staff member. In addition, the group does not have a clear mandate to manage all the Department's

⁵Other laws and regulations may apply to point source contamination, but the lack of a similar policy at USDA could create the impression that the Department condones such activities.

⁶Details of the specific conflicts among these programs are discussed further in our July 1990 water quality report.

water quality activities. For example, the group's water quality plans do not include USDA's Low-Input Sustainable Agriculture program, which is intended to provide farmers with alternative farming methods that could improve water quality while sustaining agricultural production.

Similarly, USDA's water quality working group has not developed a comprehensive water quality monitoring program—more than a year since the group prepared plans for its new Water Quality Initiative. The group does not have the authority to monitor the progress of the Department's total water quality effort or to change the direction of programs, if necessary. Instead, it oversees only the programs targeted by the Water Quality Initiative, which represent a small part of the Department's total water quality effort.

To remedy these problems, we recommended in July 1990 that USDA establish a departmentwide focal point or coordinating body, supported by dedicated, full-time staff, to be responsible for managing all aspects of the Department's water quality activities. In addition, the Food, Agriculture, Conservation, and Trade Act, enacted in November 1990, contains provisions affecting USDA's management of water quality. This act requires USDA to establish a Council and Office of Agricultural Environmental Quality to coordinate and direct all USDA environmental policies and programs. The act also requires USDA to develop a policy statement identifying the Department's goals and objectives for addressing the effects of agriculture on environmental quality and an implementation plan detailing how the Department proposes to address its policy goals.

Management Initiatives Do Not Overcome Weaknesses

As Secretary of Agriculture, you have adopted two major initiatives to improve the Department's management of cross-cutting issues: the Secretary's Policy Coordination Council and the MBO system. These efforts embrace the principal management functions essential for effectively addressing cross-cutting issues—policy-setting, planning, implementing, and monitoring. However, these efforts are not sufficiently comprehensive or integrated with other management mechanisms to establish a departmentwide approach to cross-cutting issues.

In the policy area, the Council is the Department's major mechanism for formulating departmental policy on cross-cutting issues. The Council, chaired by the Deputy Secretary, includes the under and assistant secretaries, the general counsel, and the director of public affairs. To date, the Council has set up working groups to address certain cross-cutting issues: water quality, food safety data, rural development, climate

change, and commercialization of industrial applications for agricultural products.

The Council has helped bring a departmental perspective to these issues. However, in the food safety area, we found that the Council has not comprehensively addressed or anticipated many facets of the issue. For example, the Chairman of the Council announced a fiscal year 1991 Food Safety Data Initiative in response to the Alar-in-apples crisis. The initiative focuses on collecting pesticide residue data on produce. However, it does not address emerging food safety concerns involving new types of food production and preparation technologies, new animal and plant production methods involving chemical use, or new microbiological concerns. With or without a departmentwide approach to food safety issues, USDA will have to respond to these concerns. If the Council does not develop the means for anticipating them, it will continue to react to, rather than proactively confront, emerging food safety problems.

Moreover, the Food Safety Data Initiative illustrates the problems that develop when a policy is reactive and does not take a longer view. Under this initiative, the Department would collect much of the data that were routinely collected before 1982 as part of an effort that was then discontinued because of budget pressures. Because USDA did not have data available, it could not effectively refute the charges that Alar posed a threat to human health.

The Council's limitations in addressing cross-cutting issues occur, in part, because Council members' primary commitments are, and must be, to addressing their agency's short- and long-term priorities. Council members faced with these more limited responsibilities have difficulty developing comprehensive policies for particular cross-cutting issues. Moreover, the Council's one-member support staff is not enough to overcome this agency focus. In addition, because their tenures are generally short, members may not have an institutional memory of the issues. As a result, the Council may not develop a long-term perspective on issues that require sustained efforts to ensure progress.

Like the Council, USDA's MBO system affords management an opportunity to improve its approach to cross-cutting issues. USDA uses its MBO system primarily to monitor two major agricultural goals—the expansion of U.S. agricultural markets and the encouragement of environmentally sound agricultural policies. The Department has defined milestones to

gauge its progress toward these goals and has assigned officials responsibility for achieving these milestones.

However, USDA is not fully using the MBO system as an integrated planning and monitoring tool. In its 1989 announcement of MBO, the Office of Management and Budget described the new system's multiple uses—to identify major goals, develop strategic plans for achieving these goals, and identify critical milestones for monitoring their progress. To identify the activities and milestones needed to achieve its goals, USDA selected existing agency activities, instead of conducting a comprehensive analysis to define the activities that would best achieve its goals. This approach generated a tracking system that monitors existing efforts, rather than strategic plans that define comprehensive approaches for achieving goals.

In addition, the MBO system does not comprehensively track all activities of USDA's two major goals. For example, improving water quality is a major feature of the Department's environmental goal. However, in monitoring water quality, the MBO system primarily tracks activities of the Department's new Water Quality Initiative, instead of all USDA water quality activities.

Partly because of these limitations, as well as USDA's experience with previous MBO systems, MBO has not been well accepted in the Department. Some senior agency officials responsible for implementing MBO in their agencies view it as a paperwork exercise. Therefore, MBO is unlikely to be effective as a monitoring, much less as a planning tool.

Finally, both the Council and the MBO system could be more effective if the Department were to integrate the policy, planning, implementing, and monitoring functions of each. For example, the Council is developing a monitoring system independent of the MBO system, requiring progress reports from its working groups on their efforts in cross-cutting issues. The Council system will contain milestones for some of the issues that are also being reported under the MBO system. Integrating the two systems could avoid duplication. Similarly, the activities of the Council and MBO can be better integrated with the limited policy and monitoring activities conducted by other multi-agency groups, such as the biotechnology coordinating committee and office. We believe the Council and the MBO system could provide the Department and the Secretary with a unified and integrated management system for developing policies, plans, and monitoring efforts to help ensure that all departmental activities are contributing to major goals.

Conclusions

USDA managers must deal with a growing number of policy issues that require close coordination of several internal agencies and other federal departments. Several mechanisms to manage these cross-cutting issues have not effectively addressed management problems concerning the issues we reviewed—food safety, biotechnology, and water quality. Departmental policies do not always exist, are too narrowly focused, or are too general to guide the agencies effectively. Plans are not comprehensive and do not have clear goals and objectives. Monitoring efforts are generally agency-specific and do not provide management with a departmentwide perspective.

USDA is attempting to solve these management problems, which have developed and existed over the years. Specifically, the Secretary's Policy Coordination Council and new MBO system, can, if properly implemented, strengthen USDA's management of cross-cutting issues. These actions are attempts to deal with the management challenges of balancing competing agricultural, environmental, and consumer interests and to overcome the Department's decentralized structure. As such, they are positive steps toward developing a comprehensive management approach for addressing complex issues.

However, these efforts do not consistently overcome the limitations of narrow agency perspective to provide effective management oversight of multi-agency programs. As a result, USDA management cannot ensure that its multi-agency policies and programs effectively anticipate and respond to such issues of national concern as food safety, biotechnology, and water quality.

We believe USDA could more effectively use its Council and MBO system in establishing a comprehensive and integrated approach for cross-cutting issues. Although some of the Council's limitations—the short tenure and dual responsibilities of its members—cannot easily be addressed, others, such as the level of staff support, can be. We believe that providing additional staff, under the authority of the Council, to support the Council in overseeing cross-cutting issues would help institutionalize a departmentwide approach for managing cross-cutting issues.

Likewise, we believe USDA could better use the MBO system for planning, implementing, and monitoring by comprehensively analyzing the activities needed to meet its goals and objectives and developing new implementation plans and relevant milestones to achieve these goals. These efforts should also be integrated with other departmental planning and

monitoring activities, such as the activities of the Council and departmental committees and offices responsible for coordinating cross-cutting issues.

These changes would provide USDA with a more comprehensive, integrated approach and would help to ensure that the basic management functions—policy-setting, planning, implementing, and monitoring—are mutually supportive. With top management commitment and enough resources to fully implement policy, planning, and monitoring improvements, USDA managers will be better able to adapt to the many challenges facing American agriculture.

Recommendations to the Secretary of Agriculture

To develop a comprehensive and integrated approach for addressing cross-cutting issues, we recommend that you

- define clear and comprehensive goals and policies for all major cross-cutting issues to provide a basis for developing strategies for achieving the goals;
- strengthen coordination among USDA agencies by defining and clarifying the roles and relationships of the Council, USDA coordinating committees and offices, and the MBO system in setting policy, planning and implementing activities, and monitoring progress;
- strengthen the Department's monitoring and evaluation capability by integrating existing reporting and monitoring activities, such as the MBO system, the Council, and multi-agency committees; and
- enhance USDA's capacity for strategic action by providing enough staff support for the Secretary's Policy Coordination Council to carry out its departmentwide responsibilities.

To solve specific problems identified in food safety, biotechnology, and water quality, we recommend that you

- develop departmentwide food safety and agricultural biotechnology plans that articulate more specific USDA goals and policies. This effort could serve as the model for developing an integrated departmental approach to managing cross-cutting issues.
- expand the role of the Department's biotechnology committee to monitor and report on the Department's overall progress in biotechnology. This expanded role could provide a model for other departmental efforts to create an integrated monitoring system.

Agency Comments and Our Evaluation

USDA did not comment on our recommendations, stating that it would address our recommendations in discussions with appropriate Committees of the Congress.

USDA stated that it had made a great deal of progress in coordinating its activities and would continue to make progress under the Food, Agriculture, Conservation, and Trade Act of 1990. As we state in our report, we consider the Department's establishment of the Policy Council and the MBO system as marks of progress. We also updated our report to recognize the act's provision requiring USDA to establish a Council and Office of Agricultural Environmental Quality to coordinate and direct all USDA environmental policies and programs and agree that these structures will assist the Department in managing water quality and other environmental concerns. However, the act does not contain similar provisions for other cross-cutting issues. Therefore, we continue to believe that action on our recommendations is needed to address other cross-cutting issues more successfully. (See app. V.)

The appendixes detail our examination of USDA's efforts to manage selected cross-cutting agricultural issues. Appendix I discusses the results of our food safety work; appendix II describes our agricultural biotechnology work; appendix III summarizes our July 1990 report on USDA's water quality activities; and appendix IV describes our objectives, scope, and methodology.

We conducted our work between August 1989 and May 1990, with updates through October 1990, in accordance with generally accepted government auditing standards. During this review, we consulted with Charles F. Bingman, member of the National Academy of Public Administration. This work was performed under the direction of John W. Harman, Director of Food and Agriculture Issues, who may be reached at (202) 275-5138. Major contributors are listed in appendix VI.

We are sending copies of this report to the Director, Office of Management and Budget, and to interested congressional committees and subcommittees. We will also make copies available to others upon request.

Sincerely yours,



J. Dexter Peach
Assistant Comptroller General

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Abbreviations

ABRAC	Agricultural Biotechnology Research Advisory Committee
AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CDC	Centers for Disease Control
CSRS	Cooperative State Research Service
EPA	Environmental Protection Agency
ERS	Economic Research Service
ES	Extension Service
FDA	Food and Drug Administration
FGIS	Federal Grain Inspection Service
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
HACCP	Hazard Analysis and Critical Control Point
MBO	management-by-objectives
NASULGC	National Association of State and Land-Grant Universities
USDA	U.S. Department of Agriculture

USDA Needs to Define and Pursue an Aggressive Food Safety Policy

Food safety is a long-standing concern of the U.S. Department of Agriculture (USDA). In the past, USDA has addressed this issue through such agencies as the Food Safety and Inspection Service (FSIS), the Agricultural Marketing Service (AMS), and the Extension Service (ES). Increasingly, however, food production is becoming more technically sophisticated and the public more knowledgeable and concerned about the effect of technology and production practices on the food supply. The agencies with traditional food safety responsibilities are not well organized to address these new and complicated issues across the food chain. Now, the challenge for USDA is to balance the need for food safety with the need for efficient and stable production of food.

This appendix discusses the public's growing concern with food safety; USDA's food safety activities, including initiatives responding to that concern; and the management difficulties that have developed because USDA does not have a departmental policy on food safety.

Growing Consumer Concerns About Food Safety

Although no major food safety disaster has occurred, many well-publicized food safety incidents over the past 2 years have heightened consumer concern with both the safety and quality of the food supply. They include

- Alar—a chemical that regulates appearance and growth—on apples;
- salmonella—an organism that causes a food poisoning in humans—outbreaks in eggs and poultry;
- natural carcinogens and toxins, such as aflatoxin, in the food supply;
- changes in meat and poultry inspection systems that, if not properly implemented, may generate concerns about the safety of these products;
- hormones in beef and milk;
- chemical residues in milk;
- heptachlor—a pesticide—contamination in pork and sausage;
- pesticide residues on produce, such as aldicarb on potatoes, and
- cyanide on grapes from Chile.

According to the Centers for Disease Control (CDC), precise data on the extent of food safety problems are difficult to obtain, largely because some problems go unreported. However, CDC and the Department of Health and Human Service's Food and Drug Administration (FDA) estimate that from 6.5 to 33 million Americans get sick and 9,000 die each year from contaminated food. In addition, the Environmental Protection Agency (EPA) estimates that pesticide residues in food might cause up to 6,000 cancer cases each year.

USDA's Traditional and New Food Safety Activities

Many of USDA's food safety responsibilities are defined by legislation.¹ Others, involving education and research, have developed because of the close relationship between agricultural production, distribution, and food safety. In addition, USDA is working on several new initiatives in response to recent food safety incidents. However, USDA does not have a comprehensive policy or strategic plan for comprehensively addressing all of its food safety responsibilities.

Table I.1 summarizes the actual, estimated, and requested budget for USDA food safety activities. It includes data on new initiatives, discussed later in this appendix.

**Table I.1: USDA's Food Safety Program
Expenditures**

Dollars in millions

Program	Program Level		
	1989 actual	1990 Current estimate	1991 Budget request
Ongoing Efforts			
Food Safety and Inspection Service	\$23.0	\$26.0	\$27.0
Extension Service	6.0	6.0	8.0
Federal Grain Inspection Service	0.3	0.3	0.4
Agricultural Marketing Service	9.3	9.6	11.2
Animal and Plant Health Inspection Service	0.5	0.0	0.0
Research			
Economic Research Service	0.3	0.3	0.7
Agricultural Research Service	25.2	27.5	38.3
Cooperative State Research Service	6.8	8.0	7.6
New Initiative			
Agricultural Marketing Service	0.0	0.0	15.8
National Agricultural Statistics Service	0.0	0.0	7.0
Economic Research Service	0.0	0.0	1.2
Human Nutrition Information Service	0.0	0.0	1.0
Total	\$71.4	\$77.7	\$118.2

Source: 1991 Budget Summary.

¹Other federal agencies also have significant food safety responsibilities. FDA has regulatory authority over all foods except meat and poultry shipped in interstate commerce. EPA sets registration and tolerance levels for pesticides that contaminate food.

USDA's Traditional Food Safety Responsibilities

All USDA regulatory responsibilities for food safety fall under the Assistant Secretary for Marketing and Inspection Services. However, the Assistant and Under Secretaries for Economics, Science and Education, Government and Public Affairs, and International and Commodity Programs also have food safety responsibilities.

Under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), USDA inspects the slaughter of livestock and poultry and the processing of meat and poultry products shipped interstate or to foreign markets. The primary objective is to ensure that meat and poultry products are produced under sanitary conditions, are wholesome and not adulterated, and are properly marked, labeled, and packaged. FSIS administers USDA's responsibilities for meat and poultry inspection. In addition to FSIS, AMS is responsible, under the Egg Products Inspection Act (21 U.S.C. 1031-1056), for inspecting all egg-processing plants and preventing unsanitary eggs from reaching the consumer.

Several USDA agencies have nonregulatory roles in food safety. FSIS develops and provides educational materials for consumers to help them avoid health problems resulting from eating mishandled meat and poultry. ES provides information to consumers on handling and preparing food and to producers on the effects of animal and plant production practices on food safety. The Agricultural Research Service (ARS) undertakes, primarily at other USDA agencies' request, food safety research projects. And the Federal Grain Inspection Service (FGIS), upon request, inspects grain for problems such as aflatoxin, a naturally occurring toxin.

USDA's New Food Safety Activities

In response to consumer concerns, USDA is working on several new food safety activities. Among these, the Food Safety Data Initiative and the President's Food Safety Plan have high priority. Other ongoing food safety work is receiving increased attention.

Food Safety Data Initiative

With the Food Safety Data Initiative, USDA plans to develop a data base to support decisions and policies on chemical use and residues in the food supply. USDA also intends to use the data to help farmers make more informed decisions on chemical use. USDA is requesting \$25 million for fiscal year 1991 for this initiative. The program's primary emphasis will be on collecting data about pesticide residue on produce for preventive action and educational purposes.

The proposal will involve four USDA agencies. AMS will distribute funds to states for pesticide residue testing. The National Agricultural Statistics Service will complete a 3-year cyclical survey of farm pesticide use for 30 commodities. The Economic Research Service (ERS) will analyze the impacts of alternative pesticide regulations and policies. The Human Nutrition Information Service will estimate actual levels of exposure to pesticides in the total population and in specified subpopulations. In addition, USDA is consulting with EPA, FDA, and state governments on this initiative. According to USDA, the data base will also support USDA's activities in improving water quality, influencing pesticide regulation, setting research priorities, and educating producers.

USDA's Deputy Secretary initiated this proposal largely in response to the Alar-in-apples crisis.² USDA had previously collected much of the data discussed in this initiative as part of its national-, regional-, and state-level surveys. It had conducted five national surveys between 1964 and 1982, as well as many commodity-specific surveys. These surveys collected data on pounds of active ingredient used, application rates, acres treated, and pesticide expenditures. But because of budget constraints and changing priorities, the number and extent of surveys decreased significantly after 1982. ERS, the agency responsible for collecting the data, realized that the shortage of data was a major limitation, for without these data, USDA had to make assumptions about the environmental, health, and safety effects of pesticide use. Such lack of data limits confidence in the Department's assumptions and subsequent policy decisions.

This initiative illustrates the difficulties that can occur without a long-range strategic plan to guide USDA's efforts. In the absence of such a plan, the budget tends to become the main planning instrument. However, as occurred in this instance, important efforts are vulnerable to elimination with a budget-driven approach. When funding priorities are established annually, efforts like data collection can languish until a crisis occurs, at which time they again become a high priority.

President's Food Safety Plan

The President's Food Safety Plan proposed significant revisions to the two major statutes regulating pesticides.³ These changes are designed to eliminate unacceptable risks to public health and to provide for more

²In 1989, environmental groups called the continued presence on apples of Alar, an agricultural chemical used to regulate apple appearance and growth, "intolerable" because high doses of the chemical cause cancer in laboratory rats.

³Pesticides are currently regulated under the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act.

orderly and uniform regulation of pesticides and their use. The proposal is also intended to improve coordination among the concerned federal departments and agencies by specifying where and when consultation among these organizations should occur in the regulatory process. USDA, EPA, and the Department of Health and Human Services developed the proposal as a comprehensive approach to pesticide regulation. The Congress is considering the proposal, and USDA is working with the relevant committees to develop legislation.

Expanding Communication Efforts

In response to recent food safety incidents and the growing recognition of food safety as a cross-cutting issue, several groups within USDA have initiated crisis response policies and programs. The Assistant Secretary for Marketing and Inspection Services, concerned about how USDA dealt with the Alar-in-apples crisis, decided that improved public communications were necessary. The Assistant Secretary developed a crisis response plan to provide an organized framework for responding to major reported incidents. The Department's Office of Public Affairs developed a similar initiative. Issue strategy teams, developed around the most pressing concerns facing the Department, including food safety, were established to develop coordinated responses to problems reported in the media. Either the Assistant Secretary's or the Office of Public Affairs' plans will be used to respond to crises, depending on the level of coordination required.

Finally, in late 1989, USDA created an ad hoc task force, consisting of staff from the Foreign Agricultural Service, FSIS, the EPA, FDA, the U.S. Trade Representative, and the State Department, to coordinate the nation's response to foreign governments' concerns about U.S. food safety. The purpose of the task force is to minimize food safety concerns as a trade barrier. Chaired by the Deputy Under Secretary for International Affairs and Commodity Programs, this task force meets for high-level concerns and, as of April 1990, had met twice. The Foreign Agricultural Service proposes establishing a food safety office to handle food safety concerns and international food standards issues on a more permanent basis.

Lack of a Comprehensive Policy and Plan Limits Effectiveness

The new initiatives, while worthwhile, are symptomatic of USDA's fragmented approach to food safety. Because it has not developed a comprehensive, strategic approach to food safety, USDA misses significant opportunities to further improve food safety and unnecessarily duplicates food safety activities. A model framework for a strategic approach exists, but USDA has yet to apply this framework to interagency food safety concerns.

USDA Could Seize Opportunities to Improve Food Safety

Several USDA agencies could play a greater role in food safety. If USDA adopted a systems approach to food safety, it could look at how and where to target resources most effectively to prevent potential food safety problems. Both the Animal and Plant Health Inspection Service (APHIS) and ES have resources closer to the production (farm) level than FSIS. Under a strategic approach, these agencies could focus their resources on the early stages of the food chain, thereby minimizing problems in the later processing and preparation stages. Such roles would complement other agencies' responsibilities.

Historically, epidemiology in human medicine and epidemiology in animals have been two separate fields of study. However, a growing number of scientists, veterinarians, public health officials, and educators have been combining the areas because they recognize that the epidemiology of animals and humans is often a continuum rather than two separate entities. This continuum is particularly evident for food production and safety.

The current structure of food safety regulation and oversight does little to recognize or take advantage of these links. For example, APHIS' mission is to protect plant and animal health. As part of a shifting emphasis from animal and plant disease to animal and plant health, APHIS has initiated a national monitoring system to define and improve the health of animals and plants. Although the system is designed to improve animal and plant health, according to APHIS officials, the basic structure could also address food safety and human health concerns.

If APHIS' monitoring system had food safety as a goal, it could (1) identify and locate hazards and (2) monitor any resulting controls. Producers, working with USDA, could develop more targeted quality assurance and verified production and certification procedures. In addition, the system could serve as a marketing tool to increase the public's confidence in the health and safety of animal and plant commodities.

Finally, it could provide increased quality assurance to those countries importing animal and plant products from the United States.

USDA's recent difficulties in responding to the salmonella enteritidis problem illustrate the problems resulting from a nonintegrated approach to food safety. Salmonella enteritidis is an organism transmitted through poultry to eggs that can cause illness and death in humans, even though the bird carrying the organism shows no signs of disease. USDA officials agree that testing eggs is impractical because testing, which destroys the eggs, would have to be very extensive, given the limited incidence of the disease in eggs. Since APHIS already had a program to test poultry for various poultry diseases, it attempted to incorporate salmonella enteritidis testing in this program. However, APHIS does not have authority to perform food safety activities unless the organism of concern to public health is also of concern to animal health. Therefore, participation in the program was voluntary. Not all egg and poultry producers participated, and incidents of salmonella poisoning occurred after the program had been in effect. Faced with publicity involving these events, the egg and poultry industries have agreed to a stronger program with some mandatory testing, and APHIS plans to implement a limited mandatory testing program.

APHIS officials stated that, given their lack of authority in the food safety arena and the lack of USDA-wide food safety policy and goals, it is difficult for them to focus their resources on food safety issues. Another factor restricting APHIS' ability to more successfully address food safety concerns is its budget structure. APHIS' budget consists of about 40 line items targeting specific pest control efforts. This "budget by bug" approach limits APHIS' ability to respond quickly to emergencies, such as incidents of salmonella enteritidis poisoning, and to shift resources to new, more future-oriented long-term projects, such as the animal health monitoring system.

Effectiveness of National Residue Program Could Be Improved

By focusing its efforts within areas covered by legislative requirements, instead of adopting an integrated approach, USDA is missing opportunities to make additional advances in food safety. Legislation restricts FSIS' authority to control food safety to the intermediate, slaughter, level. FSIS' National Residue Program monitors the incidence of chemical and drug residues in meat and poultry slaughtered for human consumption. However, FSIS does not have the capability to routinely identify which producers are submitting carcasses with violative residue levels because it has not established a mandatory animal identification and tracking

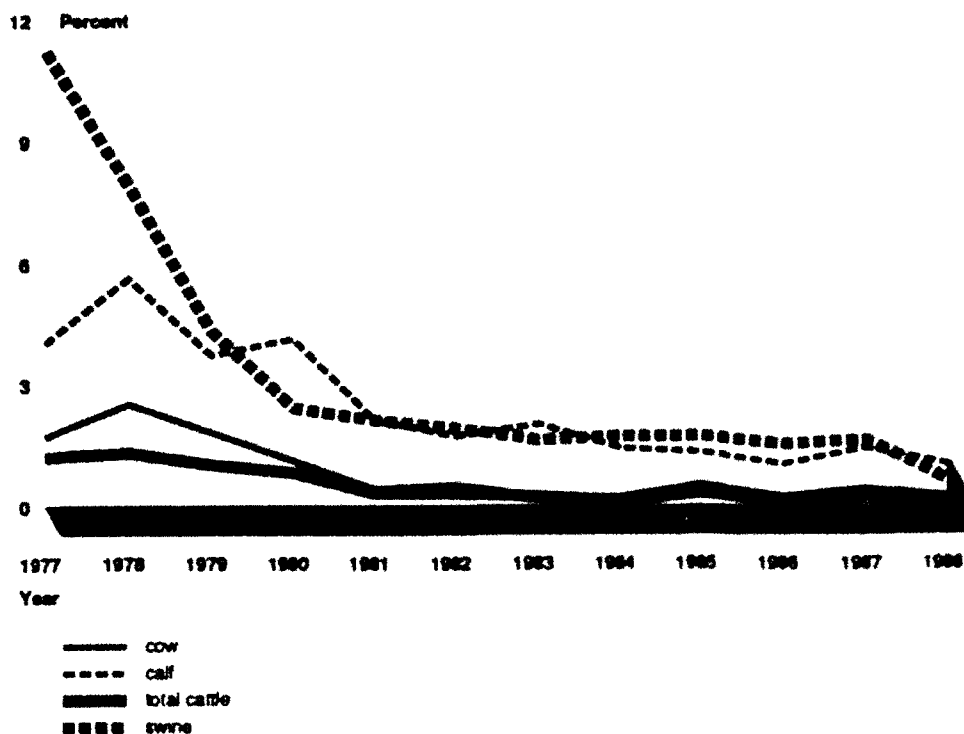
system.⁴ With little capability to target violative producers, FSIS has difficulty establishing accountability and cannot prevent future violations. In addition, other agencies that have resources at the producer level, including APHIS and ES, cannot target their efforts towards violative producers because these producers are not systematically identified.

The National Academy of Sciences, GAO, USDA's Office of Inspector General, and FSIS' own internal evaluation group have recommended mandatory animal identification to provide USDA with the capability for routinely tracing back and identifying the cause of problems originating at the producer level. Such a capability would minimize future violations. USDA has not implemented such a system.

As figure I.1 shows, the residue violation rate has decreased in the past decade, but the decreases have leveled recently. To further reduce the violation rate, each of these groups has recommended instituting a mandatory animal identification system.

⁴APHIS established a swine identification regulation, which became effective in 1988, to identify swine infected with disease.

Figure I.1: Residue Violation Rate,
1977-88



Source: USDA/FSIS

APHIS could play a role in reducing residue violations if its animal health monitoring system tracked producers with violative residue levels. In addition, FS could play a greater role. FS addresses animal residues by providing information to animal producers concerning residue avoidance practices. In the early 1980s, FS developed the Residue Avoidance Program to provide guidance to producers, with funding provided by FSIS. However, this program has gone unfunded since the mid 1980s. More recently, FS has developed the Food and Animal Residue Avoidance Database, an extensive data bank with information on drugs used in animal production. The main users of the data are veterinarians and FS agents, who pass the information on to the producers. However, these educational efforts are not targeted towards problem producers, who could be identified through FSIS' National Residue Program if identification requirements were mandatory. If USDA had an integrated approach to food safety, it would be able to use the information developed in one agency's program to improve related programs in another agency.

Fragmented USDA Efforts Result in Duplication

Given several agencies with food safety responsibilities and no coordinated departmental policy, it is not surprising that information is not systematically exchanged among agencies and that duplication of effort occurs at USDA. With the Department's increasing focus on food safety, ES and FSIS are beginning to discuss related efforts. However, the coordination between these agencies is informal and does not reflect a long-range commitment. According to an ES official, perceptions about differences in traditional agency missions are largely responsible for discouraging coordination.

Historically, ES has focused on improving the quality of family life by enhancing economic and social well-being. Food safety has been an important element of this effort. More recently, in 1989, ES introduced a new initiative called Improving Diet, Nutrition, and Health, one of five new initiatives.⁵ ES is focusing this initiative on food safety and quality, principally by generating materials for consumer and producer education.

FSIS, whose primary purpose is to ensure that meat and poultry reaching the consumer are safe and wholesome, has begun responding directly to the consumer. Both ES and FSIS have consumer outreach efforts and publication programs to educate consumers. Both agencies also operate consumer hotlines. FSIS operates a meat and poultry hotline to answer the public's calls about meat and poultry safety. This hotline gets about 50,000 calls per year. ES, with its vast network of county agents, also provides the public with food safety information. On the basis of a 1986 survey, ES estimated that it received over 3 million calls in 1 year about food safety.

ES' food safety efforts at the state and local levels are increasing, and many state Extension offices are hiring staff with food science expertise. Because ES can adapt programs to local requirements and deliver them in cooperation with state and local health departments, it has considerable advantages in developing responsive programs. ES is working on a risk communication program to train its county agents to respond more effectively to consumer concerns about potential threats to food safety, such as particular pesticides.

⁵The other four initiatives are Water Quality, Revitalizing Rural America, Youth at Risk, and Competitiveness of American Agriculture.

If USDA had a strategic approach to food safety, it could determine the extent to which FS' and FSI's efforts to achieve the same goals are desirable. Both agencies have significant, but different, strengths. FSI's strong points are more technical, whereas FS' strength is communication. A strategic approach would allow USDA to draw upon each agency's resources while minimizing duplication.

A Potential Framework for a Strategic Approach Exists

A 1989 proposal from the staff of the Assistant Secretary of Marketing and Inspection Services suggested the need for a more strategic approach to food safety. The proposal recommended developing a "systems" approach to food safety that would concentrate on safety throughout the food chain, from production to consumption. Such a system would be modeled on a system developed by private industry in the 1960s—Hazard Analysis and Critical Control Point (HACCP).

The food processing industry found that reliance on end-product testing was inadequate and recognized that a new food safety assurance system that relied on preventing problems was necessary. As one of the developers of the HACCP system stated, "safety cannot be inspected into a product and to depend on tests to monitor safety is an exercise in futility."⁶ The system consists of

- identifying and assessing hazards associated with growing, harvesting, processing, manufacturing, marketing, preparation, and consumption of a given raw material or food product;
- determining critical control points for identifiable hazard(s);
- establishing procedures to monitor critical control points, and
- establishing verification procedures to ensure that the system is working correctly.

The key to the system lies in finding the critical points that, if not controlled, could lead to unsafe food. FDA and the industry have successfully applied HACCP to low-acid canned foods. As with canned foods, a successful HACCP system will require a joint effort by industry and government. Several other groups, including the National Research Council's Subcommittee on Microbiological Criteria in 1985, and more recently the USDA's National Advisory Committee for Microbiological Criteria for Foods, have also recommended this approach.

⁶Testimony by Howard Bauman before the Committee on Agriculture, Subcommittee on Department Operations, Research and Foreign Agriculture, U.S. House of Representatives (Feb. 7, 1990), p. 8.

HACCP could provide a useful framework for viewing food safety more comprehensively. If USDA took a systems approach to food safety, it could strengthen its role by identifying opportunities for agencies with useful expertise and streamlining ongoing efforts to minimize duplication.

Of all the food-safety related initiatives we examined, the 1989 proposal from the staff of the Assistant Secretary for Marketing and Inspection Services came closest, we believe, to resembling a strategic planning effort. However, this effort has not resulted in a new system. According to the Assistant Secretary for Marketing and Inspection Services, USDA decided to pursue some of the individual proposals, but not the overall package because of coordination problems, disputes, and differences with non-USDA agencies. Although FSIS is developing a HACCP system for an individual product, FSIS' HACCP system will cover only the aspects of the product over which it has regulatory control. According to a FSIS official, the agency does not want to jeopardize its HACCP project by involving other USDA agencies. Thus, USDA will not review the process from production through consumption, but will rather continue to take a narrow agency focus.

Current Management Approach Does Not Favor a Strategic Effort

Despite its increased food safety activities, the Department's approach is largely segmented and lacks a strategic focus. None of its activities address food safety comprehensively. Even the broadest of the proposals, the Food Safety Data Initiative, addresses only pesticide residue concerns, even though most experts consider bacterial contamination a more significant food safety problem.

USDA has difficulty managing food safety in part because it lacks a mechanism for successfully integrating ongoing and potential efforts. The mechanisms USDA has used to develop its food safety initiatives vary with the nature of the initiative. In some cases, when a particular agency saw the need for an initiative, it developed one for its own use. However, agencies are not in a position to unilaterally address inter-agency concerns. In other cases, such as the Food Safety Data Initiative, the Secretary's Policy Coordinating Council, which consists of the Department's deputy, under and assistant secretaries, developed the initiative. While the Council may respond to interagency problems in crises, competing commitments and other reasons discussed in our letter have thus far prevented it from dealing with broader questions of inter-agency responsibilities and from pursuing the development of a forward-looking strategic food safety policy.

Appendix I
USDA Needs to Define and Pursue an
Aggressive Food Safety Policy

In the absence of a long-range strategic plan, USDA uses the budget as its main planning instrument. However, as the Department's experience with pesticide residue data shows, important efforts are then vulnerable to funding pressures and may be cut back or eliminated. Such budget-driven plans also encourage short-term responses with little flexibility, which are poorly suited to ongoing food safety concerns. USDA needs a strategic plan to provide the stability, continuity, and coordination that are essential to the success of its food safety program.

Organizational and Policy Improvements Needed to Implement a USDA-Wide Agricultural Biotechnology Program

Modern agricultural biotechnology holds great promise for improving the quality and availability of the nation's food and fiber supplies and for improving the nation's competitive position in international markets while enhancing the quality of our environment.¹ However, agricultural biotechnology research and commercialization efforts also raise important environmental, ethical, and socioeconomic concerns. USDA's challenge is to develop biotechnology applications to improve our international competitiveness in a way that appropriately balances biotechnology's potential benefits and competing concerns.

This appendix discusses the concerns that affect agricultural biotechnology's potential, the organizational and management problems that have impaired USDA's biotechnology activities, and the Department's partially successful efforts to correct these problems.

Competing Concerns Must Be Balanced

Biotechnology has great potential for improving the nation's agriculture. Supporters believe that the potential benefits are legion and that "the power of biotechnology is no longer fantasy."² Some believe that biotechnology can stimulate an agricultural revolution as significant as any that has already occurred.

For example, because biotechnology allows scientists to explore and manipulate the genetic material that determines heredity, agronomists and animal breeders can custom design crops and animals to meet local growing conditions and consumer preferences. Today's scientists are striving to develop plants that need less fertilizer, resist insects and disease with smaller amounts of pesticides, and produce food more efficiently than do current varieties. In addition, genes can be added to crops so that they last longer on supermarket shelves without preservatives, and to animals so that they produce leaner meat at lower cost. Such advances could help the nation's farmers compete better with other countries and lessen the adverse environmental impacts of producing agricultural commodities.

¹Biotechnology is any scientific or commercial technique that uses living organisms to improve plants or animals, to develop microorganisms for specific purposes, or to make or modify products. It includes classical breeding techniques and new technologies that allow genes to be transferred between related and unrelated organisms.

²Maryln K. Cordle and Alvin L. Young, "Agricultural Biotechnology: Environmental Choices and Challenges," *Toxicological and Environmental Chemistry*, vol. 28 (1990), pp. 25-35; and National Research Council, *Agricultural Biotechnology: Strategies for National Competitiveness* (Washington, D.C.: National Academy Press, 1987).

Biotechnology's Contribution Is Increasingly Evident

Recent research and product development trends illustrate the growing reality of these claims. Since 1979 USDA has approved 28 licenses for biotechnology-developed diagnostic tests to detect animal diseases and 6 licenses to produce and sell genetically modified vaccines for protecting swine from pseudorabies.³ As of September 20, 1990, USDA had also approved 99 applications to field test genetically modified plants, compared with 48 applications approved as of September 1989. In other food-related areas, in March 1990 FDA approved the commercial sale of a biotechnology-developed copy of the enzyme rennin used in manufacturing cheese. The agency's approval made the enzyme the first biotechnology food product available to consumers. In the pesticide area, EPA has approved the commercial use of two biotechnology-modified bacteria to control gypsy moths and other insects.

Funding trends at states' agricultural experiment stations, which receive funding from federal, state, and private sources, also illustrate an increase in biotechnology research. In November 1989 the National Association of State Universities and Land-Grant Colleges (NASULGC) compared the results of its 1982 and 1988 surveys of research programs at these facilities. NASULGC estimated that during these 6 years the institutions had increased their proportion of biotechnology research faculty from 5 percent to 11 percent of their total faculty. According to the 1989 report, "the increased participation of 409 faculty in biotechnology research represents a redirection of existing faculty and a substantial reallocation of effort" within the system. NASULGC surveys also indicated that during this time the stations' total budget for biotechnology research had increased from all federal, state, and industry sources, while the number of biotechnology research projects had doubled.

Environmental and Other Concerns Persist

Despite biotechnology's potential benefits, environmental and other groups have reservations about using biotechnology in agriculture. During the mid-1980s, a University of California experiment using genetically modified bacteria to protect strawberry and potato plants from frost was delayed for 4 years partly because of environmentalists' opposition to the test. At the time of the experiment, environmentalists feared unforeseen consequences if the genetically modified bacteria escaped from the test area and replaced similar natural forms of the bacteria. Although the researchers designed controls to meet these concerns and successfully completed the tests, uncertainty about the

³Pseudorabies is a fatal herpes-virus disease that costs the pork industry about \$60 million annually.

public's willingness to use genetically modified bacteria has stymied development of the commercial product.

During 1989 and 1990, environmental groups raised similar concerns about tests of genetically modified fish, a new rabies vaccine, and bacteria designed to improve nitrogen fixation in plants, and about the development of herbicide-resistant plants. These groups are concerned that, unless carefully controlled and monitored, biotechnology experiments conducted outdoors may entail greater risks than benefits.

Other groups question the socioeconomic implications of specific biotechnology applications. Since early 1989 biotechnology supporters and critics have extensively debated whether federal and state governments should approve the commercial use in dairy cows of bovine growth hormone produced by genetically modified bacteria. Although some scientists have conducted tests indicating that the safety of milk is not affected by injecting cows with the growth hormone, critics fear that use of the hormone will reduce production costs and lower milk prices. They contend that lower milk prices will make small dairy farmers unable to compete and will drive them out of business.

In addition, animal rights groups oppose research that manipulates the genetic structure of animals and requires scientists to raise animals to determine an experiment's effectiveness. These groups focus their concerns on the morality of experiments in which animals are given human genes and on the reduced quality of life that such genetically altered animals may face.

Clearly, if the public is to accept agricultural biotechnology products, those who have a major financial, environmental, or policy stake in such products will have to (1) educate the public about biotechnology's risks and benefits and (2) consider the public's concerns throughout product research and development. These tasks require that USDA, private industry, environmental groups, and other organizations interested in biotechnology recognize the interrelationships among biotechnology regulation, research, and education efforts and that they integrate these efforts to address the public's biotechnology questions.

USDA Responsibility for Biotechnology Is Fragmented

A leader in agricultural biotechnology, USDA implements a variety of regulatory, research, and consumer education efforts. In our March 1986 report on USDA's early efforts to organize agricultural biotechnology activities, we observed that the Department's success in the area depends on all of its agencies working together towards common goals.⁴ We also expressed concern that USDA researchers and regulators were struggling over who would be given prime responsibility for biotechnology, and we recommended that the Secretary provide the department's biotechnology coordinating committee with the authority to resolve differences among USDA's agencies.⁵

Since our report was issued, USDA has created departmentwide groups to better coordinate its biotechnology activities and has developed broad biotechnology policies defining the Department's philosophy on specific issues. However, USDA still does not manage its agencies' biotechnology activities from an overall departmental perspective. USDA does not have departmentwide goals for biotechnology, plans to achieve these goals, or organizations to monitor agencies' collective efforts.

Agencies Manage Most Biotechnology Activities

Eight USDA agencies are now actively involved in biotechnology. Two have regulatory responsibility; four support research; and two focus on consumer education and information dissemination:

- Regulatory agencies. APHIS issues permits to transport and test conventionally and genetically developed animal biologics and organisms that might be plant pests.⁶ FSIS regulates the quality and safety of meat and poultry products from conventional and genetically developed animals.
- Research agencies. ARS, ES, ERS, the Cooperative State Research Service (CSRS), and the Forest Service fund economic analyses and biotechnology research at federal facilities, universities, and colleges. Activities include experiments conducted inside enclosed laboratories and greenhouses that are designed to prevent test organisms from "escaping" outside the facility into the environment; experiments in animal barns or other semi-enclosed facilities; and tests in outdoor field plots using

⁴For further information, see our report entitled Biotechnology: Agriculture's Regulatory System Needs Clarification (GAO/RCED-86-59, Mar. 25, 1986).

⁵As of November 1985, when we completed audit work for our earlier report, USDA relied on an informal group known as the Agricultural Recombinant DNA Advisory Committee to coordinate biotechnology activity. As noted in our letter, in 1986 USDA created a more structured Committee of Biotechnology in Agriculture to carry out these responsibilities.

⁶An animal biologic is a product that diagnoses, prevents, or treats an animal disease.

fences, nets, and other techniques to limit the release of test organisms into the general environment.⁷

- Information agencies. The National Agricultural Library and the Extension Service disseminate biotechnology information to the public.

As we noted in our interim report on USDA management,⁸ additional USDA farm production and conservation agencies may unexpectedly become involved in biotechnology as the technology advances. These agencies may become part of future USDA-wide decisions on how the Department can reduce its budget, develop markets for new biotechnology products, and modify its crop support programs to encourage greater use of genetically developed crops.

USDA research and regulatory agencies have cooperated among themselves on specific projects and are aware of other agencies' overall programmatic interests. However, each agency manages its own activities. For example, APHIS, ARS, and CSRS budget for their respective biotechnology activities on the basis of their specific missions. Although USDA budget officials review and consolidate agencies' total funding requests, USDA does not have a departmentwide biotechnology plan to provide criteria for evaluating the agencies' budget requests. Without such a plan, USDA officials can not prepare a departmentwide biotechnology budget.

Departmentwide Groups Are Policy Oriented

Given the relatively large number and diverse interests of the agencies involved in biotechnology, timely and effective coordination of information about their programs can help minimize duplication and waste of effort. Since 1986, USDA has established three groups to improve communication among its biotechnology agencies:

- The Committee on Biotechnology in Agriculture. Co-chaired by the Assistant Secretaries for Science and Education and for Marketing and Inspection Services, the committee consists of the administrators from each of USDA's regulatory and research agencies involved in biotechnology. Created in 1986 and rechartered in 1990 after having been idle

⁷The use of fences, nets, and other experimental design features to prevent test organisms from escaping outside a research plot is discussed in Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms (GAO/RCED-88-27, June 13, 1988).

⁸See U.S. Department of Agriculture: Interim Report on Ways to Enhance Management (GAO/RCED-90-19, Oct. 26, 1989).

for 2 years, the committee provides a forum for discussing administrative and policy matters of mutual interest. The committee is co-chaired by two assistant secretaries because in 1986 Secretary Richard Lyng delegated responsibilities for biotechnology research and regulatory matters to these officials.

- The Office of Agricultural Biotechnology. Also created in 1986, this staff office to the biotechnology committee is charged with "coordinating all efforts" of USDA's biotechnology activities. However, USDA has not clearly defined the scope of the office's responsibility.
- The Biotechnology Council. Created in 1990, the council consists of agencies' program managers and representatives and reports to USDA's biotechnology committee. It was developed to foster exchange of information among agencies' program-level staff.

However, these three groups have little managerial impact on agencies' activities. None has the explicit authority or responsibility to set departmentwide biotechnology goals, develop plans to achieve such goals, or monitor agencies' activities. In addition, USDA officials have repeatedly disagreed about the precise authority of the Office of Agricultural Biotechnology.

Because these biotechnology groups represent the interests of USDA's biotechnology communities, they can help the Department develop a goals-oriented biotechnology program that reflects the Department's varied responsibilities and resources. However, without clear authority and accountability from the Secretary, the groups have not started this effort. Given biotechnology's potential contribution to agriculture, such a program is essential.

Broad Policies Contribute to Disagreements and Delays

Departmentwide policies can often bridge gaps between agencies and define overall goals to guide their efforts. To be effective, these policies should be sufficiently defined so that agencies can agree on what they mean and how they should be implemented.

USDA has developed broad policies on two biotechnology questions—balancing competing biotechnology research and regulatory concerns and using scientific information to support regulatory and research decisions. Its balancing policy states that USDA will

"encourage and support the responsible development and utilization of beneficial products of modern biotechnology consistent with the protection of public safety and the environment." [Emphasis added]

Appendix II
Organizational and Policy Improvements
Needed to Implement a USDA-Wide
Agricultural Biotechnology Program

Its decision-making policy states that

"Inconsistent or unnecessary procedures for regulation and research will place the U.S. scientific effort and U.S. producers at a substantial disadvantage. It also is important that safeguards be built into biotechnological research processes and that releases be based on careful evaluation while further experience is gained. Therefore, USDA feels that such regulatory and research decisions must be based on the best science available." [Emphasis added]

These statements express the Department's philosophy and define an overall direction for individual USDA biotechnology efforts. They were developed between 1984 and 1986 when USDA and other federal departments were developing the government's "Coordinated Framework for the Regulation of Biotechnology".⁹ Although broad, USDA's biotechnology policies are consistent with the framework's general principles.

USDA managers have discussed the policies and the Department's biotechnology philosophy at conferences and symposia and in departmental directives. During a 1987 USDA conference, the Assistant Secretary for Marketing and Inspection Services stated that, through APHIS, USDA "has drawn a hard line" for environmental safety but recognizes that "overregulation serves no useful purpose." At the same forum, the Assistant Secretary for Science and Education stated that the nation needs to conduct more experimental field tests if it is to remain competitive in world trade. In his opinion, this meant that USDA must "face the issue" of safeguards for introducing genetically modified material into the environment.

Working within these policies, individual USDA agencies have made progress in biotechnology regulation and research. APHIS, the first federal agency to issue final regulations for controlling field tests of genetically altered organisms, has developed a permit system that requires advance notification and approval of certain plant-related field tests. ARS has encouraged industrial use of federal research by increasing the number of cooperative agreements that it has with private companies to field test ARS work. These accomplishments contribute substantially to scientific knowledge and to public acceptance of agricultural biotechnology applications.

⁹The final 1986 Coordinated Framework discussed agencies' responsibilities for regulating biotechnology products and agencies' plans for applying existing regulatory authority to products containing genetically engineered organisms.

However, from a departmental perspective, USDA's biotechnology efforts have been marred by internal controversy and delays. USDA has not expressed its biotechnology policies' subjective terms and concepts in operational terms that its agencies can easily follow. For example, it has not defined what the policies mean by "responsible development and utilization" of biotechnology, what types of products are to be judged "beneficial," or what level of public safety and environmental protection regulations should strive to achieve.

Without such definitions, USDA's research and regulatory agencies have differently interpreted how each agency should appropriately balance competing biotechnology interests. Specifically, the Department's broad policies and the limited managerial role exercised by coordinating groups have contributed to delays in developing research guidelines for conducting safe outdoor field tests. As the government's experiences in medical research have shown, such guidelines are important to the Department's overall approach to biotechnology.

In addition, USDA's policies do not indicate how the Department will manage its overall biotechnology efforts. For example, these policies do not discuss how agencies can integrate their respective biotechnology activities into a goal-oriented, USDA-wide program; how progress towards goals can be measured; or how irreconcilable differences of opinion among agencies should be handled. These management issues must be addressed if USDA is to overcome agencies' individual mission-related perspectives on biotechnology and develop a comprehensive program that balances the scientific, environmental, and socioeconomic concerns associated with biotechnology.

Research and Regulatory Agencies Interpret Policies Differently

Agricultural biotechnology researchers and regulators have different philosophical views concerning the type and degree of regulatory oversight needed to adequately protect the public from unexpected consequences of genetically modified organisms escaping from a test area. Researchers generally believe that they should be allowed some latitude to review and approve outdoor experiments, particularly low-risk projects, using local review committees. In contrast, regulators generally believe that they should approve most outdoor test projects, and they prefer to rely on a centralized review process.

With experience, agricultural biotechnology researchers have progressed from early laboratory tests to more advanced tests at one or more outdoor field locations. As the scope of these tests has widened,

the resolution of philosophical differences between researchers and regulators and the development of a USDA-wide framework for ensuring the safety of outdoor tests have become crucial to biotechnology's progress.

Yet the Department has not completed the regulatory and administrative framework that is necessary to more fully ensure the safety of these experiments. In July 1986, USDA's research agencies published a draft of research guidelines—a key part of a departmental administrative oversight system—in the Federal Register for public comment. The agencies' notice coincided with APHIS' separate notice of proposed regulatory requirements for federal approval of tests that might involve plant pests. APHIS published its final biotechnology regulations 1 year later.¹⁰ In comparison, USDA's research community has taken 4 years to revise its guidelines for a second round of public comments. In June 1990 USDA's Agricultural Biotechnology Research Advisory Committee (ABRAC) provided USDA's biotechnology office with revised guidelines for departmental and external review.¹¹ As of October 1, 1990, USDA is revising its guidelines on the basis of comments received from USDA offices, the Office of Management and Budget, the Council on Environmental Quality, and the public.

Delays in developing the guidelines have occurred, in part, because, like other federal biotechnology organizations, USDA's research community has experienced difficulty defining the technical scope and purpose of biotechnology guidelines. Further, intra-departmental differences on the guidelines' specific provisions for administrative approval of a project and on procedures for implementing the guidelines have also contributed to the delays.

For example, USDA's proposed procedures for implementing the draft guidelines include a two-tier process for approval of projects that are not regulated by APHIS. Biosafety committees that would be associated with universities and other research institutions and that would meet

¹⁰The 1987 APHIS regulation states that all outdoor field tests with plants (1) containing genes from a known or suspected plant pest or (2) created with experimental techniques using such genes must be approved by the agency before tests can proceed. These regulations do not apply to outdoor experiments with fish that have been genetically altered or to plants modified through an experimental technique other than genetic engineering.

¹¹USDA created ABRAC in 1987 to provide scientific advice to the Department on agricultural biotechnology research. Modeled in part after the National Institute of Health's Research Advisory Committee, ABRAC includes individuals with expertise in plant, animal, and microbial sciences, law, and ethics.

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USDA committee membership requirements would approve low-risk biotechnology experiments. USDA's Office of Agricultural Biotechnology and/or its biotechnology research advisory committee would review and approve the expected small number of high-risk projects. The local committee-based review concept was modeled after the National Institutes of Health institutional biosafety committee system and is accepted in the medical biotechnology field.

However, the issue of whether a centralized or decentralized project review system works better for agricultural biotechnology illustrates the USDA regulatory and research agencies' differences concerning the guidelines. From a regulatory standpoint, APHIS has established a headquarters-level biotechnology permitting group to review and approve all applications for low- and high-risk field tests involving genetic material specified in its 1987 regulations. APHIS' scientists evaluate test plans, notify states of tests scheduled within their borders, and prepare environmental analyses before issuing permits to proceed with outdoor tests.

The agricultural research community generally believes that APHIS' centralized review of all regulated biotechnology field tests restricts biotechnology research and impedes the nation's competitiveness with other countries. The research community position is based on the perception that researchers have delayed, cancelled, or redesigned biotechnology projects to avoid the uncertain outcome of regulatory reviews. These biotechnology researchers hope that, if the two-tier review system works for nonregulated projects, APHIS will be encouraged to relax its regulations and adopt a similar streamlined system. Until this happens, these researchers believe the two-tier process would be compatible, and not in direct competition, with APHIS' 1987 biotechnology regulations and its project approval process.

APHIS officials oppose using the guidelines' proposed local committee system for regulatory purposes. They do not agree with critics that the agency's biotechnology regulations restrict innovative research or the nation's international competitiveness. They also emphasize that the APHIS regulations must differ from the research guidelines because the regulations are legal requirements with penalties for noncompliance and are enforceable by the courts. Finally, they believe the agency cannot legally delegate its biotechnology oversight responsibilities to others, such as local committees of nonfederal officials, no matter how successful the guideline's proposed project review systems become.

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APHIS has also expressed reservations about how USDA's research agencies intend to use the Department's research guidelines. The June 1990 draft guidelines state that, to receive USDA funding, biotechnology researchers must comply with the Department's requirements. APHIS officials have participated in the development of the guidelines and generally believe they can be valuable as a collection of suggestions and voluntary practices for researchers to improve the safety of outdoor tests. However, according to APHIS's Director of Biotechnology, Biologies, and Environmental Protection, APHIS does not agree with the research agencies' plans to apply the guidelines to biotechnology research projects only and to require the researchers to comply with the guidelines in order to receive USDA funding.

APHIS' Director believes that, by imposing new project review requirements on biotechnology research only, USDA would be treating biotechnology projects differently from nonbiotechnology projects. In his opinion, this would be inconsistent with the federal government's "Coordinated Framework for the Regulation of Biotechnology," which states that, for regulatory and administrative oversight purposes, biotechnology research should be treated the same as conventional research and commercial activities.

We did not assess the validity of researchers' claims that USDA's regulatory approach should be changed or of regulators' reasons for rejecting the guidelines' local committee-based alternative to the current system. However, we observed that the issue generates strong feelings among researchers and regulators and has divided USDA officials in these areas for some time. Given the intensity of differences on this issue within the Department, a departmentwide policy specifying a particular type of project review system for USDA regulators and researchers would have been warranted. Such a policy would have focused management attention on the issue early in the development of the guidelines, thereby minimizing agencies' differences of opinion and expediting the departmentwide acceptance of the guideline proposals. Further, with management approval and authority, a departmentwide group could have monitored the impact of USDA regulations on biotechnology experiments and provided independent information for resolving guideline issues. With such specific policies and management tools, USDA could more effectively have addressed the professional differences that almost inevitably develop between regulators and those being regulated.

Late Conflict-Resolution Efforts Also Delay Guidelines

Between 1986 and 1988 USDA research guidelines were also delayed by conflicts that developed between the Assistant Secretary for Science and Education and the Assistant Secretary for Marketing and Inspection Services, who are responsible for biotechnology research and regulation, respectively. The impact of this conflict was described in July 1988 by a NASULGC official:

"The development of working biosafety methods for agricultural biotechnology research, especially that related to contained or confined experiments outside the laboratory and greenhouse, has been dreadfully slow. In the USDA, there has been a counterproductive turf struggle that has delayed development of a broad consensus on biosafety procedures for agricultural research. The Committee . . . emphasizes the importance of moving ahead now in an expedited development of the remaining tasks."¹² [Emphasis added]

Occasional disagreements between top management officials on key policy questions are almost unavoidable, especially when the questions affect multiple agencies' programs. To help prevent such differences from having an adverse impact on a department's overall activities in an area, management can put structures and processes in place to recognize and appropriately deal with the conflicts. USDA's Committee on Biotechnology in Agriculture would have seemed the likely candidate either to resolve such differences affecting biotechnology, or to report them to the Deputy Secretary or Secretary. However, the committee did neither because (1) the assistant secretaries involved in the conflict co-chaired the committee, and (2) the committee did not have the authority or responsibility either to mediate the differences or to report delays in developing the guidelines to USDA's top managers. It was not until the summer of 1987—a year after USDA had published the first draft of its guidelines—that Secretary Lyng learned of the interagency controversy and instructed the officials to overcome their differences.

USDA Remedies Do Not Correct Organizational Weaknesses

USDA has made several organizational changes to relieve tensions between biotechnology research and regulatory agencies. After learning of the interagency differences, during the summer of 1987, former Secretary Richard Lyng transferred responsibility for the Office of Agricultural Biotechnology from the Assistant Secretary for Science and Education to the Deputy Secretary of Agriculture. Since then, Secretary Yeutter has appointed new individuals to the assistant secretary positions and returned the office to the science and education area.

¹²NASULGC's Committee on Biotechnology's presentation to the Federal Coordination Council for Science, Engineering and Technology's Biotechnology Science Coordinating Committee, July, 1988.

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USDA's research and regulatory officials agree that interagency relationships have improved measurably as a result of the cooperative attitudes and interpersonal skills of the assistant secretaries currently responsible for these activities. The Department has revived the Committee on Biotechnology in Agriculture, which had ceased meeting because of differences between its members. USDA research and regulatory agencies have also jointly reviewed two first-of-a-kind research projects. In addition, the agencies have cooperatively prepared position papers for a recent White House Biotechnology Sciences Coordinating Committee effort to clarify the scope of federal biotechnology regulations.

Although these changes are positive, our interviews with USDA officials indicate that they have not resolved the differences of opinions between researchers and regulators concerning the guidelines or nullified the tensions among agencies. Some USDA research and regulatory staff continue to mistrust each other's motives for proposing or resisting changes to the guidelines, or they are skeptical about the likelihood that the Department will reach a mutually agreeable position on how to balance sometimes conflicting regulatory and research goals.

Some of these differences could be the lingering aftereffects of the earlier conflicts between the two former assistant secretaries. Some may also continue because USDA has not modified certain organizational and managerial mechanisms to better detect and deal with such differences. For example, USDA has not established departmentwide goals for biotechnology. It also has not modified the biotechnology committee's charter. The charter still does not make the committee accountable for planning the Department's collective biotechnology efforts, monitoring progress towards goals, or detecting and resolving differences among agencies. Such differences continue to occur, albeit on a smaller scale. For example, the committee took 9 months to approve the creation of a biotechnology council because regulatory and research agencies disagreed as to whether the committee's charter needed to be amended to include the council.

USDA has also not clarified the role and responsibilities of the Office of Agricultural Biotechnology. Although Secretary Yeutter reaffirmed the office's authority to "coordinate all biotechnology activities" when he transferred the office to the science and education area, he did not define what coordination involves. According to some USDA officials, this omission and uncertainty over why the Secretary transferred the office are being interpreted by one group as an indication that the office should limit its coordination efforts, and by another group as an

endorsement of the office's initial charter to coordinate all USDA biotechnology activities. In addition, according to APHIS' biotechnology director, if interpreted broadly, the Secretary's memoranda are inconsistent with former Secretary Richard Lyng's 1986 delegation of authority for biotechnology regulation to the Assistant Secretary for Marketing and Inspection Services.

Thus the Secretary's efforts have not ended the differences of opinion within the Department on what the office should be doing. If the office is to contribute effectively to USDA's biotechnology effort, the Secretary needs to clarify the office's role and responsibility with respect to other biotechnology agencies and coordinating groups. The Secretary also needs to communicate these clarified roles and responsibilities more clearly throughout the Department and to confirm that USDA agencies understand and accept these clarifications.

Steps Towards Enhancing Biotechnology Management

This report recommends broad changes to the Department's management of cross-cutting issues (see our Recommendations to the Secretary of Agriculture at the end of our letter). To illustrate how USDA can apply these changes to biotechnology, we identified specific ways USDA can enhance management's structures and processes for policy setting, planning, implementing, and monitoring in the area. In biotechnology, increased authority, accountability, and responsibility for USDA's Committee for Biotechnology in Agriculture are key to improving the Department's management of the area. However, USDA can also use the Secretary's Policy Coordinating Council, its management-by-objectives system, and other mechanisms to address cross-cutting issues. The Department should consider the roles and responsibilities of the Committee on Biotechnology in Agriculture within the broader context of how it will use all its management mechanisms to manage cross-cutting issues.

For example, USDA needs a comprehensive set of policies that (1) respond to major questions facing its biotechnology activities and (2) clearly state how the policies will be implemented. The Department's two existing policies are not clearly defined and do not address such issues as the balance between research and regulatory objectives, the ethics of genetic animal research, and the socioeconomic implications of genetically engineered products. They also do not address how USDA can maintain its objectivity as a regulator while actively supporting efforts to educate the public about biotechnology.

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We believe that USDA could use the existing committee on Biotechnology in Agriculture to develop and clarify policies in these areas. The Secretary could encourage the committee to obtain the help of existing biotechnology advisory groups and other groups representing a variety of environmental and other nonagricultural views to identify alternative strategies for addressing such issues. The committee could then form a consensus and present recommendations to the Secretary concerning the Department's philosophy and direction and procedures for translating this direction into specific programs or management oversight activities.

USDA also needs to consider expanding the committee's responsibilities. The committee could assume leadership in biotechnology by defining the Department's biotechnology policies (as discussed above), by developing a departmentwide plan to implement these policies, and by reviewing the Department's overall budget for biotechnology against this plan. Combining policy definition, planning, and budget review will provide the Committee with the perspective needed to monitor the Department's overall progress in the area and to resolve any major conflicts that might develop before they seriously affect program performance. Such an expanded role would also enable the committee periodically to report biotechnology's accomplishments and remaining challenges to the Secretary and Deputy Secretary and to the Office of Management of Budget to support the program's budget requests.

To be an effective vehicle for integrating USDA's varied biotechnology activities, the committee should be structured so that the Department resolves even the most difficult issues. At present, the committee is chaired by two assistant secretaries—a division of responsibility that has, in the past, kept the committee from addressing major issues. USDA management should determine whether the committee can be restructured to resolve conflicts more effectively within the Department.

USDA officials also need to assure themselves that officials throughout the Department clearly understand the roles and responsibilities of the coordinating organizations. Unfortunately, confusion about the Office of Agricultural Biotechnology's role and responsibilities contributed to the once-prevalent atmosphere of tension and mistrust among agencies. USDA management should clarify the office's role with respect to the Department's research and regulatory agencies and should increase the Department's efforts to ensure that all agencies understand the office's responsibilities.

USDA Needs to Better Focus Its Water Quality Responsibilities

This appendix summarizes our July 1990 report, Agriculture: USDA Needs to Better Focus Its Water Quality Responsibilities (GAO/RCED-90-162, July 23, 1990). Performed in response to a request from the Chairman of the Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations, the report discussed USDA's water quality activities, including their management and coordination.

We reported that the Department's coordinating mechanisms do not provide for effective management of its water quality activities because they do not establish a single point of responsibility for planning, coordinating, and evaluating all of USDA's water quality activities. We also found that USDA did not have a single, comprehensive policy to guide its present and future activities. In September 1990, following our July 1990 report, USDA issued a single, comprehensive water quality policy. In November 1990, the Food, Agriculture, Conservation and Trade Act was enacted, requiring USDA to take several actions affecting its management of environmental policies and programs, including water quality.

Background

The agricultural sector is the nation's largest user of pesticides and fertilizers, and studies have shown that these chemicals are increasingly appearing in surface water and groundwater supplies. Agricultural activities have been identified as a source of pollution in drinking water in many states. The public increasingly perceives such exposure as a threat to human health.

While agricultural chemicals have increased the productivity of U.S. farms, their effects on the environment and human health have raised concerns. These chemicals pose a potential threat to the farmers who apply them and may eventually contaminate farm water supplies. Agricultural chemicals can also wash into surface waters or seep into groundwater reservoirs, thus affecting water quality hundreds of miles away. Nonetheless, many producers continue to practice chemically intensive farming because it reduces the need for labor and increases crop yields. In addition, the National Research Council and others have shown that USDA's commodity support programs indirectly encourage chemically intensive farming practices. That is, support programs generally encourage farmers to produce certain crops, such as corn, which require high levels of agricultural chemicals to increase yields, and thereby maximize program benefits.

USDA Has Recently Initiated Programs That More Directly Address Water Quality

Historically, USDA has added its water quality activities to existing soil conservation programs or limited them to regional surface water programs. In the late 1980s, the Department instituted broader programs and activities to address the contamination of surface water and groundwater by agricultural chemicals. USDA has developed a Water Quality Initiative for fiscal year 1990 that expands its ongoing water quality programs and establishes new programs. However, USDA's program to support low-input sustainable agriculture, which shares the primary goals of the Department's Water Quality Initiative, has not been integrated into the initiative.

Other activities carried out by the Department, such as its soil conservation and commodity assistance programs, can also directly or indirectly affect water quality. We believe that USDA needs to better understand the nature of the relationships between these programs and to identify appropriate changes to avoid conflicting goals and duplicate efforts. Further, such changes will allow the Department to make the most effective use of its available resources.

USDA's Water Quality Responsibilities Are Not Focused

Ten of USDA's 36 agencies are involved in water quality activities and plan to spend \$155 million in fiscal year 1990. As pointed out in 1988 by USDA's Working Group on Agricultural Chemicals and the Environment, policy and program coordination among these agencies is essential. USDA uses a variety of coordinating mechanisms, including the Secretary's Policy Coordination Council, ad hoc working groups, formal agreements, and the President's management-by-objectives system. However, USDA has not established a single, full-time focal point or coordinating body with responsibility and accountability for all of its water quality activities, as it has for other important cross-cutting issues, such as transportation and energy. Rather, in November 1989, the Department established a Working Group on Water Quality, which it believes adequately focuses its water quality responsibilities.

We found that this new working group (1) does not have a full-time USDA staff, other than an individual on loan from the Department's Agricultural Research Service, dedicated exclusively to water quality issues; (2) does not have clear responsibility for coordination with interested parties outside of the Department; and (3) does not have clear responsibility for all of USDA's water quality activities. Because there is no full-time, departmentwide mechanism to oversee all water quality activities, responsibility remains divided among the Working Group on Water Quality and the various under and assistant secretaries. As a result, we

are concerned that the Department may lack the organizational structure needed to effectively address this issue. Also, because USDA lacks a management system to effectively plan, coordinate, and evaluate its water quality activities, water quality may be perceived as less important than other USDA responsibilities by those in USDA as well as by those outside. To address these concerns, we recommended that the Secretary of Agriculture clearly establish responsibility and accountability for the Department's water quality efforts by creating a permanent, full-time departmentwide focal point or coordinating body for all of USDA's water quality activities.

USDA's single, broad water quality policy, issued in September 1990, does not specifically address many of the concerns raised in our July 1990 report. This policy states that the Department will (1) foster agricultural and forestry practices that protect and enhance ground and surface water, (2) develop, implement, and coordinate programs to foster protection and enhancement of surface and ground water quality while maintaining agricultural productivity, and (3) continue to cooperate with state and federal agencies to reduce reliance on regulatory approaches to meet water quality goals.

This policy, which supersedes the previous ground and surface water policies, does not recognize that practices used to protect some types of water sources could harm others. In addition, the policy does not provide a mechanism to encourage adoption of the policies the Department has developed. Further, the policy does not specifically address all water quality concerns, including considerations of how commodity programs and soil conservation activities affect water quality.

The Food, Agriculture, Conservation and Trade Act of 1990 requires USDA to take several actions affecting its management of environmental programs. These actions include (1) establishing a council of top USDA officials to coordinate and direct all of USDA's environmental policies and programs, (2) establishing an office under the council to coordinate activities, (3) preparing an environmental quality policy statement, and (4) preparing a plan to implement the policy.

Objectives, Scope, and Methodology

The objective of this review was to assess how well USDA coordinated and managed those emerging agricultural issues that cut across both agencies and under and assistant secretarial responsibilities. To accomplish this objective, we focused on how USDA managed three cross-cutting issues—food safety, agricultural biotechnology, and water quality. We selected these issues after discussions with officials and experts who believed that they represent important concerns facing USDA in the future. Food safety has always been a major concern in agriculture. However, greater public concern about residues in food is likely to intensify discussions about improvements to the existing system of food safety regulation. Agricultural biotechnology offers the potential for revolutionizing domestic and international agricultural production and improving the quality and quantity of the nation's food supply. Throughout the country, water quality is of concern to federal, state, and local governments, which often cite agriculture as a major contributor to groundwater contamination.

To assess how well USDA has coordinated and managed its food safety responsibility, we examined numerous studies and reviews, including reports by GAO, the National Academy of Sciences, and USDA's Office of Inspector General and other internal evaluation groups. From interviews with agency administrators as well as past reports, we selected food safety topics that require interagency coordination. We interviewed staff from nine USDA agencies: the Food Safety and Inspection Service (FSIS), the Animal and Plant Health Inspection Service (APHIS), the Agricultural Research Service (ARS), the Extension Service (ES), the Federal Grain Inspection Service (FGIS), the Packers and Stockyard Administration, the Foreign Agricultural Service, the Economic Research Service (ERS), and the Agricultural Marketing Service (AMS). In addition, we interviewed the Director, Center for Food Safety and Human Nutrition, Food and Drug Administration (FDA), Department of Health and Human Services.

To assess USDA's management challenges in agricultural biotechnology, we examined USDA's regulatory and research roles, responsibilities, and activities in the area. We interviewed officials and gathered documentary information from the major USDA agencies and offices with biotechnology responsibilities: the Office of Agricultural Biotechnology, APHIS, FSIS, ARS, and the Cooperative State Research Service. We also discussed biotechnology management issues with individuals from the Environmental Protection Agency, the National Institutes of Health, the White House Office of Science and Technology Policy, and the congressional Office of Technology Assessment.

Our work in the water quality issue area was based on other work done in response to a request from the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations. As part of this prior effort, we reviewed USDA's water quality activities to determine, in part, how water quality and related programs are being managed and coordinated and whether a centralized, departmental coordinating body or focal point for water or environmental issues is needed within USDA. To accomplish these objectives, we looked at USDA's historical activities, recent activities, and future plans for water quality-related programs, including the Water Quality Initiative that USDA began during fiscal year 1990. We interviewed officials and gathered documentary information from the USDA agencies with major water quality responsibilities. Further details of the objectives, scope, and methodology of our water quality work are discussed in our report, Agriculture: USDA Needs to Better Focus Its Water Quality Responsibilities (GAO/RCED-90-162, July 23, 1990).

In each of these three cross-cutting issues, USDA shares responsibility with several other federal agencies. The scope of our review was limited, however, to USDA and its coordination among its own agencies. We did not assess USDA's coordination with other federal agencies. However, we did discuss the issues with some of these other federal agencies.

In addition to these three cross-cutting issues, we reviewed two of the Department's recent major management initiatives: the establishment of the Secretary's Policy Coordination Council and the Department's implementation of the President's management-by-objectives system. We discussed the Council activities with the Deputy Secretary and staff of the Council and reviewed Council documents and plans. Similarly, we reviewed the Department's implementation plans and progress report for the MBO system and discussed the system with department and agency officials responsible for implementing it.

We conducted our work between August 1989 and May 1990, with updates through October 1990, at USDA headquarters in Washington, D.C., in accordance with generally accepted government auditing standards. During this review, we consulted with Charles F. Bingman, member of the National Academy of Public Administration. We provided a draft of this report to USDA for formal comment. USDA's comments appear in appendix V.

Comments From the U.S. Department of Agriculture



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
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JAN 14 1991

John W. Harman, Director
Food and Agriculture Issues
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Washington, D.C. 20548

Dear Mr. Harman:

Secretary Clayton Yeutter has received your letter of December 20, 1990 transmitting the draft of the proposed report entitled U.S. Department of Agriculture: Improving Management of Cross-Cutting Agricultural Issues.

The report focuses upon the need to improve the management and coordination of water quality, biotechnology, and food safety issues. Thank you for giving us the opportunity to review the draft, and to comment upon its contents. This letter will constitute our response.

The U.S. Department of Agriculture appreciates the suggestions that the Department make more effective progress in addressing the complex cross-cutting and still unclearly defined issues on food safety, biotechnology and water quality through various adjustments in procedures and organizations. The report was prepared prior to enactment of the Food, Agriculture, Conservation, and Trade Act of 1990, and for that reason we would suggest that the report be updated prior to its official publication to incorporate a recognition of the new law and its impact upon the management and coordination of USDA activities related to subjects discussed in the report.

We do not want to appear to be critical of the draft report, it is very informative, but it tells us little that we do not already know. We have made a great deal of progress in improving coordination of research, regulatory activities, and delivery of field programs. This progress will continue as we implement provisions of the new legislation. We look forward to sharing with the appropriate committees of the Congress specific actions we are and will be undertaking in the coming months. In this process, we will most assuredly address the comments and suggestions offered by the General Accounting Office.

Sincerely,

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