
August 1998

FOOD SAFETY

Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness



**Resources, Community, and
Economic Development Division**

B-280252

August 6, 1998

The Honorable John R. Kasich
Chairman, Committee on the Budget
House of Representatives

Dear Mr. Chairman:

The increasing incidence of foodborne illness has heightened concerns about the federal system's effectiveness in ensuring the safety of the nation's food supply. These concerns have focused in part on the multiple federal agencies that carry out their responsibilities under 35 different laws and spend over \$1 billion annually.¹ The primary agencies responsible for food safety are the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), which is responsible for meat, poultry, and some egg products, and the Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), which is responsible for all other food products. In addition to the more than \$1 billion that all the agencies get for their food safety activities, they received \$43 million for fiscal year 1998 and requested \$101 million for fiscal year 1999 under the national food safety initiatives announced by the President. These initiatives are intended to address areas of concern in the current food safety system and support a broad range of activities, including the monitoring of incidences of foodborne illnesses and the development of educational messages on food safety.

You asked us to (1) analyze the federal food safety agencies' budgets for fiscal year 1999 to determine whether the appropriated funds of more than \$1 billion can be spent more effectively and (2) provide our views on whether the food safety initiatives for fiscal years 1998-99 will address underlying problems in the federal food safety system.

To respond to your request, we analyzed 10 federal food safety agencies' budgets and the appropriation requests for the two food safety initiatives and made observations based on our previous reports' findings. (Prior GAO products relevant to this report are listed at the end of this report.) Furthermore, we asked federal program and budget officials to explain selected programs and activities in more detail for their agencies' fiscal year 1999 budget and for the initiatives.

¹See *Food Safety and Quality: Who Does What in the Federal Government* (GAO/RCED-91-19B, Dec. 21, 1990). See also *Food Safety: New Initiatives Would Fundamentally Alter the Existing System* (GAO/RCED-96-81, Mar. 27, 1996).

Results in Brief

More than one-fourth of the over \$1 billion federal budget for food safety—about \$271 million—could be used more effectively if most of these funds were congressionally redirected from the Food Safety and Inspection Service’s organoleptic (seeing, smelling, and touching), carcass-by-carcass slaughter inspections to a number of the other food safety activities that need attention. Funds currently used for organoleptic, carcass-by-carcass slaughter inspections do not optimize federal resources because these inspections do not detect the most serious public health threat associated with meat and poultry—microbial contamination. Instead, these inspections mostly ensure the quality of food and therefore benefit the industry more than they ensure food safety for consumers. The \$271 million could be used, for example, by the Food Safety and Inspection Service to help the smallest slaughter and processing plants with the cost of installing new science- and risk-based inspection systems. Since industry will bear most of the installation cost and the smallest plants operate at a smaller volume over which to spread this cost, these plants will be disproportionately affected by the cost of the new inspection systems. In addition to the funds that could be made available from the revisions to the carcass-by-carcass slaughter inspections, some funds used for daily inspections of meat- and poultry-processing plants could be congressionally redirected to other needs. For example, inspections could be based on the risks at other food plants, such as cereal manufacturers. If the frequency of these inspections were based on the health risk posed rather than on the Food Safety and Inspection Service’s practice of conducting processing plant inspections on a daily basis, these inspections would be more effective.

The food safety initiatives have made some improvements to the federal food safety system, but they have not comprehensively addressed the underlying problem of the fragmented nature of this system. In fact, while the initiatives provided funding for specific food safety efforts, the initiatives’ effective implementation may be impeded by the system’s fragmentation. For example, progress in carrying out the initiative’s objective of consolidating seafood inspection activities under one agency has been impeded by the slow progress of the Food and Drug Administration and the Department of Commerce in developing legislation for congressional consideration.

Background

Foodborne illness in the United States is extensive and expensive. The incidence of foodborne illness is estimated to range from 6.5 million to 81 million cases each year and result in as few as 500 to as many as 9,100

related deaths annually.² In terms of medical costs and productivity losses, foodborne illness costs the nation between \$7 billion and \$37 billion annually, according to USDA's estimates.

Public health officials believe that the risk of foodborne illness has been increasing over the last 20 years. Trends in the incidence of foodborne illness in the United States are linked, at least in part, to changes in Americans' eating habits. For example, Americans today consume more raw fruits and vegetables than they did in the past and in some cases may mishandle them by not washing them. While this change in diet has many health benefits, the mishandling of these foods and other foods, such as undercooking and/or improperly refrigerating meat and poultry, may also contribute to the spread of foodborne illnesses.

The scientific community has recognized that preventing contamination is the key to reducing the risk of foodborne illness. However, FSIS conducts organoleptic meat and poultry inspections of each and every meat and poultry carcass in order to fulfill current program requirements for carcass-by-carcass inspections in slaughtering plants. While these inspections fulfill the requirements, they primarily identify defects in quality but do not detect microbial contamination.

However, as the threat of microbial contamination has increased, a Hazard Analysis and Critical Control Point (HACCP) system has come to be considered the best approach currently available for ensuring safe food because it focuses on preventing contamination rather than on detecting it once it has occurred. The HACCP system (1) identifies hazards and assesses the risks associated with each phase of food production,³ (2) determines the critical points where the identified hazards can be controlled, and (3) establishes procedures to monitor these critical control points.

In January 1998, FSIS began to require meat and poultry plants to implement HACCP systems. Implementation is expected to take 3 years, starting with the nation's 300 largest slaughtering plants, which account for 75 percent of all meat and poultry slaughter production. In 2000, this system will be fully implemented and will have reached very small plants—those with fewer than 10 employees. The HACCP system requires FSIS' verification that a plant's overall system—not just the individual control points—is working. This verification relies on, among other things,

²See *Food Safety: Information on Foodborne Illnesses* (GAO/RCED-96-96, May 8, 1996).

³Hazards include any biological, chemical, or physical property that may cause an unacceptable risk to consumers' health.

microbial and other types of testing of product samples taken at various times throughout production. These tests contribute to verifying whether the plants meet food safety standards and alert the plants to deficiencies in the slaughtering process.

In addition to carcass-by-carcass slaughter inspections, FSIS inspects meat- and poultry-processing plants at least once per day during each operating shift. Its current inspection program practice for processing plants is labor-intensive and is not based on the health risk that a plant poses. Processing plants' operations can include the simple cutting and packaging of meat and poultry, grinding, complex canning procedures, or the preparation of ready-to-eat products.

Multiple agencies share the responsibility for ensuring the safety of the nation's food supply. In fact, 12 different federal agencies located within six federal entities are involved: HHS' Food and Drug Administration and Centers for Disease Control and Prevention (CDC); USDA's FSIS, Agricultural Marketing Service (AMS), Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), and Grain Inspection, Packers, and Stockyards Administration; the Department of Commerce's National Marine Fisheries Service (NMFS); the Department of the Treasury's U.S. Customs Service and Bureau of Alcohol, Tobacco, and Firearms; the Environmental Protection Agency (EPA); and the Federal Trade Commission. Appendix I describes these 12 agencies' roles and responsibilities in food safety, and table I.1 shows the food safety funding for and staffing levels of the agencies for selected years. This structure necessitates extensive coordination to minimize duplication of effort, prevent gaps in regulatory coverage, and avoid conflicting actions. Our past reviews have shown inconsistencies and differences between agencies' approaches and enforcement authorities that undercut overall efforts to ensure a safe food supply.⁴ In the past, we have recommended a single food safety agency to correct the problems created by this fragmented system.

In addition to the more than \$1 billion provided for routine food safety activities, the administration's food safety initiatives increased funding for federal food safety efforts by \$43 million in fiscal year 1998 and requested \$101 million for fiscal 1999. These funds went to various agencies—some

⁴Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992), Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993), Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994), and Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

of which previously did not have any food safety activities—to target efforts for collaborating on food safety priorities in six areas: (1) enhance surveillance of foodborne illnesses and build an early warning system; (2) improve the assessment of the risks associated with exposure to foodborne pathogens;⁵ (3) improve coordination among local, state, and federal health authorities; (4) improve the efficiency and effectiveness of seafood, fruits and vegetables, and other FDA inspections; (5) develop educational messages for a variety of audiences, such as consumers and schoolchildren, on the hazards associated with handling food; and (6) research methodologies for, among other things, more rapid and accurate identification and characterization of foodborne hazards. These areas represent important and specific food safety activities that, in many cases, existed prior to the initiatives but had difficulty obtaining funding through their agencies' processes for setting budget priorities. Appendix II shows, by agency, the fiscal year 1998 funding and fiscal 1999 request for these initiatives.

Funds for Food Safety Inspection Resources Could Be Spent More Effectively

A significant area in which food safety funds could be spent more effectively is inspection resources. Most of the \$271 million—over one-fourth of the food safety budget—spent annually on FSIS' organoleptic, carcass-by-carcass slaughter inspections could be spent more effectively on other food safety activities that better address food safety risks. Once HACCP is fully implemented, the funds could become available through the Congress's (1) authorizing FSIS to impose user fees on meat and poultry plants for carcass-by-carcass slaughter inspections, (2) eliminating the legislatively mandated requirement for these federal inspections and allowing slaughter plants to hire their own inspectors, or (3) combining the above options—permitting the slaughter plants to either pay the user fees for federal inspections or hire their own inspectors. In addition, if daily inspections of the processing plants—at an annual cost of about \$109 million—were replaced by inspections based on health risk, an undetermined amount of funds could be made available. All or part of the funds made available through the implementation of revisions to food safety inspections could be redirected to other food safety priorities.

⁵Pathogens are harmful bacteria, viruses, and parasites that are known to be transmitted by foods and foodborne outbreaks.

Resources From Carcass-by-Carcass Slaughter Inspections Could Be Spent More Effectively

Currently, FSIS spends about \$271 million annually on inspectors who are present at each slaughter plant nationwide every day that it is in operation. These inspectors, under current FSIS rules and regulations, inspect each carcass—over 8 billion birds and livestock annually—for visible defects, such as lesions and diseases. Under the traditional organoleptic inspection system, an inspector has about 2 seconds per bird, at the fastest line speeds, to determine whether the carcass meets federal standards for wholesomeness.

We previously reported that with the introduction of the HACCP system, the traditional system of organoleptic meat and poultry inspections of each meat and poultry carcass will become obsolete for improving the safety of meat and poultry because it does not prevent microbial contamination.⁶ Moreover, experts have recognized that post-mortem organoleptic inspections on every carcass must be changed because (1) they waste resources and cannot detect microbial pathogens, (2) the animal diseases for which they were originally designed have been eradicated in many countries, and (3) they result in unnecessary cross-contamination because the hands-on inspection techniques used virtually ensure that contamination spreads from one carcass to another. However, this type of inspection may be useful to slaughter plants, since it primarily provides an assurance of quality, such as ensuring that feathers are removed and that tumors and blood clots are not present. While these conditions do not generally threaten human health, they affect the quality of the product.

Because the organoleptic inspections of slaughtered animals primarily help to ensure quality rather than food safety, these inspections are foremost in the slaughter plants' interest. Therefore, as we previously reported, it may be appropriate to charge user fees to cover the cost of these activities.⁷ Historically, FSIS has sought but never received the authority to charge user fees for all of its inspection activities. FSIS is requesting user fees again in its fiscal year 1999 budget for all inspection activities. Although the Congress has decided in the past that it is not appropriate to impose user fees for all food safety inspections, the Congress, as a first option, may consider it appropriate to authorize user fees for the federal organoleptic, carcass-by-carcass inspection of slaughtered animals after FSIS has fully implemented the new science- and risk-based HACCP inspection system. If this authority were granted and

⁶See *Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry* (GAO/RCED-94-110, May 19, 1994).

⁷See *Food-Related Services: Opportunities Exist to Recover Costs by Charging Beneficiaries* (GAO/RCED-97-57, Mar. 20, 1997).

used, most of the \$271 million that FSIS currently spends on these inspections could be recovered.

As a second option, the Congress could amend the mandated requirement for federal carcass-by-carcass inspections by stipulating that after a slaughter plant has operated under a HACCP system for a period of time, the plant could conduct its own carcass-by-carcass slaughter inspections, with appropriate FSIS oversight. Alternatively, as we previously recommended, the Congress could revise the meat and poultry acts to provide FSIS with the flexibility and discretion to target its inspection resources to meet the most serious food safety risks.⁸

Finally, the Congress could provide for a combination of the first two options. That is, a plant could (1) pay a user fee to FSIS, adjusted periodically to reflect FSIS' increased costs, and use FSIS inspectors for carcass-by-carcass slaughter inspections or (2) hire its own employees to do these inspection activities with the appropriate FSIS oversight.

Resources From Daily Processing Plant Inspections Could Be Spent More Effectively

In prior work, we reported on the opportunity to more effectively use federal food safety resources by adopting a risk-based approach rather than the approach currently used by FSIS, which requires daily inspections at all processing plants. This inflexible, labor-intensive approach costs an estimated \$109 million annually. Under FSIS' current approach, an inspector must visit each meat and poultry processing plant every 8-hour operating shift to perform a number of tasks, such as monitoring the cleanliness of the workers' bathrooms and ensuring that the canning process operates under the right temperatures and pressures. An undetermined amount of funds could be made available by adopting a risk-based approach to determine the appropriate frequency for these inspections and to allow for more substantial inspections, if needed, when they do occur. Funds made available from this new approach could then be redirected to other food safety priorities.

Developing a risk-based system to determine the frequency of daily inspections would result in fewer inspections but also in inspections that are more closely tied to risk. Our past work pointed out the inefficiencies of FSIS' daily inspection of all 5,900 meat- and poultry-processing plants (or once per shift if a plant operates more than one 8-hour shift) with the same frequency and intensity of inspection regardless of the processing plant's

⁸See Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994).

public health risk and compliance history. In fiscal year 1997, the annual cost associated with inspectors traveling between processing plants on daily “patrol assignments,” which averaged three to six plants per day, was \$6 million. Under a risk-based approach, some of these inspections would occur less frequently because they would be based on the risk that specific food products pose to public health and the plants’ past inspection histories.

Opportunities Exist to Redirect Budget Resources to More Effective Uses

If FSIS changes its current approach to carcass-by-carcass slaughter inspections, all or part of the \$271 million annually spent on these inspections could be redirected to other federal food safety activities that better reduce the threat of foodborne illness. In prior work, we identified a number of food safety concerns that could be addressed, such as the following:

- FSIS could help to install HACCP inspection systems at the smallest meat and poultry slaughter and processing plants. Since industry will bear most of the installation cost for these new systems and the smallest plants have a smaller volume over which to spread this cost, these plants will be disproportionately affected by the cost of the new inspection systems.
- FDA could increase the frequency of its inspections of other U.S. food-processing plants, such as nonmeat soup plants, cereal manufacturers, and canned fruit and vegetable processors. Currently, FDA inspects such plants under its jurisdiction only once in 10 years, on average. These inspections are not based on the health risks that these plants pose, but rather on available resources. FDA officials informed us that if they had increased resources, FDA could increase the frequency of inspections of high-, moderate-, and low-risk firms, in that order. In general, the inspections of lower-risk firms would be based on the availability of resources.
- FDA could improve its oversight of imported foods by assisting foreign countries in developing equivalent food safety systems or it could use the funds to improve its oversight of imported foods at ports of entry.

In addition to these actions, the food safety agencies may have other priorities for the use of the funds that are made available from organoleptic slaughter inspections of meat and poultry plants or by basing the frequency of meat- and poultry-processing plant inspections on risk. For example, an ARS official stated that FDA could use additional funding to support an ongoing surveillance system of food animals. This system samples tissue from food animals that have been treated with antibiotics.

The system monitors (1) the buildup of antibiotic tolerances in animals and (2) the mutation of pathogens due to antibiotic treatment. The health concern is antibiotic resistance to pathogens in humans as a result of consuming these food animals.

National Food Safety Initiatives Identified Weaknesses, but the Fragmented Structure Persists

The national food safety initiatives were announced by the President for fiscal years 1998-99 and provided additional funds for identified weaknesses. These initiatives have improved some food safety activities. However, the initiatives do not address the fundamental problem of the system—its fragmented structure. In fact, for certain food safety activities, the initiatives intensified the need for coordination among the loosely networked group of federal food safety agencies.

Initiatives Identified Weaknesses and Provided Additional Funds

For fiscal year 1998, the administration's initiative received \$43 million for specific food safety activities to improve the nation's food safety system. Prior to the initiative, these activities had competed with other agency priorities for funding. The \$43 million in funding was aimed at, among other things, (1) improving a nationwide early-warning system for foodborne illnesses, (2) increasing seafood safety inspections, and (3) expanding research, training, and education in food safety. Under the initiative for fiscal year 1999, the administration has requested \$101 million to build upon the food safety efforts in the 1998 initiative and to enhance the safety of imported and domestic fruits and vegetables, among other things.

CDC used initiatives funding to improve its monitoring of foodborne illnesses and will expand its surveillance locations throughout the country to eight. This program, now known as FoodNet, provides national data to better identify illnesses associated with foods; these data allow for more informed decisions about dealing with microbial contamination. Prior to FoodNet, CDC had very limited information on the extent of foodborne illnesses. Since this surveillance effort was undertaken, for example, CDC has learned that the incidence of one pathogen, *Campylobacter*, is far more frequent than previously known.⁹ Policymakers can now use this information to direct research and other activities to reduce illnesses from this pathogen.

⁹*Campylobacter* is a pathogen that causes such foodborne illnesses as chronic diarrhea, meningitis, and blood poisoning. It is the most common precipitating factor for Guillain-Barre syndrome, which is now one of the leading causes of paralysis from disease in the United States. *Campylobacter* can occur from contact with such foods as raw poultry and raw milk.

Initiatives Do Not Address Fragmented Structure of the Food Safety System

While these food safety initiatives have addressed, and intend to address, some targeted problems, they do not effectively deal with the underlying fragmentation in the federal food safety system. As we have reported, past efforts to correct deficiencies in the federal inspection system for food safety have fallen short, in part because they did not address the fundamental problems in the system.¹⁰ Agencies operate under different regulatory approaches, have widely disparate budgets and staffs, and lack the flexibility needed to respond to changing consumption patterns and emerging food safety issues. These agencies' efforts are hampered by laws that were designed to address safety concerns in specific foods in a piecemeal fashion, typically in response to particular health threats or economic crises.

In addition, this fragmentation may have impeded the effective implementation of some of the activities funded through the food safety initiatives. For example, the initiatives for fiscal years 1998-99 included about \$15.7 million to FSIS, FDA, and the Cooperative State Research, Education, and Extension Service, among other agencies, to jointly develop a national campaign to educate the public about the safe handling of fruits and vegetables. However, this effort excluded EPA, which is spending about \$230,000 in fiscal year 1998 and about \$400,000 in fiscal 1999 to develop and distribute its own brochure to educate the public about pesticides and foods. While EPA attempted to coordinate its educational brochure with the other agencies, significant differences over the message still occurred. According to USDA and FDA officials and consumer groups, EPA's message implied that there are risks associated with eating fruits and vegetables treated with pesticides. These groups said that EPA's message contradicted USDA's advice to eat more fruits and vegetables. At the same time, the other agencies' effort developed a message that discussed the safe handling of fruits and vegetables and encouraged their consumption. In March 1998, after receiving comments from other agencies and the public on its draft brochure as published in the Federal Register, EPA began revising its brochure to reflect the concerns of the other agencies and advised us that it is still in that process.

Even when an activity under the initiatives has been designed to address a fragmentation problem, there is no assurance that it will be successful. For example, in January 1997, the President's Food Safety Initiative (Food Safety From Farm to Table: A National Food Safety Initiative) proposed improving seafood inspection activities by consolidating seafood

¹⁰See Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

inspections under one agency by October 1998. Under the proposal, NMFS' voluntary fee-for-service seafood inspection program would be moved to FDA. Progress on this consolidation has been slow because some of the necessary legislative changes are still being drafted. As of May 1998, NMFS officials told us that they have drafted legislation, in conjunction with FDA, to transfer the program to FDA but budget issues have delayed the legislation from being sent to the Office of Management and Budget for its review and approval. Consequently, the Congress has not had the opportunity to decide on the proposed legislation. Commerce's fiscal year 1999 budget request does not show NMFS' program as part of Commerce's fiscal 1999 budget, because Commerce assumed that legislation to transfer the program would be enacted during fiscal 1998. In addition, neither FDA's fiscal year 1999 budget nor its initiative funds provide for transferring NMFS' program to FDA, which has primary responsibility for seafood inspections. FDA officials told us that they did not include the transfer in their fiscal year 1999 budget request because they had not received the legislative authority to charge the user fees that are associated with NMFS' inspection program.

Agency Comments and Our Response

We provided the Department of Commerce, the CDC, EPA, FDA, and USDA with a draft of this report for their review and comment. The following summarizes their comments, which are shown in their entirety with our point-by-point responses, in appendixes III through VII.

USDA disagreed with the draft report and had concerns with (1) the draft's description of the Department's food safety inspection operations as well as the laws supporting these operations and (2) any implication that food safety resources should be transferred out of the Department. Concerning the former, USDA stated that we mischaracterized the statutory authorities for FSIS' programs that ensure the safety of the meat and poultry supply and inaccurately described FSIS' current inspection practices. For example, USDA noted that, in contrast to statements in the draft report, the statutes do not mandate how carcass-by-carcass inspections are to be carried out nor do they state the frequency of processing inspections. We used the Department's comments, where appropriate, to clarify certain aspects of the report. These clarifications are described in more detail in appendix VII. However, none of these revisions changed the fundamental description of the Department's inspection operations. Furthermore, they do not change our principal observation that USDA's current carcass-by-carcass inspection process as well as its daily processing plant

inspection process are not risk-based and, therefore, in our view, may not be an efficient use of federal food safety resources.

USDA's second concern stemmed from a misinterpretation of the draft. USDA officials incorrectly inferred that the report implied that any resources made available by revising the Department's current carcass-by-carcass inspection and daily plant inspection processes should be redirected outside FSIS. The report does not say this; rather, it presents several food safety activities that these resources could be redirected toward, both within and outside of FSIS.

EPA and FDA each had one primary concern about the draft report. This concern related to one of several examples used to illustrate our observation that the food safety initiatives did not address the underlying problems of fragmentation in food safety regulation. More specifically, the draft report noted that under the food safety initiative for fiscal year 1999, USDA and FDA had planned to consolidate efforts for monitoring microbial contamination in fruits and vegetables but had missed an opportunity to take a similar approach to monitor for pesticide residues in these foods. In commenting on the draft, both FDA and EPA stated that the objectives of USDA's and FDA's pesticide-monitoring efforts differed significantly enough that it would be difficult to develop a single monitoring program that would satisfy both agencies' monitoring objectives. On the basis of their concerns, we eliminated this particular example. However, our overall observation concerning fragmentation and the problems it creates for ensuring food safety remains unchanged.

The Department of Commerce and CDC generally agreed with our report and provided several technical corrections, which we incorporated as appropriate.

Scope and Methodology

You asked us to (1) analyze the federal food safety agencies' budgets for fiscal year 1999 to determine whether the appropriated funds of more than \$1 billion can be spent more effectively and (2) provide our views on whether the food safety initiatives for fiscal years 1998-99 will address underlying problems in the federal food safety system.

To address the first question, we reviewed the two food safety agencies with the largest budgets and another seven agencies with budgetary increases in their fiscal year 1999 budget requests for selected food safety programs and projects. In total, we examined 10 agencies' budgets: FDA

and CDC, within HHS; FSIS, AMS, APHIS, ARS, the Grain Inspection, Packers, and Stockyards Administration, and the Cooperative State Research, Education, and Extension Service, within USDA; NMFS, within the Department of Commerce; and EPA. In addition, we asked the agencies' program and budget officials to explain budget justifications in more detail for selected programs and projects to ascertain if these various agencies' budgets represented the best way to spend \$1 billion on federal food safety activities through appropriations and user fees. In order to provide our views on whether the food safety initiatives for fiscal years 1998-99 will address the underlying problems in the federal food safety system, we reviewed the administration's initiatives on food safety, examined four of the six priority areas identified within the initiatives because these areas had the largest budgets, and interviewed knowledgeable food safety agencies' program and budget officials on selected projects within those four areas.

In addition, to address both issues, we used information from our prior reports and reports from the Congressional Research Service. We conducted our review from February through May 1998 in accordance with generally accepted government auditing standards.

We are sending this report to various congressional committees because of their role in overseeing the activities and funding of the issues discussed. We are also sending copies of this report to the Secretaries of Agriculture, Commerce, and HHS; Administrator, EPA; and Director, Office of Management and Budget. In addition, we will make copies available to others on request. See appendix VIII for major contributors to this report. Please contact me at (202) 512-5138 if you or your staff have any questions.

Sincerely yours,



Lawrence J. Dyckman
Director, Food and
Agriculture Issues

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Table I.1: Changes in Funding and Staffing Levels for Food Safety at 12 Federal Agencies

Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
ATF	Bureau of Alcohol, Tobacco, and Firearms
CDC	Centers for Disease Control and Prevention
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
GAO	General Accounting Office
GIPSA	Grain Inspection, Packers and Stockyards Administration
HACCP	Hazard Analysis and Critical Control Point
HHS	Department of Health and Human Services
NMFS	National Marine Fisheries Service
USDA	U.S. Department of Agriculture

Responsibilities of Federal Agencies Involved With Food Safety

Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), is responsible for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. The Federal Food, Drug, and Cosmetic Act, as amended, is the major law governing FDA's activities to ensure food safety and quality. The act also authorizes FDA to maintain a surveillance of all animal drugs, feeds, and veterinary devices to ensure that drugs and feeds used in animals are safe and properly labeled, and produce no human health hazards when used in food-producing animals.

Centers for Disease Control and Prevention (CDC), within HHS, is charged with protecting the nation's public health by providing leadership and direction in preventing and controlling diseases and responding to public health emergencies. CDC conducts surveillance for foodborne diseases; develops new epidemiologic and laboratory tools to enhance the surveillance and detection of outbreaks; and performs other activities to strengthen local, state, and national capacity to identify, characterize, and control foodborne hazards. CDC engages in public health activities related to food safety under the general authority of the Public Health Service Act, as amended.

Food Safety and Inspection Service (FSIS), within the U.S. Department of Agriculture (USDA), is responsible for ensuring that meat, poultry, and processed egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, labeled, and packaged. FSIS carries out its meat and poultry inspection responsibilities under the Federal Meat Inspection Act, as amended, and the Poultry Products Inspection Act, as amended. Amendments to these acts require that meat inspected by state inspection programs as well as imported meat are to meet inspection standards "at least equal to" those of the federal program. Furthermore, the Department of Agriculture Reorganization Act of 1994 transferred to FSIS some food safety inspections previously performed by other organizations within USDA.

Animal and Plant Health Inspection Service (APHIS), within USDA, is responsible for ensuring the health and care of animals and plants. APHIS has no statutory authority for public health issues unless the concern to public health is also a concern to the health of animals or plants. APHIS identifies research and data needs and coordinates research programs designed to protect the animal industry against pathogens or diseases that are a risk to humans to improve food safety.

Appendix I
Responsibilities of Federal Agencies
Involved With Food Safety

Grain Inspection, Packers and Stockyards Administration (GIPSA), within USDA, is responsible for establishing quality standards and providing for a national inspection system to facilitate the marketing of grain and other related products. Certain inspection services, such as testing corn for the presence of aflatoxin, enable the market to assess the value of a product on the basis of its compliance with contractual specifications and FDA requirements. Those requesting inspection services, typically the owner of the grain, are responsible for complying with FDA regulations. GIPSA has no regulatory responsibility regarding food safety. Under a memorandum of understanding with FDA, GIPSA reports to FDA certain lots of grain, rice, pulses, or food products (which were officially inspected as part of GIPSA's service functions) that are considered objectionable under the Federal Food, Drug, and Cosmetic Act. GIPSA carries out its responsibilities under the U.S. Grain Standards Act, as amended, and the Agricultural Marketing Act of 1946, as amended.

Agricultural Marketing Service (AMS), within USDA, is primarily responsible for establishing the standards of quality and condition and for grading the quality of dairy, egg, fruit, meat, poultry, seafood, and vegetable products. As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. AMS carries out its wide array of programs to facilitate marketing under more than 30 statutes—for example, the Agricultural Marketing Agreement Act of 1937, as amended; the Agricultural Marketing Act of 1946, as amended; the Egg Products Inspection Act, as amended; the Export Apple and Pear Act, as amended; and the Export Grape and Plum Act, as amended. AMS is largely funded with user fees.

Agricultural Research Service (ARS), within USDA, is responsible for conducting a wide range of research relating to the Department's mission, including food safety research. ARS carries out its programs under the Department of Agriculture Organic Act of 1862; the Research and Marketing Act of 1946, as amended; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended.

National Marine Fisheries Service (NMFS), within the Department of Commerce, conducts its voluntary seafood safety and quality inspection programs under the Agricultural Marketing Act of 1946, as amended, and the Fish and Wildlife Act of 1956, as amended. In addition to the inspection and certification services provided for fishery products for human consumption, NMFS provides inspection and certification services for animal feeds and pet foods containing a fish base.

Appendix I
Responsibilities of Federal Agencies
Involved With Food Safety

Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or distributed in the United States and setting maximum allowed residue levels—tolerances—for pesticides on food commodities and animal feed. EPA’s activities are conducted under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Federal Food, Drug, and Cosmetic Act, as amended.

Federal Trade Commission (FTC) enforces the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. FTC’s food safety objective is to prevent consumer deception through the misrepresentation of food.

U.S. Customs Service, within the Department of the Treasury, is responsible for collecting revenues and enforcing various customs and related laws. Customs assists FDA and FSIS in carrying out their regulatory roles in food safety.

Bureau of Alcohol, Tobacco, and Firearms (ATF), within the Department of the Treasury, is responsible for administering and enforcing laws covering the production (including safety), use, and distribution of alcoholic beverages under the Federal Alcohol Administration Act and the Internal Revenue Code.

**Appendix I
Responsibilities of Federal Agencies
Involved With Food Safety**

Table I.1: Changes in Funding and Staffing Levels for Food Safety at 12 Federal Agencies

Dollars in millions

Agency	Funding			Staffing		
	Fiscal year 1989	Fiscal year 1994	Fiscal year 1998 ^a	Fiscal year 1989	Fiscal year 1994	Fiscal year 1998
FDA ^b	\$158	\$239	\$254	2,648	2,999	2,796
FSIS	457	606	676	10,399	10,109	9,702
APHIS ^c	c	c	c	c	c	c
GIPSA ^d	42	44	0	860	685	0
AMS ^e	9	14	10	183	33	42
ARS	25	38	55	168	134	167
NMFS ^d	12	16	13	265	285	174
EPA ^f	90	95	127	624	786	970
CDC	3	4	15	25	34	50
FTC	2	2	9	29	23	9
Customs ^c	c	c	g	c	c	g
ATF ^c	c	c	g	c	c	g
Total	\$798	\$1,058	\$1,150	15,201	15,088	13,901

^aAppropriated funds for fiscal year 1998.

^bFDA's data include funding and staffing for various programs across FDA that are involved with food safety activities, including the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the field components for these centers, and overall agencywide support.

^cThe agency did not specify its food safety resources.

^dAgencies' funding and staffing levels are for both safety and quality inspection activities.

^eAMS' funding and staffing totals for fiscal year 1989 reflect egg inspection activities, which were transferred to FSIS in 1994. Totals for fiscal years 1994 and 1998 include data for the Pesticide Data Program, which began in 1991.

^fNumbers for EPA are from the following sources: Fiscal Year 1991 President's Budget, 1989 Actuals; Fiscal Year 1996 President's Budget, 1994 Actuals; and Fiscal Year 1999 President's Budget, 1998 Enacted, and includes the total Office of Pesticides Programs.

^gWe did not review these agencies' food safety budgets because of the small amount of funds for these activities in previous years.

Source: GAO's analysis of federal agencies' data.

Food Safety Initiatives by Category and Dollar Amount

Dollars in thousands

Six Initiative categories	Fiscal year 1997	Fiscal year 1998		Fiscal year 1999	
	Actual expenditure ^a	Budget appropriation	Change from FY 1997	Budget request	Change from FY 1998
Surveillance					
Food Safety and Inspection Service	\$1,000	\$1,500	\$500	\$1,500	0
Economic Research Service	32	32	0	285	253
Food and Drug Administration	678	3,838	3,160	6,038	2,200
Centers for Disease Control and Prevention	4,500	14,500	10,000	19,000	4,500
Subtotal	6,210	19,870	13,660	26,823	6,953
Coordination					
Food and Drug Administration	6,598	7,148	550	7,348	200
Subtotal	6,598	7,148	550	7,348	200
Inspections					
Food Safety and Inspection Service	0	565	565	8,412	7,847
Food and Drug Administration	67,376	75,246	7,870	102,846	27,600
Subtotal	67,376	75,811	8,435	111,258	35,447
Risk Assessment					
Agricultural Research Service	5,461	4,498	-963	4,818	320
Cooperative State Research, Education, and Extension Service	145	150	5	1,962	1,812
Food Safety and Inspection Service	0	0	0	1,000	1,000
Economic Research Service	33	33	0	686	653
Office of the Chief Economist	62	60	-2	158	98
Food and Drug Administration	2,382	6,332	3,950	13,532	7,200
Subtotal	8,083	11,073	2,990	22,156	11,083
Education					
Cooperative State Research, Education, and Extension Service	2,365	2,365	0	7,365	5,000
Food Safety and Inspection Service	0	0	0	2,500	2,500
Food and Consumer Service	0	0	0	2,000	2,000
Office of the Chief Economist	27	38	11	38	0
Economic Research Service	420	420	0	420	0
Food and Drug Administration	4,415	6,485	2,070	10,085	3,600

(continued)

**Appendix II
Food Safety Initiatives by Category and
Dollar Amount**

Dollars in thousands

Six Initiative categories	Fiscal year 1997	Fiscal year 1998		Fiscal year 1999	
	Actual expenditure ^a	Budget appropriation	Change from FY 1997	Budget request	Change from FY 1998
Centers for Disease Control and Prevention	0	0	0	500	500
Subtotal	7,227	9,308	2,081	22,908	13,600
Research					
Agricultural Research Service	44,186	50,351	6,165	64,001	13,650
Cooperative State Research, Education, and Extension Service	3,724	6,250	2,526	10,438	4,188
Agricultural Marketing Service	0	0	0	6,257	6,257
Food and Drug Administration	19,127	25,527	6,400	34,727	9,200
Subtotal	67,037	82,128	15,091	115,423	33,295
Total			\$42,807		\$100,578

Legend

FY = fiscal year.

^aThe first initiative started in fiscal year 1998; data for fiscal year 1997 are provided as a baseline. The resources reflected above are for the Food Safety Initiatives only and do not include funding for the agencies' other food safety activities.

Comments From the Department of Commerce

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



THE SECRETARY OF COMMERCE
Washington, D.C. 20230

JUN 24 1998

Mr. Lawrence J. Dyckman
Director, Food and Agriculture Issues
Resources, Community, and
Economic Development Division
General Accounting Office
Washington, D.C. 20548

Dear Mr. Dyckman:

Enclosed is the Department of Commerce's reply to the General Accounting Office draft report entitled "Food Safety: Opportunities to Enhance Effectiveness by Redirecting Federal Resources and Funds (GAO/RCED-98-224)."

These comments are prepared in accordance with the Office of Management and Budget Circular A-50.

Sincerely,

A handwritten signature in black ink, appearing to read "William M. Daley", written over a horizontal line.

William M. Daley

Enclosure

**Appendix III
Comments From the Department of
Commerce**

See comment 1.
Now on pp. 10-11.

COMMENTS:

Page 16 - last paragraph - Following the words "there is no assurance that it will be successful", insert the following sentences:

For example, in January, Spring 1997, an interagency food safety report prepared for the President suggested the first initiative proposed improving seafood inspection activities by consolidating seafood inspections under one agency by October 1998. Under the proposal, the National Marine Fisheries Service's voluntary fee-for-service seafood inspection program would be moved to FDA. Progress on this consolidation has been slow because necessary legislative changes are still being drafted. As of May 1998, Fisheries Service officials told us that they are drafting drafted legislation, in conjunction with FDA, to transfer the program to FDA, but budget issues have delayed the legislation from being had not been sent to the Office of Management and Budget for its review and approval.

Page 16 - last paragraph - Delete the sentences that follow beginning "For example, in January..," and ending with, "...for its review and approval."

The statement regarding Commerce's 1999 budget request not showing the Fisheries Service's program as part of Commerce's 1999 budget would be more accurate if the words "because it assumed legislation to transfer the program would be enacted during FY 1998."

See comment 2.
Now on p. 11.

**Appendix III
Comments From the Department of
Commerce**

The following are GAO's comments on the Department of Commerce's letter dated June 24, 1998.

GAO's Comments

1. We revised the report to reflect the Department of Commerce's language changes. However, we did not delete the "January 1997" date because we wanted to clearly demonstrate the time frame involved with the activity.
2. We revised the report to reflect the language requested by the Department.

Comments From the Centers for Disease Control and Prevention

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUN 25 1998

Lawrence J. Dyckman
Director, Food and Agriculture Issues
U.S. General Accounting Office

Dear Mr. Dyckman:

Thank you for the opportunity to review the draft GAO report entitled, "FOOD SAFETY: Opportunities to Enhance Effectiveness by Redirecting Federal Resource and Funds." The Centers for Disease Control and Prevention's technical comments are listed below for your consideration.

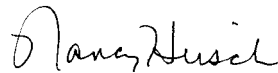
Page 14, line 6: Please change the end of this sentence to read, "... expand its surveillance locations throughout the country to eight sites."

Page 22, para 5, (section on CDC responsibilities): After the first sentence, please insert the following:

It conducts surveillance for foodborne diseases; develops new epidemiologic and laboratory tools to enhance surveillance and outbreak detection; and performs other activities to strengthen local, State, and national capacity to identify, characterize, and control foodborne hazards.

If you should have any questions concerning these comments, please contact me (404.639-0440) or Joe Davis (404.639-4002)

Sincerely,


for Carolyn J. Russell
Director, Management Analysis
and Services Office

See comment 1.

Now on p. 9.

Now on p. 16.

**Appendix IV
Comments From the Centers for Disease
Control and Prevention**

The following are GAO's comments on CDC's letter dated June 25, 1998.

GAO's Comments

1. We revised the report to reflect the language requested by CDC.

Comments From the Environmental Protection Agency

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

JUL 6 1998

Mr. Lawrence J. Dyckman
Director
Food and Agriculture Issues
U.S. General Accounting Office
Washington, D.C. 20548

I am responding to your June 17 letter requesting the Environmental Protection Agency (EPA) review and comment on a General Accounting Office (GAO) draft report. The draft report is entitled, Opportunities to Enhance Effectiveness by Redirecting Federal Resources and Funds (GAO/RCED-98-224).

General Comment

The Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and the EPA have reviewed and discussed the draft report. As GAO is aware, the challenge and responsibility of ensuring that the American food supply is safe, and of meeting the public expectations, is enormous. FDA, USDA, EPA and the Centers for Disease Control (CDC) are working closely together to implement the President's Food Safety Initiative (see Food Safety From Farm to Table: A National Food Safety Initiative) to ensure the safety of food consumed by the American public. The program is science/risk-based, conforms with the revitalization goals of the Government Performance Reform Act, and will increase the agencies' efficiency. The Food Safety Initiative (FSI) calls for close coordination among the food safety agencies in planning food safety activities, in surveillance activities, and in addressing problems as they arise. Numerous cooperative efforts to prevent or contain food borne illnesses have been undertaken with a particular focus on coordinated research, improved risk assessment, cooperative inspections, surveillance and monitoring, partnerships in educational programs, and more rapid, coordinated and effective control of food contamination outbreaks. These coordinated efforts are expected to continue and increase in the future.

Below are EPA's specific comments referenced to the draft report.

Page 15, paragraph 2 - Consumer Brochure

As background, the Food Quality Protection Act of 1996 requires EPA, in consultation with the Food and Drug Administration and the United States Department of Agriculture, to

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Now on p. 10.

**Appendix V
Comments From the Environmental
Protection Agency**

annually prepare and distribute information to "large" retail grocers for public display as of August 1998. Information must include at a minimum:

- Risks and benefits of pesticide use on food
- Listing of any benefits-based tolerances granted by that date
- Reasonable substitutes for foods with those tolerances
- Ways consumers can reduce their exposure to pesticides.

In March 1997, the Agency established a workgroup, the Pesticide Program Dialogue Committee (29 members), which included FDA and USDA representatives. We have sought the advice of the advisory committee throughout the development of the draft brochure. The Agency also met with representatives of these agencies early on to discuss joint issues of concern. You should also be aware that the Agency solicited comments on the draft through the Federal Register, and conducted focus groups to obtain consumer input as well.

EPA strongly supports the federal governments advice to eat a balanced diet of fruits and vegetables. By law, it is also our responsibility to provide consumers with information on the risks and benefits of pesticides. It is not the Agency's intent to imply that there are unreasonable risks associated with eating fruits and vegetables grown using pesticides. The draft brochure is undergoing further review. In the final brochure we will strive to strike the appropriate balance by informing the public about the use of pesticides on foods while emphasizing the importance of a balanced diet and by providing tips for reducing exposure. We believe this approach is consistent with the law's intent.

With regard to FY 1998 funding for the consumer brochure, the Agency has spent approximately \$200, 000 and expects to spend an additional \$30,000 by August 1998. Although funding for fiscal year 1999 is not available at this time, we have never projected that it would cost the Agency "about \$1 million dollars in fiscal year 1999 to develop and distribute" this material.

Page 16, paragraph 1, line 11 - Monitoring Programs

Rewrite to read: "In fiscal year 1998, EPA relied on monitoring programs conducted by AMS and FDA to provide information on pesticide residues in/on fruits and vegetables. For information on pesticide residues on meat and poultry, EPA relied on FSIS's monitoring program. Because the AMS program is limited to a few crops, FDA will continue to conduct its own monitoring program for pesticide residues."

Additionally, the implication of the discussion on pg. 16 is that it would be more efficient and cost-effective to have pesticide residue monitoring done by USDA's Agricultural Marketing Service (AMS). By law, FDA's pesticide residue monitoring program is to ensure compliance with federal standards for acceptable levels of pesticide residues and to use this information for enforcement actions; this monitoring is targeted toward potential problems. EPA strongly

See comment 1.

See comment 2.

**Appendix V
Comments From the Environmental
Protection Agency**

supports FDA continuing to monitor pesticide residues to ensure compliance. FDA also conducts market basket surveys to examine residue levels at the point of purchase. AMS' sampling is not designed to serve either of these purposes.

Page 23, Attachment II - Changes in funding and Staffing Levels for Food Safety at 12 Federal Agencies

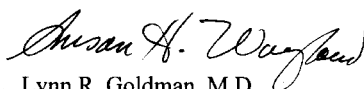
Below in bold are the correct funding levels for EPA:

	Funding (dollars in millions)			Staffing		
	FY 1989	FY 1994	FY 1998	FY 1989	FY 1994	FY 1998
EPA*	90	95	127	624	786	970
EPA (as reported in GAO report)	55	93	56	624	785	681

* Numbers are from the following sources:
 FY 1989: FY 1991 President's Budget, **1989 actuals** (total Office of Pesticides Programs)
 FY 1994: FY 1996 President's Budget, **1994 actuals** (total Office of Pesticides Programs)
 FY 1998: FY 1999 President's Budget, **1998 enacted** (total Office of Pesticides Programs)

Thank you for the opportunity to review and comment on the draft report. I look forward to receiving the final report.

Sincerely,


 for Lynn R. Goldman, M.D.
 Assistant Administrator
 Office of Prevention, Pesticides and Toxic Substances

See comment 3.
Now on p. 19.

The following are GAO's comments on EPA's letter dated July 6, 1998.

GAO's Comments

1. The report now reflects the \$230,000 that EPA expects to spend on the effort for fiscal year 1998. In addition, the \$1 million estimate for fiscal year 1999, which EPA's budget officials had previously provided us with, has been revised to reflect EPA's current estimate of \$400,000.
2. This section of the report was deleted. Originally, this section discussed a specific example of how the food safety initiative did not address underlying problems associated with the fragmentation of food safety responsibilities. In particular, the example noted efficiencies that could be gained by combining FDA's and USDA's pesticide-residue-monitoring programs for fruits and vegetables. This action would have been consistent with FDA's and USDA's plans under the 1999 food safety initiative to combine their systems for monitoring the microbial contamination of fruits and vegetables. However, FDA's letter expressed concerns about whether the proposed combined microbial-contamination-monitoring program would satisfy its monitoring needs and has similar concerns about combined pesticide residue monitoring. (See app. VI.) In view of these concerns, as well as similar concerns expressed in EPA's letter, we eliminated the discussion of this particular example. However, we did not change the report's overall observation concerning the food safety initiative's failure to address fundamental fragmentation problems.
3. We revised the draft report to reflect EPA's most recent funding and staffing estimates.

Comments From the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857


JUL 07 1998

Mr. Lawrence J. Dyckman
Director, Resources, Community, and
Economic Development Division
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, N.W., Room 2T23
Washington, D.C. 20548

Dear Mr. Dyckman:

Attached are the Food and Drug Administration's comments on the draft report entitled, "Food Safety: Opportunities to Enhance Effectiveness by Redirecting Federal Resources and Funds." RCED-98-224.

Sincerely,


Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

**Appendix VI
Comments From the Food and Drug
Administration**

COMMENTS OF THE FOOD AND DRUG ADMINISTRATION ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: OPPORTUNITIES TO ENHANCE EFFECTIVENESS BY REDIRECTING FEDERAL RESOURCES AND FUNDS GAO/RCED-98-224

The Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and the Environmental Protection Agency have reviewed and discussed the draft report. As GAO is aware, the challenge and responsibility of ensuring that the American food supply is safe, and of meeting the demands of public expectations is enormous. FDA, USDA, EPA, and the Centers for Disease Control (CDC) are working closely together to implement the President's Food Safety Initiative (see Food Safety From Farm to Table: A National Food Safety Initiative) to ensure the safety of food consumed by the American public. The program is science/risk-based, conforms with the revitalization goals of the Government Performance Results Act, and will increase the agencies' efficiency. The FSI calls for close coordination among the food safety agencies in planning food safety activities, in surveillance activities, and in addressing problems as they arise. Numerous cooperative efforts to prevent or contain food borne illnesses have been undertaken with a particular focus on coordinated research; improved risk assessment; cooperative inspections, surveillance and monitoring; partnerships in educational programs; and more rapid, coordinated and effective control of food contamination outbreaks. These coordinated efforts are expected to continue and increase in the future.

The FSI is innovative and progressive, utilizing programs such as the Hazard Analysis Critical Control Point (HACCP) concept to strengthen FDA's ability to address manufacturing problems and prevent their occurrence whenever possible. HACCP is grounded in the premise that the manufacturer/producer is responsible for assuring its products are in compliance with the Federal requirements for food safety, and that specific points in the manufacturing process are critical to producing a safe food. These points can be identified and controls instituted to guard against failure. The HACCP program requires continuous record-keeping, which gives both the producer and FDA the ability to identify problems and take corrective action before the manufacturing process deteriorates to a violative level. FDA believes the use of such preventive controls will enhance the safety of food reaching American tables.

In addition, FDA's close working relationships with State and local governments have been strengthened and more effective partnerships have been established. The states share responsibility for ensuring the safety of the food supply by monitoring intrastate food production and taking corrective action as necessary under their own authorities. FDA contracts with various States for work such as inspections of food producers under the Federal Food, Drug, and Cosmetic Act (FFDCA) authorities. Many States also have entered into cooperative "partnerships" with FDA, to provide a network that meets the Agency's needs as well as those of the States and local governments. The working relationship with each State is individually negotiated to meet both its needs and interests while also meeting the needs of the Federal government. Overall, the program of working closely with the States and local governments effectively provides a high level of consumer protection and expands FDA's reach.

**Appendix VI
Comments From the Food and Drug
Administration**

The Agency also is looking for ways to enhance its control of imported foods, which have become increasingly important to the American diet. During fiscal year 1997, FDA began phased in use of the Operational and Administrative System for Import Support (OASIS), an automated import entry and control program that allows the Agency to concentrate its food import resources on the highest risk entries, such as seafood, low acid canned food, or entries from areas of the world where, based on experience, problems are most likely to arise. The OASIS is being enhanced to make certain aspects more accessible to inspectors and to make the system easier to use. Currently, most food entries are being processed electronically by importers/brokers, saving time for the importers and allowing FDA to select appropriate entries to examine/sample based on criteria that are aimed toward identifying products that may be hazardous. As the OASIS database grows, it will become even more useful for identifying potential problem entries and allowing safe products to proceed without physical examination.

FDA is committed to streamline and consolidate functions/activities wherever possible to make the most effective use of the government's limited resources. The Agency has demonstrated this commitment through efforts to consolidate. As an example, discussions are underway to consolidate the seafood activities of the National Marine Fisheries Service (NMFS) and FDA.

Finally, we would like to correct a few misconceptions. The statement that, "FDA has agreed that this effort at AMS will also meet its needs for the sampling and testing of fruits and vegetables for microbial contamination." is incorrect. The AMS monitoring program, as it is planned currently, will not meet FDA's needs for sampling and testing fruits and vegetables for microbial contamination because of significant differences between the occurrence of pesticide residues and the occurrence of microbial contamination, as well as differences in sampling and testing procedures that must be used. For FDA's enforcement purposes, sampling and analyses must be targeted to potential problem areas. The AMS proposed program would not target problem areas, but would statistically sample a few commodities to determine a baseline of microbial contamination.

As you know, pesticides are regulated through a pre-market approval system established by EPA whereby restrictions are placed on the use of a pesticide and limits (tolerances) are established for residues that may occur. Microorganisms, on the other hand, are not pre-approved for use at safe levels, and they occur naturally in the environment or are transferred through worker handling, animal wastes, etc. The mere presence of microorganisms on food does not signal a public health risk. Furthermore, under most circumstances, microorganisms are not deliberately applied to the crop, so distribution within a crop or growing area is random and unpredictable. There is no scientific profile on which to base sampling that would be representative of an entire crop, nor is there a premarket approval system which could identify the microorganisms most likely to be found on a particular crop or in a particular area. The number of microorganisms is never static and may be affected by handling, contact with infected individuals, or exposure to unsanitary conditions, as well as growing conditions. For consumer protection and enforcement purposes the specific pathogenic microorganism must be identified. The scientific community is now in the process of developing a battery of testing methods which may be used to

See comment 1.

**Appendix VI
Comments From the Food and Drug
Administration**

recover/determine pathogenic organisms in produce. This is one of the components of the Food Safety Initiative.

The draft report statement that, “While FDA has a regulatory responsibility to enforce compliance with pesticide standards, the information it needs for monitoring could be obtained from AMS’ monitoring program.” is misleading. Further, the implication of the discussion on page 16 is that it would be more efficient and cost-effective to have pesticide residue monitoring done by USDA’s Agricultural Marketing Service, which is not the case. The AMS program is a statistically random data-collection effort that is designed to provide information, particularly to EPA, regarding the occurrence of pesticides on certain domestic crops. FDA, on the other hand, monitors pesticide residues for purposes of enforcing established tolerances. By law, the intent of FDA’s pesticide residue monitoring program is to ensure compliance with federal standards for acceptable levels of pesticide residues and to use this information for enforcement actions. Unlike the AMS monitoring program, FDA’s monitoring is targeted toward potential problems and includes coverage of imported food as well as domestically produced food. Data for reports to be published are derived from the data acquired for enforcement purposes and from the Total Diet Study, which periodically assesses the total diets of selected strata of the population to determine their total pesticide burden. The Total Diet Study is unique in that the food is selected to include the total diet as it would actually be eaten rather than as it would appear in the market place. No other source of information will provide the same or similar information. Sampling for determination of compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA follow strict protocols with respect to sample collection, protection of sample integrity and the chain of custody from collection through analysis, and validation of analytical results to ensure that the findings will sustain challenge in court if necessary.

See comment 1.

The following are GAO's comments on FDA's letter dated July 7, 1998.

GAO's Comments

1. This section of the report was deleted. Originally, this section discussed a specific example of how the food safety initiative did not address underlying problems associated with the fragmentation of food safety responsibilities. In particular, the example noted efficiencies that could be gained by combining FDA's and USDA's pesticide-residue-monitoring programs for fruits and vegetables. This action would have been consistent with FDA's and USDA's plans under the 1999 food safety initiative to combine their systems for monitoring the microbial contamination of fruits and vegetables. However, FDA's letter expressed concerns about whether the proposed combined microbial contamination monitoring program would satisfy its monitoring needs and has similar concerns about combined pesticide residue monitoring. In view of these concerns, as well as similar concerns expressed in EPA's letter (see app. V), we eliminated the discussion of this particular example. However, we did not change the report's overall observation concerning the food safety initiative's failure to address fundamental fragmentation problems.

Comments From the U.S. Department of Agriculture

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

JUL 7 1998

Mr. Lawrence J. Dyckman
Director, RCED Division
Food and Agriculture Issues
U. S. General Accounting Office
441 G Street, NW, Room 2T23
Washington, D.C. 20548

Dear Mr. Dyckman:

Thank you for the opportunity to provide Departmental comments on the Draft Report RCED-98-224, "Food Safety: Opportunities to Enhance Effectiveness by Redirecting Federal Resources and Funds." We have provided you with both general and specific comments in order to address several erroneous assumptions and mischaracterizations of USDA programs and the National Food Safety Initiative contained within the draft report.

I. GENERAL COMMENTS

BACKGROUND

The GAO has mischaracterized the statutory authorities for the FSIS programs that ensure the safety of the meat and poultry supply and inaccurately described FSIS' current inspection practices, including post-mortem inspections. FSIS utilizes carcass-by-carcass slaughter inspections as one of many methods of monitoring and ensuring food safety. Additional efforts have gone into checking animals for diseases and antibiotic residues.

The U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have reviewed and discussed this draft report. As GAO is aware, the challenge and responsibility of ensuring that the American food supply is safe, and of meeting the demands of public expectations are enormous. USDA, EPA, FDA and the Centers for Disease Control are working closely together to implement the President's Food Safety Initiative (see Food Safety From Farm to Table: A National Food Safety Initiative) to ensure the safety of food consumed by the American public.

See comment 1.

This initiative is science/risk-based, conforms to the goals of the Government Performance and Results Act, and will increase the agencies' efficiency. The Food Safety Initiative calls for close coordination among the food safety agencies in planning food safety activities, in carrying out food safety surveillance activities, and in addressing food safety problems as they arise. Numerous cooperative efforts to prevent or contain foodborne illness have been undertaken with a particular focus on coordinated research, improved risk assessment, cooperative inspections, surveillance and monitoring, partnerships in educational programs and more rapid, coordinated and effective responses to outbreaks of food contamination. These coordinated efforts are expected to continue and increase in the future.

II. The Draft Report Contains Fundamental Errors and Omissions about FSIS' Inspection System

A. The Draft Report Contains Fundamental Errors

The draft GAO report contains errors so fundamental in describing FSIS' activities in slaughter and processing plants that it does not provide an understanding of what FSIS does to protect the safety of meat and poultry, and what the Agency is doing to improve the effectiveness of its inspection systems. FSIS believes that in its rush to support a single food safety agency, the draft report ignores the nature and scope of the important work that FSIS is doing, and the significant progress that FSIS has made to enhance food safety. At numerous points in the draft report, it states that, at slaughter, FSIS engages in statutorily mandated carcass-by-carcass inspections that are only capable of ensuring quality and not food safety. The draft report is fundamentally in error in two basic respects. First, while the Federal Meat Inspection Act states that there is to be post mortem inspection of the carcasses of all animals prepared at a slaughtering or similar establishment (21 USC 604), and the PPIA states that there is to be post mortem inspection of the carcass of each bird processed (21 USC 455), neither statute states how these inspections are to be conducted. There is no statutory requirement that the inspections be accomplished as currently conducted under FSIS' inspection program and regulations.

See comment 2.

Second, it is not true that these inspections help only to ensure product quality. FSIS inspectors look for numerous serious problems that could render meat and poultry products injurious to health. For example, inspectors look for evidence of diseases that can be transmitted to humans. They examine carcasses for fecal material and ingesta that are significant sources of pathogens. They check the environment in which the animals are slaughtered to ensure that it is not a source of contaminants or pathogens that can render the products injurious to health. They collect samples for animal drug residue and salmonella testing.

See comment 3.

**Appendix VII
Comments From the U.S. Department of
Agriculture**

They ensure that the carcasses are promptly and properly cooled to prevent pathogen growth. This is just a brief list of some of the important tasks that FSIS inspectors accomplish that are designed to ensure that meat and poultry are safe. These significant food safety activities are completely ignored by the draft report.

See comment 4.

The draft report is equally in error in its description of FSIS' inspection of processing operations. The report asserts that FSIS is mandated to inspect meat and poultry processing plants at least once per day during each operating shift. Again, there is no basis in the statutes for this statement. FSIS must inspect all carcasses and parts of carcasses and meat products in any meat-processing establishment. Further, as determined by the Secretary, FSIS inspects poultry carcasses and processed poultry products. Again, the important point is that the statute is silent on how FSIS is to accomplish this inspection mandate.

See comment 5.
Now on p. 4.

The draft report seriously misstates the health risks presented by and associated with processing operations. The draft report, (pages 5-6) for example, states that processing plants' operations can include such "simple" processes as grinding. This statement reflects a serious misunderstanding of the food safety risks associated with meat and poultry processing operations. Contamination of meat by E. coli O157:H7, a deadly pathogen, is one of the serious risks associated with grinding operations. The importance of FSIS' inspection of grinding and other processing operations can not be dismissed as the draft report would have the reader believe.

See comment 6.

B. The Draft Report's Assertion That Resources May Safely Be Transferred From FSIS Has No Basis In Fact

This draft report offers no comparative risk assessments to justify transferring funds. No other category of foods is associated with 5,000,000 illnesses and 4,000 deaths annually. What is even more shocking about the draft report is that it fails to mention the fact that FSIS has long recognized the desirability of fundamental changes in its meat and poultry inspection program to improve food safety, reduce the risk of foodborne illness in the United States, and make better use of the Agency's resources (61 Fed. Reg. 38806, 38807 (July 25, 1996)). Indeed, this FSIS strategy has been publicly announced in its PR/HACCP rule. As explained in detail below, FSIS is now engaged in a far-reaching effort to bring about the necessary changes in its program. The first step was promulgating the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems final rule (61 Fed. Reg. 38806). The adoption of HACCP should produce significant efficiencies in how the Agency deploys its slaughter and processing inspectors. In addition, FSIS intends to scientifically investigate the possibility of similar improvements in efficacy and efficiency in its deployment of its inspectors in slaughter plants.

However, even if efficiencies in deployment of FSIS' inspectors can be realized, it does not mean that FSIS' resources can be safely transferred away from meat and poultry. To ensure the safety of meat and poultry for consumers, there must be a strategy for the control of food safety hazards throughout the continuum of animal production, slaughter, processing, distribution, and sale of meat and poultry products (61 Fed. Reg. 38810). To carry out this strategy, resource savings realized in slaughter and processing establishments will need to be redeployed to other parts of the continuum.

In addition, the changing work that will be done by FSIS' inspectors as a result of HACCP and increased attention by FSIS to the full farm-to-table continuum, means that FSIS will need a better educated, more scientifically trained, and thus likely higher graded, inspector work force.

Finally, the meat and poultry industries are dynamic and growing significantly, both domestically and for export. The meat and poultry industries have increased their export from two- to eight-fold, respectively. Quite apart from the need to redeploy FSIS' resources to new tasks based on sound science and solid assessment of risks, FSIS' workforce must grow with the industry if the safety of meat and poultry products is to be adequately protected. FSIS recognizes that significant improvements in the productivity and efficiency of the entire Agency will also be critical to the success of its food safety mission.

For these reasons, FSIS has a clear and continuing need for its current level of resources to ensure the safety of meat, poultry, and eggs products. There simply is no basis for the draft report's claim that funds appropriated to FSIS could be more effectively used if redirected from the Agency. FSIS is making significant efforts to redesign itself to ensure that its resources are used as efficiently and effectively as possible to enhance the safety of meat, poultry, and egg products. Those efforts are outlined below. The essential point is that FSIS efforts are bound to fail if there is a significant reduction of the Agency's resources.

C. The Direction of the FSIS Food Safety Programs

FSIS is changing how its resources are allocated to improve regulation of the meat and poultry industries after complete implementation of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems final rule. Every aspect of traditional FSIS methods of inspection for slaughter and processing is being reconsidered. All current methods are subject to change as long as the Agency can still fulfill its responsibilities to ensure that these industries produce safe, wholesome, unadulterated and properly labeled meat and poultry products. The Agency is also considering adding methods to better ensure food safety in distribution channels where further contamination occurs.

See comment 7.

FSIS has solicited community and industry participation in the development of new inspection models for slaughter and processing in a HACCP environment. FSIS stated its goal as follows: "To reduce the risk of foodborne illness associated with the consumption of meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible measures are taken at each step in the food production process where hazards can enter and where procedures and technologies exist or can be developed to prevent the hazard or reduce the likelihood it will occur."

The PR/HACCP rule mandates substantial change within every inspected meat and poultry establishment. The new regulations: (1) require that each establishment develop, implement, and follow written sanitation standard operating procedures (SSOP's); (2) require regular microbial testing by slaughter establishments to verify the adequacy of their process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for Salmonella that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a risk-based system of preventive controls known as HACCP to improve product safety.

In mandating these reforms, FSIS recognized that in-plant technological and procedural solutions could not address foodborne illness hazards occurring in meat and poultry products outside official establishments. These components of the goal can be achieved only through a more comprehensive food safety strategy that would bring about improvements in risk management at each step in the meat and poultry production chain. Efforts must extend throughout the farm-to-table continuum.

FSIS is exploring alternatives to its current inspection design and resource deployment models. If these studies prove feasible, resources would be allocated to new in-plant functions associated with oversight, evaluation, and verification of the PR/HACCP rule implementation. Other redeployed resources could be assigned to in-distribution oversight. FSIS must be left free to work through the redeployment process.

III. The Draft Report Mistakenly Includes Resources Directed at Assuring Marketing Quality as Being Available for Food Safety

This GAO study should not include the programs of the Grain Inspection, Packers and Stockyards Administration (GIPSA); the Animal and Plant Health Inspections Service (APHIS); or the commodity grading programs of the Agricultural Marketing Service (AMS) because these programs have no regulatory responsibility for food safety. We believe that it is a mistake to include government agencies or programs with no responsibilities for food safety.

See comment 8.

**Appendix VII
Comments From the U.S. Department of
Agriculture**

For example, under the GIPSA grain inspection program, customers may request a test for the presence of certain mycotoxins, pesticide residues, or other quality factors. Customers typically request this service to comply with contract terms. These services are offered to facilitate the marketing of U.S. grain, not to regulate food safety. It is the responsibility of the customer (owner of the grain) to comply with Food and Drug Administration (FDA) regulations and it is the responsibility of FDA officials to enforce these regulations. Under a memorandum of understanding with FDA, GIPSA reports to FDA certain lots of grain, rice, pulses, or food products (which were officially inspected as part of GIPSA's service functions) that are considered objectionable under the Federal Food, Drug, and Cosmetic Act.

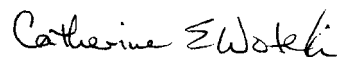
AMS grading and certification programs have no food safety components. AMS commodity graders inspect product for quality factors based on requests within the food marketing chain. Inspection and test results, which are often elements of those inspections, are provided at a fee and are used in production and marketing decisions by AMS' customers. AMS voluntary grading and certification programs have no statutory food safety responsibilities or authorities.

The GAO report should not include the specified of programs GIPSA or APHIS, or the AMS commodity grading programs in Appendix II, table 1: Changes in Funding and Staffing Levels for Food Safety at 12 Federal Agencies. However, if it is determined that GIPSA will be included in Appendix II, then the description should be revised to read as follows:

"Grain Inspection, Packers and Stockyards Administration (GIPSA), within USDA, is responsible for establishing quality standards and providing for a national inspection system to facilitate the marketing of grain and other related products. Certain inspection services, such as testing corn for the presence of aflatoxin, enable the market to assess the value of a product based on its compliance with contractual specifications and Food and Drug Administration (FDA) requirements. Those requesting inspection services, typically the owner of the grain, are responsible for compliance with Food and Drug Administration (FDA) regulations. GIPSA has no regulatory responsibility regarding food safety. Under a memorandum of understanding with FDA, GIPSA reports to FDA certain lots of grain, rice, pulses, or food products (which were officially inspected as part of GIPSA's service functions) that are considered objectionable under the Federal Food, Drug, and Cosmetic Act."

We have also enclosed a number of detailed comments to further clarify the contents of the report. If you have any questions or need further assistance, please contact William West, Acting Deputy Administrator, Office of Management, at (202) 720-4425.

Sincerely,



Dr. Catherine E. Woteki
Under Secretary Food Safety

See comment 9.

The following are GAO's comments on USDA's letter dated July 7, 1998.

GAO's Comments

1. We do not believe that we have seriously mischaracterized descriptions of the Food Safety and Inspection Service's programs and activities. USDA's specific comments in this regard and our responses are addressed below. (See comments 2, 3, 4, and 5.)

2. We revised the language to more clearly explain that the law requires carcass-by-carcass inspections but does not specify who should conduct the inspections nor how the inspection should be performed. However, USDA has historically fulfilled this mandate through organoleptic inspections, which are accurately described in this report. Our point remains that the inspections are not risk based and, therefore, resources used for them could be used more effectively in other areas of the federal food safety system.

3. We agree that organoleptic inspections do not solely ensure product quality. In fact, in the draft report, we noted that these inspections provide some measure of safety. However, we continue to believe that they primarily are meant to ensure product quality rather than detect the most serious food safety risk—microbial contamination. Furthermore, experts have increasingly questioned the public health benefits of these inspections. For example, an October 1993 conference of the World Congress on Meat and Poultry Inspection, an international association of government regulators from meat-trading countries, concluded that post-mortem carcass-by-carcass organoleptic inspection must be changed because (1) it wastes resources and cannot detect microbial pathogens, (2) the animal diseases for which it was originally designed have been eradicated in many countries, and (3) it results in unnecessary cross-contamination because the hands-on inspection techniques used virtually ensure that contamination spreads from one carcass to another.

4. We recognize that a statute mandating the frequency of processing plant inspections does not exist and have clarified the report language accordingly. However, the fact remains that FSIS continues to conduct these inspections on a daily basis. The frequency of these inspections is not risk based and therefore, in our view, may not be an efficient use of federal food safety resources.

5. Our use of the word simple was to illustrate the range of processing operations from simple cutting and packing operations through grinding to

more complex operations, such as canning and the preparation of ready-to-eat products. We were not describing risks associated with any particular aspect of meat-processing operations. We revised the language of the report to avoid any misinterpretation.

6. The report does not assert that resources should be transferred from FSIS. Instead, the report identifies examples of food safety resources that could be used more effectively if they were redirected to other food safety activities. As we point out in the report, these activities may be within or outside of FSIS' area of responsibility. Furthermore, as USDA correctly points out, we did not conduct comparative risk assessments for prioritizing which other food safety activities could be carried out if the resources were redirected. Instead, we present a list of possible activities where food safety resources could be more effectively used, recognizing that food safety officials may have other priorities.

7. The report does not claim that funds appropriated to FSIS could be more effectively used if redirected from the agency. (See comment 6.)

8. While APHIS, AMS, and GIPSA have no regulatory responsibilities for food safety, they do perform food safety activities and provide the food safety regulatory agencies with information. For example, AMS conducts sanitation inspections when doing grading activities. When AMS identifies problems, it notifies the appropriate food safety regulatory agencies.

9. We included this more detailed description of GIPSA's food safety activities in appendix I.

Major Contributors to This Report

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Related GAO Products

GAO Reports

Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable ([GAO/RCED-98-103](#), Apr. 30, 1998).

Food Safety: Fundamental Changes Needed to Improve Food Safety ([GAO/RCED-97-249R](#), Sept. 9, 1997).

Food-Related Services: Opportunities Exist to Recover Costs by Charging Beneficiaries ([GAO/RCED-97-57](#), Mar. 20, 1997).

Food Safety: Information on Foodborne Illnesses ([GAO/RCED-96-96](#), May 8, 1996).

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Meat and Poultry Inspection: Impact of USDA's Food Safety Proposal on State Agencies and Small Plants ([GAO/RCED-95-228](#), June 30, 1995).

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Food Safety and Quality: Who Does What in the Federal Government ([GAO/RCED-91-19B](#), Dec. 21, 1990).

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GAO Testimonies

Food Safety: Reducing the Threat of Foodborne Illnesses ([GAO/T-RCED-96-185](#), May 23, 1996).

Food Safety: A Unified, Risk-Based Food Safety System Needed ([GAO/T-RCED-94-223](#), May 25, 1994).

Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety ([GAO/T-RCED-94-71](#), Nov. 4, 1993).

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