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Report to the Chairman, Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives

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FOOD SAFETY

Changes Needed to Minimize Unsafe Chemicals in Food

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GAO

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Resources, Community, and
Economic Development Division

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September 26, 1994

The Honorable Edolphus Towns
Chairman, Human Resources and
Intergovernmental Relations
Subcommittee
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

This report examines the underlying causes of deficiencies in the federal government's programs to ensure that food does not include harmful chemical residues. We are recommending that the Congress take actions to fundamentally change the federal approach to monitoring chemicals in food to increase the effectiveness of federal programs to prevent and control unsafe chemicals in food.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 7 days from the date of this letter. At that time, we will send copies of this report to other appropriate congressional committees and subcommittees; the Secretary of Agriculture; the Secretary of Health and Human Services; the Administrator, Environmental Protection Agency; the Commissioner, Food and Drug Administration; the Secretary of Commerce; the Director, Office of Management and Budget; and other interested parties. We will also make copies available to others on request.

This work was performed under the direction of John W. Harman, Director, Food and Agriculture Issues, who can be reached on (202) 512-5138. Other major contributors to this report are listed in appendix VIII.

Sincerely yours,

Keith O. Fultz
Assistant Comptroller General

Executive Summary

Purpose

Although the use of chemicals has helped to improve the quality and quantity of the U.S. food supply, concerns remain about the health implications of chemical residues in food. Over the last two decades, GAO and others have reported recurring problems in the federal government's programs to ensure that only safe chemicals are approved for and used in food production. GAO undertook this review to determine the underlying causes of the deficiencies in the current system. Specifically, this report addresses four issues pertaining to the federal government's efforts to monitor chemicals in food: (1) the methodologies and data used to identify chemical risks, (2) the legal and regulatory structure, (3) the federal enforcement processes, and (4) the safety of imported foods. Because of an ongoing interest in food safety issues, the Chairman, Human Resources and Intergovernmental Relations Subcommittee, House Committee on Government Operations, asked GAO to report its findings to the Subcommittee.

Background

Potentially unsafe chemicals may enter the food supply from a variety of sources, including chemical residues and environmental contaminants. Chemical residues may occur in food from the use of pesticides, animal drugs, and food additives. Food-use chemicals must be approved by a federal agency before they can be used legally in the United States. A food may legally contain a number of chemical residues as long as they are within allowable levels (tolerances). Environmental contaminants (such as lead and mercury), unlike chemical residues, are not intentionally used in food production but enter the food supply because they occur in the environment, naturally or as a result of pollution. The responsibility for monitoring chemical residues and environmental contaminants in domestic and imported food is fragmented. The primary responsibility rests with the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). These responsibilities are imposed by a variety of laws that provide federal agencies with the authority to (1) approve food-use chemicals before they can be used, (2) sample and test food products to ensure their safety (end-product testing), and (3) take regulatory actions when violations occur. Federal agencies spend about $150 million annually to monitor chemicals in food.

Results in Brief

Fundamental weaknesses exist in the federal programs to monitor chemicals in food. Because of fragmented responsibility, federal efforts to assess the risks posed by chemicals are inconsistent. Also, chemicals

posing similar risks may be regulated differently under different laws. Moreover, illegal residues in food are often not detected because of the weak federal enforcement system, which relies principally on end-product testing and interagency referrals for action against identified violations. Finally, the problems we have identified for domestic foods are also relevant for imported products. A unified federal system for monitoring chemicals in food would overcome many of the structural weaknesses identified.

Principal Findings

Identifying Unsafe Chemicals

Federal agencies responsible for ensuring that food is safe from harmful chemicals do not assess risk in the same way; as a result, they may arrive at different risk estimates for the same chemical. This inconsistency raises questions about the reliability of agencies' decisions on which chemicals and what levels of chemicals may be in food. These decisions are also debatable because they may be made without essential information on food consumption and actual chemical levels in foods.

Agencies' Efforts to Reduce Risks

Different standards in the laws regulating the approval and use of chemicals in food present several problems in ensuring that the safety net for food is intact. Because of these problems, chemicals posing similar risks may be regulated differently under different laws. Also, federal law does not generally require agencies to periodically reevaluate compounds approved in the past against the most current scientific standards. Moreover, unapproved and potentially hazardous chemicals may be in food because agencies' emergency use provisions have resulted in the long-term, widespread use of these compounds. Finally, while about 60,000 industrial chemicals are used in the United States and have some potential to enter the food supply through air, water, and soil pollution, no food safety law specifically requires federal agencies to monitor environmental contaminants in food.

Federal Enforcement Mechanisms

Federal agencies' current enforcement mechanisms—end-product testing and interagency referrals—cannot detect and prevent contaminated food products from entering the food supply and do not effectively penalize violators and deter future violations. End-product testing requires

extensive resources to (1) obtain comprehensive information on chemicals in use for all products and (2) develop test methods to detect all chemicals of concern. However, agencies have limited resources that cannot adequately satisfy the needs of end-product testing. To overcome the limitations of end-product testing, some sectors of the food industry have developed and adopted a new approach—Hazard Analysis and Critical Control Point—that better ensures safety and quality from the very start of food production. This new approach is based on the principle of identifying and controlling hazards at critical points throughout the production process. While federal agencies have begun to acknowledge the relevance of this new approach, they have put into place only a few such programs. However, even if end-product testing is replaced by this new approach, FDA will still lack adequate enforcement tools, such as detention of food products and civil penalty authorities.

Chemicals in Imported Foods

Because federal agencies have less control over imported foods than over domestic foods, ensuring the safety of these products is often more problematic. Although meat and poultry can be imported only from countries with equivalent inspection systems, no such requirement is in place for other types of food products. As a result, the federal government has limited assurance that many of these imported products have been adequately inspected in the country of origin. Moreover, federal resources to test imported foods have not kept pace with their growing volume. Even the testing that does occur cannot ensure that the most critical compounds of concern are examined because (1) agencies often lack data on the chemicals used in exporting countries and (2) some import-testing programs focus only on domestic compounds of concern. Finally, as with domestic food products, FDA lacks the authority to effectively deter or prosecute violators.

Recommendations to the Congress

Because the problems associated with the current fragmented system cannot be solved by individual agencies' efforts, the Congress should, at a minimum, take steps to (1) enact uniform food safety laws that resolve differences in chemical standards and provide agencies with adequate oversight authorities and (2) direct agencies to develop systems that prevent, rather than simply identify, chemical problems. The Congress should also consider requiring that all foods eligible for import be produced under equivalent food safety systems, as is required for meat and poultry. Ideally, as GAO has stated in the past, food safety would be better

ensured if the Congress created a single agency responsible for carrying out the requirements of a cohesive set of food safety laws.

Agency Comments

GAO received comments on a draft of this report from USDA, the Department of Commerce, EPA, and FDA. USDA generally concurred with GAO's conclusions and recommendations. The Department of Commerce did not fully agree with GAO's conclusions and believes that better interagency coordination can rectify the deficiencies of the current system; however, it agreed with GAO's recommendations. EPA disagreed with GAO's recommendation on the need for a single food safety agency and suggested the creation of an interagency council. However, GAO disagrees that improved interagency coordination can resolve all of the inefficiencies of the current system or the problems caused by inconsistent legislation. FDA did not concur with the report and stated that the information contained in the report is outdated and does not support the conclusions and recommendations. GAO disagrees with FDA's comments. The widespread recognition of the problems with the current system is evidenced by over 90 reports that GAO and others have issued over the past 20 years. Many of the problems identified in this review were compiled from reports issued between 1990 and 1994, and only the most current available program-specific data were used. Furthermore, as GAO has stated in this report and in the past, the imbalances in the current regulatory system are primarily the result of the fragmented legal structure that divides responsibility among multiple federal agencies. This fragmentation has resulted in gaps and duplication in federal food monitoring activities. GAO believes that a unified food safety system that allocates resources according to the greatest human health threats is needed.

All four agencies suggested several technical revisions that have been incorporated in the report. (See apps. IV through VII for the full text of the comments received from each agency and GAO's specific responses.) GAO also contacted organizations that represent various sectors of the food industry, to obtain their views on the effectiveness of the current federal system and alternative approaches to improve it. The views of these officials have been incorporated in the report.

Contents

Abbreviations

AMS	Agricultural Marketing Service
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
CWA	Clean Water Act
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FGIS	Federal Grain Inspection Service
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
NAS	National Academy of Sciences
NASS	National Agricultural Statistics Service
NMFS	National Marine Fisheries Service
NRP	National Residue Program
OIG	Office of Inspector General
PDP	Pesticide Data Program
PMIA	Pesticide Monitoring Improvements Act
PPIA	Poultry Products Inspection Act
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture

Introduction

The success of U.S. agriculture is, to an important degree, attributable to the effective use of chemicals that have improved both the quantity and quality of the nation's food supply. However, this heavy reliance on chemicals raises many concerns about the presence of unsafe chemicals in food and their potential threat to human health. Although chemical hazards generally fall below biological hazards when ranked in importance as public health issues, the long-term and chronic effects of these hazards represent an important public health concern. Moreover, consumers perceive the risks from chemical contamination in food as their major food safety concern. For example, a 1993 nationwide poll found that almost 70 percent of Americans were very concerned about the health effects on young children of chemicals used to grow food. Similarly, a 1994 study reported that residues, such as pesticides and herbicides, continued to be rated as the preeminent health hazard by 72 percent of those surveyed, and antibiotics and hormones in meat and poultry were considered a serious health hazard by 50 percent of those surveyed.[1]

Sources of Chemical Residues and Environmental Contaminants in Foods

Potentially unsafe chemicals can enter the food supply from a variety of sources, including chemical residues and environmental contaminants. Chemical residues can result in food from the use of pesticides, animal drugs, and chemical additives during food production. These chemicals must be approved by a federal agency before they can be legally used in the United States. If a chemical leaves a residue in food, the cognizant agency is responsible for establishing a tolerance level—the amount of residue that can legally remain in or on raw and processed foods.[2] A food may legally contain a variety of chemical residues as long as they are within allowable levels. Some chemical residues in excess of their tolerance levels may have serious health consequences for consumers. For example, some pesticides may cause cancer, and some animal drugs may produce allergic reactions in sensitive persons. Environmental contaminants are another source of potentially unsafe chemicals that can enter the food supply. Unlike chemical residues, these chemicals are not intentionally used in food production but enter the food supply through their occurrence in the environment.

Pesticides (including herbicides, insecticides, rodenticides, fungicides, nematicides, acaracides, disinfectants, fumigants, and plant growth

[1]Trends in The United States: Consumer Attitudes and the Supermarket 1994 (Food Marketing Institute, Washington, D.C.).

[2]Some chemicals may have a zero tolerance level, and therefore no residues of the chemical are allowed in food, while others may not require a tolerance.

regulators) are used widely for both agricultural and nonagricultural purposes in the United States. Pesticides kill or control undesired insects, weeds, rodents, fungi, bacteria, or other organisms. Approximately 440 pesticides (active ingredients) have been registered for use on food and animal feed in the United States. Every year the Environmental Protection Agency (EPA) approves between 10 and 15 new pesticides for use in the United States. In 1991, an estimated 817 million pounds of pesticides (active ingredients) valued at over $6 billion were used for agricultural application.

Animal drugs, including prescription drugs dispensed by licensed veterinarians, nonprescription (over-the-counter) drugs, medicated feeds, and veterinary medical devices, are used to treat a large percentage of U.S. livestock and poultry for therapeutic, reproductive, and production purposes. Animal drugs may be used in more than one species and are often administered to whole herds or flocks. In 1993, 748 animal drugs had been approved for use on food-producing animals in the United States. Every year the Food and Drug Administration (FDA) approves about 17 new drugs for use in food-producing animals. In 1992, sales of animal health products were estimated at $2.3 billion.

Environmental contaminants are chemicals that either occur in the environment naturally or are introduced into the environment in the form of air, water, or soil pollution. Some chemicals, such as mercury and lead, naturally occur at trace levels in the environment, and some, such as selenium, may in fact be essential nutrients at these levels, but when they concentrate at higher levels—for example, because of pollution or groundwater contamination—they may become a public health concern. In addition, the improper or illegal disposal of industrial wastes may result in water and soil pollution, and industrial emissions may result in dangerous air-borne elements that may also be absorbed into food produced in polluted areas. Over 60,000 industrial chemicals are used in the United States.

Federal Approach to Monitoring Chemicals in Food

Monitoring chemical residues in food can generally be divided into three broad phases.[3] The initial phase involves approving a chemical for use and setting acceptable levels of that chemical's residues (tolerances) in food. The federal agencies' decisions to approve a chemical and set tolerances

[3]For this report, we defined "monitoring" in its broadest sense to denote any activity conducted by a federal agency that has an impact on ensuring that food is free of chemical contamination. This includes, among other things, pre-market reviews and evaluations of chemicals, food sample collection, laboratory analysis of food samples, follow-up on violations of chemical use, enforcement actions, and research and development activities.

for it are based on (1) an analysis of the available scientific data and (2) a determination that the chemical does not present a risk above acceptable levels to human health and/or the environment (see chs. 2 and 3). The second phase involves sampling and testing the food supply to ensure that it is free from illegal residues. Illegal residues include those of approved chemicals that exceed their established tolerance levels or any unapproved or banned chemicals. The final phase of federal food monitoring involves enforcement activities, when violative residues are discovered. These activities are designed to identify the cause of contamination and ensure that future violations do not occur (see ch. 4). A number of federal agencies, in cooperation with state agencies, are responsible for implementing the government's program to monitor chemical residues in food. These federal and state responsibilities are discussed in greater detail below.

Federal agencies do not monitor environmental contaminants in the same way that they monitor chemical residues. The difference exists because unlike chemical residues, environmental chemicals are not intentionally added to food and therefore do not have to receive a pre-market clearance like other food-use chemicals. As a result, tolerances are set and the food supply is sampled and tested for environmental contaminants only when a public health concern arises. (This issue is discussed in greater detail in ch. 3.)

Multiple Federal Agencies Are Responsible for Monitoring Chemical Residues and Environmental Contaminants in Foods

The responsibility for monitoring chemical residues and environmental contaminants in food is split among many different agencies. Primary responsibility rests with FDA, in the Department of Health and Human Services; several agencies in the U.S. Department of Agriculture (USDA); and EPA. In addition, the National Marine Fisheries Service provides a voluntary fee-for-service inspection program for fish products. These responsibilities are imposed by a variety of laws designed to (1) ensure that food-use chemicals receive a pre-market review by a federal agency before they are legally marketed and used in the United States, (2) provide federal agencies with oversight authority to sample and test products to ensure that they are not contaminated with chemical residues and/or environmental contaminants, and (3) provide federal agencies with the authority to take regulatory actions when a contaminated food product or chemical-use violation is detected. Because the laws divide the authority and responsibility for monitoring chemicals in food among various agencies, one agency may be responsible for approving a chemical's use, while a second agency may be responsible for monitoring the presence of

that chemical's residue in the food supply. Furthermore, state agencies may be ultimately responsible for taking regulatory enforcement action for misuse of the chemical. The federal government spends about $157 million annually to monitor chemical residues and environmental contaminants in food. (Table 1.1 provides an overview of the responsibilities of various food safety agencies and the laws that regulate them, and table 1.2 is a list of funds allocated by the primary agencies for monitoring chemicals in food.)

Table 1.1: the Federal Chemical Residue and Environmental Contaminants Monitoring System

	Chemical of concern		
	Pesticide residues	**Animal drug residues**	**Environmental contaminants**
Chemical may occur in	All foods—raw and processed, imported and domestic—and in drinking water	Meat, poultry, eggs, seafood, and dairy products, both imported and domestic	All foods—raw and processed, imported and domestic—and in drinking water
Principal laws	Federal Insecticide, Fungicide, and Rodenticide Act; Federal Food, Drug, and Cosmetic Act; Federal Meat Inspection Act; Poultry Products Inspection Act; Egg Products Inspection Act; Pesticide Monitoring Improvements Act	Federal Food, Drug, and Cosmetics Act; Federal Meat Inspection Act; Poultry Products Inspection Act; Egg Products Inspection Act	Federal Food, Drug, and Cosmetics Act; Federal Insecticide, Fungicide, and Rodenticide Act; Toxic Substances Control Act; Clean Water Act; Federal Meat Inspection Act; Poultry Products Inspection Act; Safe Drinking Water Act
Pre-market approval required for use on food?	Yes	Yes	No
Agency responsible for setting tolerances or standards	Environmental Protection Agency	Food and Drug Administration	Food and Drug Administration for food and the Environmental Protection Agency for water quality
Agency responsible for testing food for chemicals	Department of Agriculture for meat, poultry, and egg products; Food and Drug Administration for all other foods	Department of Agriculture for meat, poultry, and egg products; Food and Drug Administration for all other foods	Department of Agriculture for meat, poultry, and egg products; Food and Drug Administration for all other foods
Agency with enforcement authority to ensure proper use of chemicals	Environmental Protection Agency in cooperation with state agencies	Food and Drug Administration in cooperation with state agencies	Environmental Protection Agency

Table 1.2: Estimated Expenditures by Primary Federal Agencies on Monitoring Chemicals in Food, Fiscal Year 1993

Primary department/agency	Planned expenditures for fiscal year 1993
U.S. Department of Agriculture	
Food Safety and Inspection Service	$28,534,000
Federal Grain Inspection Service	200,500
Agricultural Marketing Service (Dairy Division)	25,000
Agricultural Marketing Service (Science Division)	190,000
Agricultural Marketing Service (Poultry Division)	22,000
Agricultural Marketing Service (Pesticide Data Program)	11,563,000
Agricultural Research Service	23,700,000
National Agricultural Statistics Service (Pesticide Usage Data)	3,500,000
Department of Commerce	
National Marine Fisheries Service	1,475,000
Food and Drug Administration	
All Centers	63,615,000
Environmental Protection Agency	
Office of Water	595,000
Office of Pesticide Programs	3,908,000
Office of Research and Development	19,700,000[a]
Total	**$157,027,500**

[a]This amount includes estimated expenditures on drinking water safety.

Food and Drug Administration

FDA is the primary federal regulatory agency for ensuring the safety of all domestic and imported foods, excluding meat and poultry, and some egg products. It carries out its responsibilities primarily under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, and is responsible for enforcing the provisions of the act. FDA is also responsible for carrying out the provisions of the Pesticide Monitoring Improvements Act (PMIA).

The FFDCA is designed to ensure that food sold in interstate commerce, including imported food, is safe, sanitary, wholesome, and properly labeled. The FFDCA requires FDA to control foods adulterated by added substances as well as those occurring naturally. The FFDCA also regulates pesticides, food and color additives, and new animal drugs. The act requires (1) the establishment of a maximum acceptable level of pesticide residues in food and animal feed and (2) pre-market approval for food and

color additives, new animal drugs, and additives to animal feed. Under FFDCA, foods are considered adulterated if they contain pesticides, animal drugs, or other chemical residues above established tolerance levels.

To implement FFDCA, FDA (1) enforces pesticide residue tolerances for a wide variety of raw agricultural and processed foods, and animal feeds; (2) ensures that environmental contaminants in food and animal feed are within safe levels; (3) regulates the use of animal drugs, including approving new animal drugs and enforcing their proper use. To address the first two objectives, FDA monitors foods by sampling and testing domestic and imported products under its various compliance programs to determine whether they contain chemical residues and/or environmental contaminants above the established tolerance levels. FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for developing and overseeing the regulation and enforcement of the food safety, quality, and labeling requirements of the FFDCA. Relevant CFSAN activities include developing analytical methods for measuring residues in foods, determining the incidence and level of occurrence of pesticides and chemical contaminants in food, carrying out field-monitoring programs for selected contaminants, and taking regulatory action as appropriate.

For the third objective, FDA's Center for Veterinary Medicine (CVM) is responsible for approving, regulating, and ensuring the safety of animal drugs and livestock feeds marketed in interstate commerce. CVM's two major projects are (1) the pre-approval evaluation of new animal drugs and food additives to ensure that they are safe and effective for their intended use and (2) the monitoring of animal drugs, feeds, and medical devices marketed in interstate commerce to ensure that they are safe and effective, and not adulterated or misbranded, and that harmful residues do not enter the human food supply.

Under the PMIA, FDA also (1) develops data management systems to track, summarize, and evaluate pesticide-monitoring data, (2) enters into cooperative agreements with foreign countries to obtain pesticide usage data in these countries for crops exported to the United States, and (3) develops a plan to guide the development of methods to improve the efficiency of food monitoring.

Department of Agriculture

Several agencies within USDA have programs that monitor chemical residues and environmental contaminants in foods—primarily in meat, poultry, and egg products. The Food Safety and Inspection Service (FSIS) is responsible for ensuring that meat and poultry products sold for human

consumption are safe and wholesome and properly marked, labeled, and packaged. FSIS operates under the authorities of the Federal Meat Inspection Act (FMIA), as amended, and the Poultry Products Inspection Act (PPIA), as amended. These laws were enacted to ensure that domestic and imported meat and poultry products are wholesome and properly labeled. Generally, the acts prohibit adulteration and misbranding of meat and poultry products and require FSIS to perform antemortem and postmortem inspections of meat and poultry sold in interstate commerce as well as inspections of slaughter and processing facilities for sanitation. Under the acts, adulterated meat and poultry products include those that contain poisonous or deleterious substances that may render the product injurious to health. These include pesticides, animal drug residues, and environmental contaminants above established tolerances. The FMIA and PPIA also require that imported meat and poultry be produced under inspection systems that are at least equal to that of the United States. Imported products must meet inspection, sanitary, quality, species verification, and residue standards applied to domestic meat and poultry.

The Agricultural Marketing Service (AMS) has similar responsibilities for eggs under the Egg Products Inspection Act, as amended. AMS inspects egg product processing plants and firms marketing eggs to ensure that egg products are wholesome, unadulterated, and truthfully labeled. Inspections of egg products include chemical residue tests for various industrial and environmental contaminants, trace elements, and drug residues.

Other USDA agencies with chemical residue monitoring responsibilities include the Federal Grain Inspection Service (FGIS) and the National Agricultural Statistics Service (NASS). FGIS is responsible for ensuring that U.S. grain for export and domestic consumption is safe and of high quality. FGIS' current chemical residue monitoring activities include testing grains for about 19 pesticide residues. NASS, in conjunction with AMS, monitors chemical residues in foods through the Pesticide Data Program. Under the Pesticide Data Program, AMS collects statistically valid information on some pesticide residues in certain fruits and vegetables, and NASS collects data from farmers on their pesticide use on fruits, vegetables, nuts, and field crops.

Two other agencies within USDA, the Agricultural Research Service and the Cooperative State Research Service, are also involved in providing research support to USDA. Their activities primarily focus on developing

new, rapid, and improved analytical test methods to detect harmful chemicals in food.

Environmental Protection Agency

EPA's primary responsibilities for chemical residues and environmental contaminants in food are to (1) register pesticides for use in the United States after ensuring that their use will not cause an unreasonable risk to the environment or people; (2) establish the legal maximum level of pesticide residues allowed in each specific food or animal feed product for those pesticides that will leave a residue; and (3) obtain information on industrial chemical effects and for chemicals that present an unreasonable risk to people and the environment, take steps to control their manufacturing, processing, distribution, use, and disposal. EPA has no direct responsibility to enforce pesticide residue or environmental contaminant levels in food. Therefore, the agency conducts only limited monitoring of pesticides and industrial chemicals in food as part of its monitoring of these contaminants in the environment.

EPA conducts its pesticide registrations under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA). The act requires the registration of pesticides with EPA before they can be marketed for use in the United States. EPA is also authorized to specify the terms and conditions of use and remove unreasonably hazardous pesticides from the marketplace. The act requires EPA to take into account the economic, social, and environmental costs and benefits in making decisions about pesticide usage.

EPA is also responsible for establishing the criteria used by the states to develop water quality standards. Although water quality standards are only indirectly linked to food safety, some of EPA's responsibilities directly affect the safety of seafood and freshwater fish, especially fish consumed intrastate and not covered by FDA under the FFDCA. One of the important environmental laws that affect water quality and seafood that EPA administers is the Clean Water Act. Under the Clean Water Act, as amended, EPA has the authority to set water quality standards with the objective of restoring and maintaining the integrity of the nation's waters and protecting and propagating fish, shellfish, and wildlife. EPA is also responsible for regulating and establishing enforcement standards for contaminants in drinking water under the Safe Drinking Water Act.

In addition, under the Toxic Substances Control Act (TSCA), EPA is responsible for reviewing and maintaining an inventory of industrial chemicals that may pose an unreasonable risk to health and the

environment and can be used in the United States. TSCA was enacted to provide a safeguard against the introduction of additional contaminants into the environment and to address the risks posed by existing ones. Under this act, EPA may require chemical manufacturers and processors to test potentially harmful chemicals for the purpose of assessing their health and environmental effects. EPA has the authority to ban or restrict the use of chemicals that pose an unreasonable risk. In addition, EPA can issue advisories to warn the public of chemical dangers.

National Marine Fisheries Service

The National Marine Fisheries Service (NMFS), of the National Oceanic and Atmospheric Administration, within the Department of Commerce, conducts a voluntary seafood inspection program that includes inspection of seafood processing plants, fishing vessels, and seafood products for microbial and chemical contamination. Because FDA has regulatory responsibility for ensuring seafood safety, it set up an Office of Seafood in 1991 to cooperate with NMFS in overseeing seafood inspections. NMFS applies FDA's standards during its voluntary inspections of seafood and seafood processing plants. NMFS also administers a Product Quality and Safety Research Program that conducts research on issues affecting the optimum use of living marine resources. The safety efforts of this research program address concerns about the impact of environmentally and process-induced contamination of seafood on consumers and the fishing industry.

Federal-State Cooperative Agreements

A number of food safety programs are also administered by the states in cooperation with federal agencies.[4] For example, FDA has a memorandum of understanding with the National Conference on Interstate Milk Shipments (a voluntary organization of state officials), under which the states are allowed to carry out most of the monitoring, enforcement, and other regulatory functions to ensure the safety and wholesomeness of fresh milk and cream in the United States. This organization is also responsible for testing milk and cream for animal drug residues. FDA also has a cooperative program with many states to ensure the safety and sanitation of shellfish, which includes testing the quality of water where shellfish are harvested for known or suspected contaminants. In addition, FDA contracts with the states to obtain assistance in inspecting food firms that are under FDA's jurisdiction. Some of these contracts include

[4]The primary focus of this report is on the monitoring activities of federal agencies, not the activities of state agencies. However, because many federal programs rely on cooperation with the state agencies, where appropriate, references have been included to identify the role of the states in ensuring that the food supply is safe from chemical residues and environmental contaminants.

programs to monitor pesticide residues in foods, drug residues in edible animal tissue, and toxins in shellfish.

To help conduct their programs, EPA, FSIS, and NMFS also have cooperative arrangements with various state agencies. For example, EPA has cooperative agreements with states and Indian tribes for enforcing pesticide-use violations and for training and certifying those who apply pesticides; FSIS has a federal-state cooperative inspection program in which FSIS monitors state inspection programs for meat and poultry that will be sold only in intrastate commerce; and NMFS has cooperative agreements with some states to perform voluntary inspection services for seafood products, which NMFS oversees.

Problems With Federal Monitoring of Chemicals in Food Have Been Widely Recognized

Problems with federal efforts to monitor chemical contamination in food have been identified for decades in many previous reports by GAO and others. Over the years, federal agencies have been unsuccessful in completely addressing the many specific problems identified by GAO, the Offices of Inspector General, the Office of Technology Assessment, the National Academy of Sciences, and others.

Since the 1970s, GAO and others have issued about 90 reports that have identified systemic problems that question the effectiveness of the federal system to monitor chemical contamination in food. (See app. III for related reports by GAO and others.) The significant problems that we have identified in the past cover a host of issues, such as the lack of interagency coordination and cooperation, the limitations associated with end-product testing, limited sampling and program coverage, and the ineffective use of deterrents to prevent future occurrences. The National Academy of Sciences, the Office of Technology Assessment, and the Offices of Inspector General have also raised similar concerns about various aspects of the system.

In response to such criticisms, the responsible federal agencies have implemented numerous corrective actions to improve program operations. However, while some problems have been resolved, many are as significant today as they were in the 1970s and continue to weaken the system. For example, in 1978 we identified major concerns with EPA's special pesticide registration provisions. In particular, we noted that EPA has allowed the extensive and recurrent use of unapproved pesticides under its emergency pesticide exemption provisions. We questioned the emergency nature of many of these special exemptions and reported that

this practice may allow pesticides of unknown safety to be used over long periods of time (see ch. 3). When we revisited these issues in 1981 and again in 1991, we found that problems still persisted.[5] Similarly, in 1979 we identified problems with USDA's ability to prevent the distribution to U.S. consumers of meat and poultry containing harmful chemical residues.[6] In 1985, the National Academy of Sciences found that while USDA had taken some corrective actions, improvements were still needed. Between 1986 and 1991, USDA's Office of Inspector General also issued a series of reports on this same issue and found that program improvements were still needed. This year, we again reported that USDA's National Residue Program continues to suffer from many of the problems identified in 1979 (see ch. 4).[7]

Objectives, Scope, and Methodology

Given the widespread recognition of problems with the federal system to monitor chemical residues and environmental contaminants in food, we sought to identify the underlying causes for deficiencies in the current system. This report addresses the (1) methodologies and data used to identify risk, (2) legal and regulatory structure, (3) federal enforcement processes, and (4) safety of imported foods. Because of his ongoing interest in food safety issues the Chairman, Human Resources and Intergovernmental Relations Subcommittee, House Committee on Government Operations, requested that we report our results to the Subcommittee.

To obtain information on the federal requirements in place to control chemical residues and environmental contaminants in food, we reviewed pertinent laws and regulations. To obtain information on deficiencies identified in the past, we obtained and reviewed about 90 reports by GAO, the Congressional Research Service, the Office of Technology Assessment, the Offices of Inspector General, the National Academy of Sciences, and others. To obtain information on the corrective actions taken over time and the current status of various aspects of federal chemical residue and environmental contaminants monitoring programs, we obtained documents and interviewed officials at the Food and Drug Administration; the U.S. Department of Agriculture's Agricultural Marketing Service,

[5]Special Pesticide Registration by the Environmental Protection Agency Should Be Improved (CED-78-9, Jan. 9, 1978); Stronger Enforcement Needed Against Misuse of Pesticides (CED-82-5, Oct. 15, 1981); Pesticides: EPA's Repeat Emergency Exemptions May Provide Potential for Abuse (GAO/T-RCED-91-83, July 23, 1991).

[6]Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues (HRD-79-10, Apr. 17, 1979).

[7]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (RCED-94-158, Sept. 26, 1994).

Agricultural Research Service, Food Safety and Inspection Service, Federal Grain Inspection Service, Human Nutrition Information Service, and National Agricultural Statistics Service; the Environmental Protection Agency; and the National Marine Fisheries Service. We also obtained information on industry programs through trade journals and conferences as well as from trade associations, such as the National Turkey Federation and the Animal Health Institute. To obtain an industry perspective on the adequacy of the current federal system and alternative approaches to monitoring chemicals in food, we interviewed officials at the American Meat Institute, Food Marketing Institute, National Broiler Council, National Fisheries Institute, and the National Food Processors Association.

We conducted our review between January 1993 and July 1994, in accordance with generally accepted government auditing standards.

Inconsistent Methodologies and Incomplete Data Impede Identification of Chemicals Posing Risk

To identify chemicals that pose a risk to human health in food, federal agencies rely on risk assessments. Although risk assessments are inherently uncertain, federal agencies compound this uncertainty. First, they employ inconsistent methodologies that may produce different estimates of risk for the same compound. Second, the agencies often lack essential data, such as current food consumption patterns and actual residue levels in food.

Differences in Agencies' Methodologies Cause Variations in Chemical Risk Estimates

Risk assessment—the use of factual information to define the health effects of exposure of individuals or populations to hazardous chemicals or situations—is inherently uncertain. (See app. I for a detailed discussion of the risk assessment process.) But problems with how federal agencies conduct risk assessments exacerbate the uncertainties and leave open to debate the results of risk assessments. Specifically, because agencies lack uniform guidelines, risk assessments for the same chemical may vary from agency to agency.

In assessing federal agencies' risk assessment efforts, in 1983 the National Academy of Sciences (NAS) concluded that "agency guidelines [governing risk assessment methodologies] have varied markedly in form and content. Without a deliberate coordinating effort, there is no reason to assume that guidelines will become more nearly uniform." The report went on to conclude that uniform guidelines are feasible and desirable for federal agencies conducting risk assessments.

Despite this recommendation, differences in methodology persist between agencies. For example, when extrapolating the results of animal studies to humans for carcinogenic risk assessments, EPA and FDA use different cross-species scaling factors.[1] This difference in methodology is one of the chief causes of variation among estimates of a chemical's potential human risk, even when the assessments are based on the same data. EPA's cross-species scaling factor relates the data on metabolic rates and toxicity to body surface area, while FDA's approach relates these data to average body weight. According to FDA and EPA officials, EPA's method provides a more conservative risk assessment than FDA's and may result in differences in estimates between the two agencies by a factor of as high as 10. An interagency work group was established to address this difference. Although no final action had been taken as of July 1994, this work group's draft report, published in the Federal Register in June 1992, provides a

[1]Scaling is the mathematical process used to adjust the dosage of chemicals administered to one size or species of animals to achieve comparable effects in another size or species of animals.

unified approach for the agencies to use when extrapolating results from animal studies to humans. This new approach combines aspects of both EPA's and FDA's strategies.

Similarly, the agencies apply different methodologies to determine how the high doses administered to animals in laboratory tests correlate to the low doses that humans may be exposed to. Because humans are not exposed to the high levels of chemicals used in laboratory experiments, federal agencies must determine how the animal test data correlate to human dietary exposure. However, the differences in low-dose extrapolation methods between agencies may result in different low-dose estimates of a chemical for the same level of risk, according to an FDA official. For example, EPA's and FDA's low-dose extrapolations for a given chemical at a given level of risk may vary by a factor as much as 2.

Finally, some agencies balance benefits and risks in determining whether to approve a chemical compound as part of their regulatory responsibility, while others do not. As a result, decisions about a chemical's safety may also vary between agencies.

Agencies' Decisions Are Often Based on Incomplete Human Exposure Data

The uncertainty in the risk assessment process is further compounded by the federal government's lack of crucial data, such as the types and levels of food consumed by American consumers and the chemical residues in food. Even the data collected often cannot be used by multiple agencies, or within the same agency, because of limitations in federal data management practices. As a result, the agencies' decisions on chemical approval and use may not be as informed as they need to be.

Despite Numerous Programs, Agencies Lack Adequate Data

Despite ongoing programs to collect reliable and accurate data, some of the data elements critical to the risk assessment process are not available to federal agencies. For example, to estimate human dietary exposure to chemicals, the agencies need, among other things, accurate food consumption data for the general population and subpopulations, as well as reliable data on chemical residue and environmental contaminant levels in food. The quality of exposure estimates is directly linked to the quality of both of these data sets. However, quality data for both sets are generally unavailable because the cognizant agencies lack a coordinated strategy to collect these data.

For example, USDA is responsible for collecting food consumption data through its Nationwide Food Consumption Survey—a household and individual food intake survey conducted every 10 years. However, USDA's last survey, conducted in 1987-88, was so flawed that federal agencies were unable to use the information collected, according to FDA and EPA officials. Consequently, federal agencies have had to base their exposure assessments on the results of USDA's 1977-78 survey, which cannot provide current and accurate food consumption patterns for the national population. According to USDA officials, the agency is trying to overcome its data collection problems. But until it does so, FDA and EPA officials told us that their risk assessments are not as definitive as they could be.

Moreover, when determining exposure to chemical residues and environmental contaminants, federal agencies must consider the differences in the levels of consumption of food by certain subpopulations. These subpopulations may be at greater risk to some chemical residues because of differences in their dietary patterns. However, neither the Nationwide Food Consumption Surveys nor USDA's new Continuing Survey of Food Intake of Individuals adequately represents the food consumption patterns of subpopulations or special food classes, such as seafood consumption, according to agency officials. We and others have in the past identified the lack of adequate consumption data on subpopulations—such as infants and children and pregnant women—as a critical deficiency in the federal risk assessment process. Agency officials told us that inadequate resources constrain their efforts to collect these essential data elements. Similarly, the federal government lacks data on consumption patterns for special food items like seafood and ethnic foods, which are consumed in larger quantities than the national average by some subgroups. Officials from EPA, FDA, and the National Marine Fisheries Service told us that no comprehensive or reliable national seafood consumption survey has been conducted since the 1970s. As a result, the agencies often have to make inferences on consumption levels from a variety of information sources that may be inconsistent, may have collected data at different times, and may have used different methodologies.

In commenting on a draft copy of this report, the Department of Commerce told us that to overcome the lack of data on consumption and contaminants in seafood, it is developing a Seafood Contamination Risk Information System that will incorporate data on contaminants in and consumption of seafood.

To assess human exposure, the agencies also need reliable data on the actual level of chemical residues in food. Without such data, agencies such as EPA have to assume that residues will occur in food at the maximum level, which may not realistically represent the actual residues consumed.[2] Although FDA and USDA have ongoing programs to collect data on residues in food, they can provide EPA with statistically valid data for only about a dozen fruits and vegetables and for only a limited number of pesticides. Not only has the fragmentation of food safety responsibility led to such gaps in data, but it has also resulted in duplicate federal data collection programs. USDA and FDA are both spending over $35 million annually to collect pesticide residue information that may be duplicative. In 1992 we reported that USDA's Pesticide Data Program (PDP), which collects statistically based data on fruits and vegetables, may be duplicating the efforts of FDA's pesticide surveillance activities.[3] EPA officials who use the PDP information for pesticide regulatory decisions believe that the USDA data has filled a void that could not be filled by either FDA's surveillance and compliance programs or the Total Diet Study Program.

Although both USDA and FDA, in commenting on a draft of this report, deny any duplication in their programs, citing differences in their objectives and missions, we continue to question the need for two separate federal efforts for collecting pesticide residue data on fruits and vegetables. We are especially concerned because FDA has recently started its own pilot program to collect statistically based residue data, as well. Under this pilot program, FDA is conducting statistically based testing of selected fruits and vegetables at an estimated cost of $1 million per commodity per year, according to agency officials. These officials told us that the data from the pilot program will provide a basis for comparison and allow them to determine if any significant differences exist in the results of their nonstatistically based surveillance sampling and their statistically valid sampling. We question why, in June 1992, FDA implemented sampling and testing under this pilot effort without first comparing its surveillance residue data with the PDP residue data available from USDA. FDA officials could not provide us with any rationale for continuing with their pilot program beyond the fact that they had committed to this effort long before USDA's PDP was implemented.

[2]In its comments on a draft of this report, EPA stated that when maximum residue levels are used for risk assessment and result in a determination that the risk is acceptable, then no value is added by obtaining actual residue data. Therefore, using maximum residue levels as a "first cut" in the dietary risk assessment process may minimize the generation of unnecessary data.

[3]Food Safety: USDA Data Program Not Supporting Critical Pesticide Decisions (GAO/IMTEC-92-11, Jan. 31, 1992).

Inadequate Federal Data Management Practices Further Limit Data's Usefulness

Generally, federal agencies' data management practices limit the usefulness of the extensive amounts of data that they do collect. Neither EPA nor FDA has designed or managed information systems to promote access to and/or use of the available data. For example, we reported in November 1992 that EPA has had difficulty in identifying needed information from pesticide data that may be scattered throughout its various data management systems or kept in paper files.[4] Consequently, EPA cannot develop a comprehensive and reliable profile of a given pesticide's review status. After 3 years of effort and $14 million invested in a system to track the pesticide reregistration process, EPA still could not easily assemble accurate, reliable, and complete information on chemicals in the reregistration process. These problems largely result from inadequate system planning and poor data management practices. We concluded that compiling information about pesticides undergoing reregistration remains difficult, labor-intensive, and time-consuming.

Without reasonable access to data, a regulatory agency may be unable to respond effectively in an emergency situation. For example, when a hazardous pesticide—metam-sodium—spilled into the Sacramento River in the summer of 1991, EPA was not even aware that it had received information that the pesticide metam-sodium could cause birth defects.[5] Because it lacked adequate tracking and data management systems, EPA had not identified, reviewed, or acted upon relevant studies and therefore could not issue appropriate warnings to pregnant women and others at risk. Although we did not review the adequacy of EPA's actions, the agency has taken steps to prevent such incidents from occurring in the future.

We found similar problems with FDA's data management and information systems. In January 1992, we reported that because of weaknesses in FDA's management information system for inspection data on new animal drugs, FDA reviewers and management could not obtain reliable and adequate inspection information to assist in approving new animal drugs or in efficiently allocating limited inspection resources.[6] The data in FDA's data base were inconsistent and incomplete, and the agency lacked formal policies and procedures to ensure the reliability of the information in this

[4]Pesticides: Information Systems Improvements Essential for EPA's Reregistration Efforts (GAO/IMTEC-93-5, Nov. 23, 1992).

[5]Pesticides: EPA Lacks Assurance That All Adverse Effects Data Have Been Reviewed (GAO/T-RCED-92-16, Oct. 30, 1991).

[6]Food Safety and Quality: FDA Needs Stronger Controls Over the Approval Process for New Animal Drugs (GAO/RCED-92-63, Jan. 17, 1992).

data base. Similarly, in its 1991 report on FDA,[7] the Advisory Committee on the Food and Drug Administration (also known as the Edwards Committee) stated that deficiencies in the agency's information systems were "acutely apparent, and FDA has frequently been unable to respond in a timely fashion to the most fundamental questions from Committee members. Some responses to the most basic questions had to be tabulated manually." Furthermore, the Committee stated that FDA's current management information systems preclude the effective use of available resources and that fundamental changes are critical. Although FDA recognizes the need for better management information systems, because of resource constraints, the agency has been unable to develop such systems.

[7]Final Report of the Advisory Committee on the Food and Drug Administration (Washington, D.C., May 1991).

Problems in the Legal and Regulatory Structure Compromise Agencies' Efforts to Reduce Risk

Chemicals posing similar risks may be regulated differently under different laws. Chemicals not allowed under one law or regulation may be allowed under another and may therefore enter the food supply. Moreover, unapproved chemicals may be in food because agencies' regulatory policies that allow the emergency use of such compounds are misused, and chemicals intended for infrequent use become commonplace. Finally, many highly toxic chemicals, present in the environment from industrial pollution (environmental contaminants), are not specifically required to be regulated by federal food safety laws.

Different Legal Standards Result in Differences in Allowable Chemicals

Differences in federal food safety laws have resulted in different standards for chemicals posing similar risks. Consequently, consumers may be exposed to chemicals that at least one agency, operating under one act, considers allowable, but which another agency, operating under different legislation, may not consider allowable. Also, federal agencies are generally not required to periodically reevaluate chemicals approved in the past against current scientific standards.

Some Laws Establish Different Standards for Chemicals Posing Similar Risks

No matter how successfully agencies identify chemical risks through the scientific risk assessment process, they may have to regulate chemicals presenting similar risks differently. This happens because (1) some provisions of the laws allow agencies to consider both risks and benefits while others do not and (2) federal laws prescribe different standards of acceptable risk for chemicals that otherwise pose similar risks.

Agencies may differ in their determination of what is an allowable chemical because some provisions of the federal laws may allow one agency to consider both risks and benefits but not allow another agency to do so. For example, under the Clean Water Act, EPA issues water quality criteria that state agencies may use to determine if the levels of contamination in water render the fish harvested from it harmful to consumers' health. EPA is required only to consider risks to human health and aquatic life when conducting water quality assessments. However, under the FFDCA, FDA is responsible for setting tolerance levels for chemical contamination in fish and shellfish that move in interstate commerce. FFDCA allows FDA to consider both health risks and benefits in establishing tolerances for chemical contaminants in food. Therefore,

FDA's standards for some chemicals are often less stringent than those developed by EPA, according to EPA officials.

These differences in EPA's and FDA's standards result in much confusion for the state agencies that are ultimately responsible for monitoring the safety of local fish and for issuing fish consumption advisories. According to a 1990 EPA study, states do not use consistent risk assessment methodologies or agree on the levels of fish consumption considered safe in a given situation. For example, while 34 states use FDA's methodology to determine the level of concern in fish, 10 use EPA's, and 8 have developed their own methods. Therefore, situations may arise in which one state may ban consumption of fish from a certain body of water, while a neighboring state, using a different federal approach, may allow consumption of fish from the same body of water. For example, Minnesota—using EPA's criteria—advises fishermen not to consume certain fish from a 20-mile stretch of the St. Croix River between Stillwater, Minnesota, and Prescott, Wisconsin. But Wisconsin—using FDA-based criteria—does not consider fish from the same body of water a health risk and permits their consumption.

Concerned about the differences in EPA's and FDA's guidance, state officials have requested that the federal government provide them with consistent risk assessment guidelines. Nevertheless, EPA and FDA continue to provide separate guidance documents based on their differing legislation. For example, EPA is currently working on a four-volume set of comprehensive guidance documents to help states assess chemical contaminant data for use in determining the need for fish advisories. The first volume on Fish Sampling and Analysis was published in August 1993, the second volume on Risk Assessment and Fish Consumption Limits was published in July 1994, and two other volumes on Risk Management and Risk Communication are currently being developed. In 1993, FDA also issued five contaminant-specific documents to the states to help them determine the need for fish advisories and has plans to issue another seven documents in the near future. Both EPA and FDA officials justified pursuing these separate efforts because of the need to fulfill the requirements of their separate legal mandates.

Similarly, as we recently reported, section 409 of the FFDCA contains a general food safety clause that requires agencies to determine whether the use of an additive to food "will be safe." However, EPA and FDA interpret

this clause differently. EPA believes that this clause allows it to consider both risks and benefits when setting tolerances for noncarcinogenic pesticide residues. FDA, on the other hand, believes that this clause allows only a risk-based standard and therefore does not consider any benefits when approving and setting tolerances for other food additives, including animal drugs.

Furthermore, some federal laws prescribe different standards for chemicals that otherwise pose similar risks. As a result, EPA may allow the use of a chemical on certain foods but disallow it on other foods. EPA may approve a carcinogenic pesticide that presents a negligible risk for use on food under FIFRA and establish a tolerance for this pesticide's residue on raw agriculture products under section 408 of the FFDCA. The FFDCA also allows this carcinogenic residue to remain in processed food as long as it does not concentrate to a level above the raw food tolerance and as long as the pesticide is not added during or after processing. However, section 409 of the FFDCA, which applies to all pesticides that concentrate in processed foods or that are added to foods during or after processing, includes a different provision—the Delaney Clause—for carcinogenic compounds. Under the Delaney Clause, EPA must use a zero-risk standard for carcinogenic pesticide residues that concentrate in processed food or are added to food during or after processing, no matter how negligible the risk. Therefore, EPA may issue a tolerance for a carcinogenic pesticide on raw tomatoes if the risk is negligible, and a tolerance for canned tomatoes if the pesticide's residues do not concentrate above the raw tomato tolerance. But it may not issue a tolerance for tomato paste if the pesticide's residues concentrate above the raw food tolerance. As we recently reported, this difference in standards has resulted in EPA's approving tolerances under section 408 for pesticides that it found to be potentially more carcinogenic to humans than other pesticides for which it has not been able to issue a tolerance under section 409.[1]

In 1987, the National Academy of Sciences recommended that consistent standards be set for all pesticide residues in foods. To overcome this difference, EPA established in 1988 a negligible risk standard to regulate all pesticide residues, including those covered by the Delaney Clause. Under this standard, EPA could approve a carcinogenic pesticide and set a 409 tolerance if its use results in negligible risk or a cancer risk of 1 in 1 million from a lifetime of exposure. However, EPA's policy was overturned by the Ninth Circuit Court of Appeals in July 1992 as incompatible with the Delaney Clause. In response to the court's ruling,

[1]Pesticides: Options to Achieve a Single Regulatory Standard (GAO/RCED-94-57, May 13, 1994).

EPA has identified about 30 pesticides approved since 1988, under the negligible risk standard, whose tolerances may have to be revised to bring them into compliance with the Delaney provision of section 409. These compounds are used in about 100 different raw and processed food applications.

For almost a decade, we and others have concluded that the Congress should reconsider the differences between the FFDCA's sections 408 and 409 and FIFRA. Over the last few years, a number of policy options have emerged to resolve the differences in the federal pesticide laws. The three policy options proposed are

- allowing a zero risk of cancer with no consideration of benefits,
- allowing a negligible risk with no consideration of benefits, and
- allowing a negligible risk with limited consideration of benefits.

In April 1994, the administration proposed comprehensive pesticide policy reform legislation that includes, among other things, amending the FFDCA to require EPA to set tolerances for pesticide residues in all types of food in accordance with a health-based safety standard. This standard would require a reasonable certainty of no harm to consumers and would establish a negligible risk for carcinogens.

Not All Agencies Required to Reevaluate Compounds Approved Under Earlier Scientific Standards

Although advances in scientific knowledge may raise questions about the safety of compounds approved in the past, federal law does not generally require the agencies to periodically and systematically reevaluate these compounds. Only EPA is required by FIFRA to update information on all pesticides approved under less stringent government standards and to reregister those chemicals that meet current standards. FDA has no such requirement for animal drugs and reviews and/or withdraws approved drugs only if a problem comes to its attention.

To meet its FIFRA requirement, EPA has developed a formal system to reevaluate the pesticide products approved in the past against current scientific standards. Although the Congress has mandated that EPA complete the reregistration process for about 20,000 pesticide products generally by 1998, we reported in May 1993 that this formidable and complex task may not be completed before the year 2006. EPA still needs to review a large number of studies to allow pesticides to be fully reassessed.[2]

[2]Pesticides: Pesticide Reregistration May Not Be Completed Until 2006 (GAO/RCED-93-94, May 21, 1993).

In the interim, previously registered pesticides may continue to be used on food under their existing registrations and tolerances. Since EPA began the reregistration process, hundreds of pesticides have been voluntarily canceled by pesticide registrants because the fees and costs of developing new data to meet EPA's current pesticide requirements would outweigh the expected income from sales.

Recognizing the importance of reevaluating approved pesticides against current scientific standards, in its April 1994 proposed pesticide reform legislation, the administration recommends, among other things, a "sunset provision." Under this provision, a pesticide's registration would expire after 15 years, unless EPA approved a registrant's new application. The new application would have to meet the current scientific standards for safety. In our October 1993 comments on these provisions, we said that such a provision would help ensure that pesticides not meeting the most current scientific standards would be taken off the market.[3]

In contrast, FDA has not undertaken such a reevaluation of approved animal drugs because it is not required to do so. FDA officials told us that while they had considered the need to reassess older animal drugs on a cyclical basis in the past, they did not have the resources to implement such a program. Therefore, FDA reassesses approved compounds only on a causal basis—as the need arises. According to FDA officials, about six older animal drugs have actually been reassessed and their approvals withdrawn because of safety and efficacy concerns. FDA officials told us that while some compounds on the market have not been reevaluated since first approved, they generally believe that the market share of these drugs is relatively small; consequently, reevaluating them is a low priority for FDA. However, without definitive evidence that this is the case, we question FDA's low priority classification for reevaluating animal drugs approved in the past.

Regulatory Policies Weaken Controls Over Unapproved Compounds

Both EPA and FDA allow users of pesticides and animal drugs access to unapproved compounds to address emergency situations. However, we have questioned EPA's repeated use of emergency pesticide exemptions and have reported that extra-label drug use[4] has been misused. As a result, the use of unapproved chemicals has become a routine practice. The

[3]Pesticides: Reregistration Delays Jeopardize Success of Proposed Policy Reforms (GAO/T-RCED-94-48, Oct. 29, 1993).

[4]Under the FFDCA, if an animal drug is used in a manner other than that specified on its FDA-approved label, it is considered to be an extra-label use and is in violation of the act.

long-term, widespread use of these policies also places chemical manufacturers that seek approval of their products at a competitive disadvantage.

Repeat Emergency Pesticide Exemptions May Provide Potential for Abuse

Since 1978, we have reported several times that EPA repeatedly grants emergency exemptions for pesticides, and we have questioned whether some of these situations were true emergencies. Section 18 of FIFRA allows EPA to grant emergency exemptions for unregistered pesticides if emergency conditions exist that warrant such an exemption. Under the EPA regulations, before the agency grants an emergency exemption, it must judge, among other things, whether an emergency situation exists, whether the pesticide will result in adverse health and environmental effects, and, for repeat exemptions, whether reasonable progress has been made toward registration.

In 1991, we reported that EPA generally tends to approve over 70 percent of the emergency exemption applications it receives every year. Since 1978, almost 4,500 emergency exemptions have been granted for unregistered pesticides.[5] Moreover, as we reported, EPA has repeatedly granted emergency exemptions for the same pesticide uses for several years; in one case, these exemptions had been granted for as many as 12 years.

Part of our concern with repeat emergency exemptions stems from the lack of specific criteria for defining emergencies and of complete applications for registration. In June 1992, EPA issued guidance for state and federal agencies that explains EPA's requirements for an emergency exemption application, the documentation required, and the policies and criteria that the agency uses when evaluating an emergency application request. According to EPA officials, this guidance should clarify the agency's requirements in the future.

Nevertheless, in a 1987 and 1988 report prepared by EPA's Registration Division summarizing emergency exemptions, EPA recognized that a repeat exemption "represents or at least gives the appearance of circumvention" of the registration process. Two principal concerns result from these exemptions. First, a greater public health concern exists about these pesticides because they have not gone through EPA's registration process, which would subject them to a review of human health and environmental effects. Therefore, the extent of their safety is not known. Second, these

[5]Pesticides: EPA's Repeat Emergency Exemptions May Provide Potential for Abuse (GAO/T-RCED-91-83, July 23, 1991).

exemptions may be placing companies that register pesticides and incur the cost associated with registration at a competitive disadvantage with those companies that are able to sell their chemicals for uses that are not registered.

Use of Unapproved Animal Drugs Is Widespread

Extra-label drug use is widespread and raises questions similar to those posed by emergency pesticide exemptions. By allowing extra-label drug use, FDA enables the users to bypass important safeguards for tolerances and withdrawal times. FDA established an extra-label use policy for animal drugs with the intention that such uses would be rare—for emergency situations only. The extra-label use policy allows veterinarians to treat animals with unapproved drugs when certain conditions are met; FDA does not take enforcement action in these situations.

We reported in 1992 that, contrary to FDA's intent, extra-label drug use was not an uncommon or rare practice but was actually widespread in dairy cows.[6] Several veterinarians who treat dairy cows told us that between 40 percent and 85 percent of their dairy cow prescriptions are for extra-label uses. The National Academy of Sciences reported similar concerns about the unapproved use of animal drugs in aquaculture. Although disease is a limiting factor in the culture of aquatic animals, only five animal drugs have been approved for use in aquaculture. Because of the lack of approved drugs, the aquaculture industry is using in cultured fish about 50 animal drugs approved for terrestrial food-producing animals.[7] This practice may pose a risk to human health if residues persist in the edible tissue of the fish. FDA has modified its drug approval program to help expedite the approval of animal drugs for aquaculture, but it may be many years before some of these drugs have adequate data to support their safety and efficacy and are reviewed and approved for use by FDA.

Moreover, the extra-label drug use policy, like EPA's pesticide emergency exemption policy, may discourage animal drug manufacturers from seeking approval for additional uses of their drugs. If manufacturers know that they can sell the drugs without incurring any additional regulatory costs or enforcement action, they are not likely to incur the additional costs of seeking approval.

[6]Food Safety and Quality: FDA Strategy Needed to Address Animal Drug Residues in Milk (GAO/RCED-92-209, Aug. 5, 1992).

[7]FDA has classified 13 of the 50 unapproved drugs used in aquaculture as having low regulatory priority.

Current Laws Do Not Encourage Agencies to Monitor Environmental Contaminants

Although over 60,000 industrial chemicals, regulated under the Toxic Substances Control Act, are currently in use in the United States, no food safety law specifically requires agencies to develop plans to monitor the presence of these chemicals in food. Instead, action is taken and resources allocated to these chemicals only when an incident that may threaten human health, or even life, occurs. Even if such laws were in place, federal agencies would require a substantial investment in staff and funds to establish a risk-based system to identify and monitor how many of this large number of chemicals are in the food supply.

Any food-monitoring activities that FDA and USDA conduct for environmental contaminants are authorized by the general food safety provisions of their principal legislation. The FFDCA, FMIA, and PPIA all specify that if any poisonous or deleterious substance is added to food, it will render the food unsafe and unfit for human consumption. FDA is the primary agency responsible for setting tolerances for environmental contaminants in food. However, because the FFDCA does not specifically require FDA to set these tolerances, the agency has done so only when it believes that such tolerances are necessary. For example, for seafood, FDA has set one formal tolerance—for polychlorinated biphenyls,[8] a banned carcinogenic industrial compound—and 15 informal residue standards for other chemical contaminants.[9]

Although FDA ranks environmental contaminants, such as lead and mercury, as being a significant food safety concern, at least as important as pesticide residues, it has established few tolerances for these chemicals. According to FDA officials, unlike pesticides and animal drugs, no sponsor is required to submit the data necessary to establish tolerances for environmental contaminants. Therefore, FDA must gather all the data itself, which is both costly and time-consuming, especially if the agency has to gather data for all possible environmental contaminants.

The lack of tolerances for some environmental contaminants—such as heavy metals—affects other federal and state agencies' efforts to look for these contaminants in the food they monitor. We recently reported that USDA was not testing either domestic or imported meat products for environmental contaminants, specifically heavy metals, because these

[8]Polychlorinated biphenyls include more than 200 different compounds that were used in a variety of industrial applications before they were banned in the late 1970s.

[9]When adequate data are not available to justify the setting of formal tolerances, FDA may choose to set an informal standard for a chemical; informal standards, unlike tolerances, are not binding on the agency or industry.

compounds did not have U.S. tolerances.[10] Although USDA was aware that foreign countries were experiencing a problem with some of these contaminants and had found violative residue levels in their own domestic testing programs, USDA did not request FDA to consider establishing regulatory standards for such contaminants until 1994.

Given the large number of potential environmental contaminants that could enter the food supply, developing a risk-based approach will be critical to effectively monitoring these compounds in the food supply. However, developing a risk-based system to monitor these contaminants will require additional resources so that federal agencies can obtain the necessary data and expertise to assess the risks from these compounds. Monitoring environmental contaminants in food is made even more complex by the fact that many of these chemicals are a concern only at the local or regional level. FDA officials told us that developing national standards and monitoring programs for such chemicals may be an ineffective use of resources. Given the highly toxic nature of some environmental contaminants, we believe that setting national standards for these compounds should be a high priority for the federal government and that monitoring programs could be improved through greater federal-state cooperation in this area.

[10]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994).

Fundamental Weaknesses in Federal Enforcement Processes

Under existing approaches, the federal government cannot ensure compliance with the standards it has put in place for chemicals in food. Federal agencies' efforts to test the food supply for the presence of unsafe levels of chemicals are resource-intensive, inefficient, and ultimately ineffective. Moreover, even when violations are detected, responsive enforcement action often does not occur. An alternative monitoring approach now being employed by food processing companies could provide a more efficient avenue for future federal efforts to ensure compliance.

End-Product Testing Is Ineffective and Does Not Use Limited Resources Efficiently

Federal efforts to test the food supply for compliance with chemical standards rely on the approach of end-product testing—testing products during the final stage of production. To be effective, this approach requires agencies to expend considerable resources to (1) obtain comprehensive information on chemicals in use for all products and (2) develop test methods that detect all chemical compounds of concern. The agencies generally lack the resources to implement this approach in the comprehensive fashion that is necessary for it to be effective at the retail level.

Agencies Rely on End-Product Testing to Ensure Compliance

To ensure that the U.S. food supply complies with federal standards, FDA and the Food Safety and Inspection Service have historically sampled and tested food products for the presence of chemical residues and environmental contaminants before they are marketed. While the compounds/commodities tested each year may vary, the agencies have generally relied on the results of sample analysis to assure consumers that the food supply is safe from harmful chemical contamination.

Both FDA and FSIS use a two-pronged approach to their chemical residue and environmental contaminants monitoring programs. FDA monitors chemicals in food through (1) surveillance monitoring—used when there is no reason to suspect a problem, and (2) compliance monitoring—used for commodities where a violation has been found in the past or is suspected. In fiscal year 1992, FDA had 10 chemical-monitoring programs through which it sampled and analyzed over 17,000 domestic and imported food products for pesticides, animal drugs, and industrial chemicals. (See app. II for a list of FDA's compliance programs and assignments for fiscal year 1992.) FSIS monitors chemical residues and environmental contaminants in meat and poultry through its National Residue Program (NRP). The NRP has both (1) a monitoring program to collect and analyze

routine random samples and (2) a surveillance program to test samples when contamination is suspected.[1] In 1992, FSIS conducted almost 375,000 chemical residue analyses on domestic and imported meat and poultry samples for pesticide and animal drug residues.[2] (See app. II for a list of compounds that FSIS' NRP tested for in 1992.)

Lack of Usage Data Limits the Comprehensiveness of End-Product Testing

Generally, federal agencies have been unable to target their inspection resources to the chemical/food combinations most likely to be hazardous because they lack reliable and comprehensive data on the chemicals used in food production. As a result, their nontargeted testing efforts may not adequately cover all the chemicals of concern.

The agencies are limited in their ability to obtain reliable chemical-use data because of insufficient resources, according to agency officials. In 1992, we found that FDA did not have reliable information on the total number of animal drugs, both approved and unapproved, that were being used on dairy cows. Consequently, the number of animal drug residues that may be present in milk was unknown. To develop a list of such drugs (82 in all),[3] GAO turned to multiple sources, such as state surveys and market research data, as well as our own interviews and observations at the farm level. According to the Director of the Office of Surveillance and Compliance in FDA's Center for Veterinary Medicine, reliable and comprehensive drug usage information would (1) improve FDA's efforts to monitor drug residues in milk and (2) help the agency provide critical information to FSIS for its national residue program for meat and poultry. In 1992, Center for Veterinary Medicine officials told us that the agency is hampered in its efforts to collect information from veterinarians/users of animal drugs because this is a resource-intensive activity. According to these officials, FDA's limited resources, the large number of users of animal drugs, and the extensive paperwork involved has precluded the agency from collecting drug-use information. The agency has largely relied on the purchase of commercially available data as their primary source of drug-use information.

[1]In addition, the NRP has exploratory and individual enforcement testing programs as part of the overall program.

[2]FDA and FSIS do not track samples and analyses in the same manner. FDA tracks the total number of physical samples that it collects, not the number of chemical tests that a sample is analyzed for. FSIS, on the other hand, tracks the total number of analyses performed, not the total number of physical samples.

[3]FDA has since expanded this list to 85 drugs.

Usage data have also been lacking until recently for pesticides used on domestic crops. Since fiscal year 1990, as part of USDA's Water Quality and Food Safety Initiatives, the National Agricultural Statistics Service has been collecting such data for on-farm pesticide use on fruits, vegetables, and field crops. According to both EPA and FDA officials, this program has provided them with much needed information, and they would like to see the program's limited scope expanded to include data for pesticides used on all agricultural commodities. In addition, an EPA official told us that the agency would like to receive information on the pests being targeted and on post-harvest chemical applications. Officials from both agencies were concerned that while this program provides critical data for their efforts to monitor chemical residues, no assurance exists that the program would continue to receive funding from USDA.

To overcome the limitations in usage data and resources, federal agencies have set risk-based priorities for monitoring chemical compounds. Although such a risk-based approach is the most logical method for ensuring safety, these programs are not effective because of implementation problems. As a result, monitoring of even those chemicals the agencies consider most harmful is often incomplete.

More specifically, FSIS has been unable to monitor the chemical compounds in meat and poultry that pose the greatest risk to human health because it is backlogged in its evaluation of these compounds. FSIS includes in its monitoring program those chemicals that have a high priority based on the agency's evaluation of the chemical's risk. However, we recently reported that of the 367 potential compounds of concern that FSIS identified, 240 had not yet been evaluated and ranked. As a result, these chemicals were not included in the program for testing, and it is not known how many of them are entering the meat and poultry supply.[4] Moreover, although FSIS' criteria require that when no violative results appear after 1 to 3 years of testing, the compound should be a candidate to be cycled out of the program, we reported that many of these compounds continued to be included in the program. As a result, FSIS' limited testing resources were being diverted to monitoring low-risk compounds.

FDA also has been unable to fully monitor its list of priority pesticides because of competing demands for its limited testing resources. In its 1990 plan for pesticide residues, FDA targeted for its monitoring programs 225 priority agricultural pesticides. These pesticides were identified from a

[4]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994).

master list of about 700 potential pesticides used in the United States and abroad. However, FDA has been unable to test all the chemicals identified in its 1990 plan, according to FDA's Strategic Manager for Pesticides and Chemical Contaminants. Outside pressures and unanticipated incidents have required the agency to redirect resources to commodities/chemical combinations not included in the plan.

Lack of Multi-Residue Test Methods Further Limits Effectiveness of End-Product Testing

The effectiveness of the federal government's end-product testing is further compromised by the lack of adequate analytical test methods to identify and quantify all chemical compounds of concern. While chemical registrants/sponsors must provide an analytical method for their compound, these methods are usually single-residue methods—methods that can detect only one compound—which federal agencies prefer not to use for routine monitoring purposes. Generally, federal agencies prefer to use multi-residue methods that detect multiple compounds in a single test and are therefore more cost-effective than single-residue methods. Federal agencies must develop their own multi-residue methods because chemical sponsors cannot be required to do so. However, the agencies are constrained in their multi-residue test development, not only by resources but also by differing regulatory needs and changing technology.

Because test method development requires extensive expenditures and time, agencies have been unable to develop all the multi-residue tests that they need. For example, FDA has five primary multi-residue tests for pesticides. If all five tests are conducted on a food product, they can detect only about half of the approximately 300 pesticides with approved tolerances. Similarly, FSIS has adequate detection methods for only about 36 of the 48 compounds identified as being highly hazardous to consumers of meat and poultry.[5]

To overcome resource constraints, FDA has in recent years taken two actions to shift to chemical registrants/sponsors the responsibility for developing test methods that will meet its needs. First, FDA requested, and EPA implemented, a requirement that pesticide registrants indicate whether a new pesticide is recoverable by any of FDA's existing multi-residue methods. Second, FDA has developed guidelines to shift the responsibility for test method validation—proof of the test method's effectiveness to collect analytical data—for animal feeds to the industry. Currently, the federal government must maintain a complete laboratory infrastructure to

[5]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994).

support method validation trials. If this program is successful, FDA hopes to expand it to animal drugs.

Federal agencies could use resources more efficiently if they better coordinated their efforts to develop test methods. Agency officials told us that they need to develop test methods separately because their regulatory needs for precision in test results differ. However, we and others believe that a more coordinated federal test method development program might use resources more efficiently and foster the development of additional test methods. In 1988, the Office of Technology Assessment concluded that the amount of resources available for methods research for pesticide residues increases the need for coordination between agencies. Similarly, in its 1993 report, the Federal Coordinating Council for Science, Engineering, and Technology concluded that to effectively meet future research challenges, including methods development, federal regulatory agencies would need the collective and coordinated policy and resources of the federal government.

Interagency coordination and the efficient use of resources become even more critical because advances in technology can also impede the development of test methods. For example, changes in the chemical structure of pesticides have impeded FDA's efforts to develop new multi-residue tests. Newer pesticides are made from more chemically diverse compounds than older pesticides, and they also degrade more quickly. These characteristics significantly increase the scientific task of developing adequate multi-residue methods, according to a 1987 study by the Congressional Research Service. To try to keep pace with the changing technology, agencies such as FDA are developing selective multi-residue methods, which detect only a few compounds versus the 50 to 100 compounds detectable by traditional multi-residue methods.

End-Product Testing Is Not Statistically Representative

The results of end-product testing can be extrapolated to the total food supply only if statistically representative sampling is conducted. However, federal agencies either do not conduct such sampling or have poorly implemented statistically representative methodologies, thereby compromising their results.

For end-product testing to accurately depict the level of chemical residues and environmental contaminants in the food supply, federal agencies would have to conduct statistically representative sampling and testing. The results of a statistically representative sample could be projected to

determine the level of a given chemical in the entire food supply. However, statistically representative sampling does not generally occur. Most of FDA's testing is conducted under its surveillance program, which does not have a statistically based sampling process. FDA cites a lack of resources and competing priorities as factors inhibiting its ability to conduct statistically representative testing of the food supply. For example, for pesticide residues alone, a statistically representative monitoring program for all commodities would cost over $45 million annually, according to FDA's estimates. Currently FDA allocates between $20 and $30 million annually to monitoring both pesticides and industrial chemicals in food.

Even FSIS, which has a statistically representative residue monitoring program for meat and poultry, has implementation problems that compromise the validity of its test results. We and USDA's Office of Inspector General have found examples of FSIS inspectors' improperly implementing the sampling plan. Most recently,[6] we found that (1) random selection procedures were not followed consistently by FSIS inspectors when selecting samples for testing, (2) climatic/geographic and seasonal adjustments were not made for all affected species, and (3) different animal species were not sampled at the same rate for the same compound, nor were the same species sampled at the same rate for different compounds.

Despite these problems with their sampling plans, federal agencies tend to make broader conclusions about the level of chemical residues in the food supply than their test results warrant. For example, in 1990 we reported that FDA could not support its conclusion that the milk supply was free of harmful drug residues.[7] We found that the three surveys on which FDA had based its conclusion were only "snapshots" in time and that the limitations in methodology should have precluded FDA from reaching its conclusion.

Similarly, FSIS has made statements about the trends of residues in meat and poultry that we and others have questioned. As we recently reported, to reach its conclusion FSIS combines and averages the test results for the different residues tested. However, this approach is not a valid one because it assumes that a sample contaminated with one kind of residue will not contain any other kind of chemical contamination. In the past, we

[6]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994).

[7]Food Safety and Quality: FDA Surveys Not Adequate to Demonstrate Safety of Milk Supply (GAO/RCED-91-26, Nov. 1, 1990).

estimated that the true violation rate for meat and poultry is probably closer to the sum of the violation rates for all residues tested.

Newer Monitoring Approaches That Could Overcome the Inefficiencies of End-Product Testing Have Not Been Implemented

End-product testing, by itself, is not an efficient approach to ensuring food safety. It does not prevent problems from occurring. It only detects them after they have developed and after they may have entered the food supply. Newer approaches, generally based on the Hazard Analysis and Critical Control Points (HACCP) approach, could overcome the weaknesses inherent in end-product testing. Some food organizations have voluntarily adopted HACCP-based approaches to ensuring food safety. However, the federal government has made little progress in encouraging or requiring the use of such programs.

Some Food Companies Are Using HACCP

Some food companies and industries are voluntarily using monitoring plans—often based on the HACCP approach—that serve as an alternative to the traditional system of end-product inspection. HACCP is a systems approach to contaminant control and management and is as applicable to chemical residues as it is to microbial contamination—the contaminant that HACCP was originally developed to control. By emphasizing a complete-systems approach and ensuring quality and safety from the very start of the food process, the HACCP concept overcomes many of the weaknesses that are inherent in a safety system that depends on end-product testing. The HACCP approach has three fundamental components:

- identifying the hazards and assessing the risk associated with each stage of food production, including growing, harvesting, processing, marketing, preparation, and use;
- determining the critical points where the identified hazards can be controlled; and
- establishing procedures to monitor these critical control points.

We found numerous examples of food industry establishments and organizations using or promoting the use of residue control programs that move away from end-product testing as the primary quality control mechanism. These programs focus on (1) controlling the proper use of chemicals through good manufacturing practices so that raw materials used by processors contain acceptable levels of residues and (2) ensuring that the final product is in compliance with federal food safety standards. These plans also contain a critical element of the HACCP approach—moving

to the industry the responsibility for pre-market testing of food products for compounds of concern.

For example, the National Turkey Federation has developed a program to avoid pesticide and drug residues and environmental contaminants in turkey production so that "the tissue of turkeys produced and slaughtered in the United States will not contain any chemical residues which may adversely affect the health of the consuming public." The plan calls for good manufacturing procedures, including specific requirements for feed, farm site, water, medication, and vaccines. It also emphasizes the proper and controlled use of chemicals as well as accurate recordkeeping and flock identification systems to help trace the source of violations when violative residues are found. Turkey producers are also required to test their products for violative residues of polychlorinated biphenyls, pesticides, chlorinated hydrocarbons, and drugs.

Similarly, the Campbell Soup Company has taken a total systems approach to pesticide control that is premised on "Know thy supplier" as the key to effective pesticide management. This plan controls the presence of illegal pesticide residues in the company's products by (1) controlling pesticide application and requiring suppliers to use approved pesticides at the appropriate concentrations and application rates, (2) emphasizing the use of integrated pest management strategies to reduce overall pesticide use on crops, (3) requiring companies to sample and test products for pesticides before processing to ensure that they are free of any unacceptable residues, and (4) emphasizing the need for proper lot identification and recordkeeping in case a problem is discovered.

Federal Government Making Slow Progress in Implementing the HACCP Approach

Although the federal government realizes the relevance of the HACCP approach to controlling residues in foods, little progress has been made toward implementing such programs. The only federal HACCP programs currently in place are an FDA-mandated plan to control microbial contamination in low-acid canned foods and a voluntary fee-for-service plan for NMFS-inspected seafood establishments. FDA developed and implemented the low-acid canned food regulations in 1974, after an outbreak of botulism from canned mushrooms. NMFS announced the availability of its voluntary fee-for-service inspection program, based on HACCP principles, in July 1992. This program includes measures to identify and control chemical hazards in seafood. USDA and FDA are developing other HACCP-based programs. USDA is developing a plan to implement a mandatory HACCP-based system for meat and poultry inspection that will

address microbial, physical, and chemical hazards.[8] However, even though the Secretary of Agriculture announced in May 1993 that USDA would announce its HACCP plans within 90 days, these plans were still unavailable as of August 1994. FDA has also drafted a HACCP-based mandatory seafood inspection plan. This plan was published for public comment in January 1994.

Federal officials we spoke to agree that a HACCP-based approach is a logical and cost-effective method of controlling contamination in food and that it is a movement away from the federal government's traditional approach for monitoring food safety. Under federal plans, the federal government would oversee industry-based HACCP programs. The food industry would be required to have in place adequate programs to monitor the safety of its products as well as conduct and document day-to-day monitoring activities. The Commissioner, FDA, stated in January 1994, when announcing the proposed mandatory HACCP plan for seafood:

"It's time to overhaul the system. . . .the best way to provide safe food is to build safety into food products during the production process. Under the current federal system, food products are simply examined for safety after the fact."

Similar concerns were echoed by the Secretary of Agriculture, when announcing USDA's plans to institute a mandatory HACCP program for the meat industry. The Secretary stated that it "was necessary to modernize and revolutionize an archaic system that must do a better job of protecting consumers. We cannot continue to run a system based on 1933 standards and procedures in 1993."

A shift to a HACCP-based approach may not be easily accomplished, according to FDA officials and others. The officials we spoke to said that the effective implementation of a HACCP plan would require legislative changes to grant them authorities that they currently do not have, such as access to industry records. Some public interest groups have also raised concerns that without additional authorities and funding, the government's effort to implement HACCP will be ineffective in improving the safety of the U.S. food supply.

[8]Physical hazards include hair, bone, and other such contaminants that may occur in meat and poultry.

Enforcement Mechanisms Do Not Prevent Distribution of Contaminated Food or Deter Future Violations

Compliance with federal standards for chemical residues in food is also not ensured because of problems in the enforcement mechanisms available to federal food agencies. The enforcement system generally requires monitoring agencies to report violations to FDA, the enforcing agency, for follow-up action (interagency referrals). However, responsive enforcement action often does not occur. Moreover, because FDA lacks the authority to detain products or assess civil penalties, it cannot effectively prevent the distribution of violative products to consumers or prevent future violations from occurring.

Reliance on Interagency Referrals Is Ineffective

Enforcement agencies do not always act on violations referred by other agencies. For example, FSIS reports over 4,000 illegal drug residue violations every year to FDA. However, according to a 1992 report by FDA's Extra-Label Use Task Force, because of limited resources, FDA is unable to conduct follow-up investigations on the majority of these referrals. In 1992, FDA and state agencies together were able to investigate only about 1,100 (or 25 percent) of USDA's referrals for illegal drug residues in meat and poultry. This lack of follow-up on referrals clearly reduces the effectiveness of federal efforts to enforce compliance with chemical residue standards.

Federal agencies could investigate more violations if they made better use of state resources in overseeing the safety of many food products. In 1991, we reported that FDA could improve its oversight over bottled water by using state inspection testing results, which would eliminate the duplication of inspection efforts and free up limited FDA resources for other activities.[9] Similarly, in 1992 we reported that FDA lacks a comprehensive strategy to monitor drugs in milk that optimizes the state's and industry's monitoring efforts.[10] Finally, according to a National Academy of Sciences study on seafood, inspection efforts by FDA and various state and local public health agencies are designed to ensure safety but are insufficient to ensure in all cases that the regulatory guidelines defined by FDA and EPA are not being exceeded.[11] The report also stated that "recognizing the advantages of regional/local control and surveillance is essential" to ensure seafood safety.

[9]Food Safety and Quality: Stronger FDA Standards and Oversight Needed for Bottled Water (GAO/RCED-91-67, Mar. 12, 1991).

[10]Food Safety and Quality: FDA Strategy Needed to Address Animal Drug Residues in Milk (GAO/RCED-92-209, Aug. 5, 1992).

[11]Seafood Safety (Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, 1991).

Ability to Prevent the Distribution of Violative Products Is Inconsistent

The ability of FDA and USDA to prevent the distribution of contaminated products to consumers is inconsistent. As we reported in 1992, the FFDCA does not give FDA the authority to prohibit the marketing of domestic products without a court order.[12] As a result, while FDA is obtaining a court order for seizure, potentially unsafe foods can be shipped and sold to consumers. In contrast, FSIS and AMS have the authority to temporarily hold suspect food for up to 20 days without a court order.

In the past, we and others have reported on the need to provide FDA with detention authority. In our 1984 report on FDA's enforcement authorities and again in 1986, we asked the Congress to consider providing FDA with the authority to detain products suspected of being adulterated.[13] Similarly, a 1991 report from the Department of Health and Human Services' Office of Inspector General concluded that FDA's lack of immediate detention authority can allow adulterated foods to enter the marketplace.

Enforcement Authority Against Violators Is Often Insufficient

Federal agencies also lack adequate authority to take enforcement action against violators. This happens because FDA, which has primary enforcement responsibility for most residue violations in food, lacks the authority to assess civil penalties. As a result, FDA must rely on the Department of Justice to follow through with criminal charges. However, criminal charges are rarely assessed because they take considerable time and significant resources to pursue. Without the authority to assess civil penalties, FDA is unable to deter future violations from occurring because producers know that penalties will rarely be assessed, even in those instances when violations are detected.

The number of cases pursued under the criminal law is minuscule. In fiscal years 1989 through 1992, FDA investigated only about 4,500 cases of the over 21,000 violative residues in meat and poultry referred to it. Of those cases investigated, 383 resulted in FDA warning letters and 15 cases resulted in criminal proceedings—either an injunction, citation, or prosecution. The Edwards Committee stated in its 1990 report on FDA that the number of formal court enforcement actions pursued by FDA had declined sharply since the 1970s. In the past, we and others have asked the

[12]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

[13]Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public From Adulterated Food Products (GAO/HRD-84-61, Sept. 26, 1984); Need to Enhance FDA's Ability to Protect the Public from Illegal Residues (GAO/RCED-87-7, Oct. 27, 1986).

Congress to consider providing FDA with additional enforcement authorities, including civil penalty authority, to effectively deter the marketing of food with illegal residues and overcome the difficulties associated with pursuing criminal penalties. The April 1994 pesticide reform bill introduced by the administration proposes granting FDA additional enforcement authorities for pesticide violations, including the authority to assess civil penalties.

In contrast, EPA, the federal agency responsible for following up on pesticide-use violations, has under FIFRA a broader array of enforcement authorities than FDA, including the assessment of civil penalties up to $5,000 for each violation of the act. According to EPA's Enforcement Response Policy, "A civil penalty is the preferred enforcement remedy for most violations." The majority of pesticide violation follow-up actions are conducted by state agencies under EPA's federal-state cooperative agreement program. However, for about 70 percent of those cases for which it was responsible in fiscal year 1992, EPA assessed civil penalties.

Fewer Controls Exist for Imported Foods

U.S. agencies have no jurisdiction over food producers in exporting countries. As a result, to ensure compliance with U.S. food safety standards, federal agencies must rely on the adequacy of exporting countries' food safety systems and/or U.S. inspection and testing of imported products at the port of entry. However, federal agencies have limited assurance that exporting nations adequately inspect food shipped to the United States, and FDA's inspection resources cannot keep pace with the growing volume of imported food. Moreover, federal agencies may not test some imported products for compounds that are used in exporting countries but are not approved for use in the United States. This occurs because (1) the agencies may have incomplete data on these chemicals and/or (2) some U.S. inspection programs focus only on domestic compounds of concern. Finally, as a result of weaknesses in its regulatory authorities, FDA has been unable to prevent the distribution of contaminated products to U.S. consumers.

Exporting Countries' Inspection Systems May Not Be Adequate

Although the United States relies only in part on the adequacy of exporting nations' inspection systems to ensure the safety of food imports, even such limited reliance is not always appropriate. We reported in 1990 that exporting nations' monitoring of chemicals, such as pesticides, is limited and may not provide assurances that food exported to the United States is safe. For example, although many exporting countries consider EPA's pesticide registration and cancellation actions when making their own decisions, some chemicals that have been canceled in both countries continue to be sold and used in exporting countries even 15 years later.

Moreover, some exporting governments are not testing for chemicals that are used in their countries but that are not registered for use in the United States. For example, in 1990 we found that four out of the five Latin American countries that we reviewed had limited government monitoring and enforcement activities for pesticide residues.[1] These countries lacked the resources not only to monitor pesticide distribution and perform field sampling and testing, but also to obtain information on U.S. requirements.[2] We found similar problems in 1992 when we reviewed Mexican pesticide testing standards and enforcement practices.[3] We reported that the

[1]The United States imports about 2.5 million metric tons of fruits and vegetables annually from these five countries.

[2]Five Latin American Countries' Controls Over the Registration and Use of Pesticides (GAO/T-RCED-90-57, Mar. 28, 1990).

[3]Pesticides: Comparison of U.S. and Mexican Pesticide Standards and Enforcement (GAO/RCED-92-140, June 17, 1992).

Mexican government had limited capabilities for monitoring the safety of exported produce and did not have a program to monitor produce grown for domestic consumption. The Mexican government generally expects the private sector to monitor exported produce for pesticide residues.

Deficiencies have also been documented for exporting countries' meat inspection systems. In 1989, USDA's Office of Inspector General (OIG) reported deficiencies in some exporting countries' (1) ability to detect certain key hazardous drug residues, (2) product sampling plans, and (3) quality assurance programs to ensure the accuracy of test results. Moreover, the OIG reported that two of the five countries it reviewed lacked adequate control and accountability over U.S. export certificates, which could result in the exportation of meat that did not meet U.S. standards. According to USDA, all of these problems have been rectified. However, the OIG is conducting a follow-up review to determine if corrective actions have indeed been taken by the countries involved.

FDA's Inspection Resources Have Not Expanded With Growing Imports

FDA's inspections have not kept pace with the growing volume of imported foods. For example, we reported in 1992 that FDA-regulated shipments of imported food increased by 140 percent, from 500,000 in 1973 to 1.2 million in 1990, and now account for almost 10 percent of the total U.S. food supply. In contrast to the 140-percent increase in import volume, FDA staff devoted to monitoring shipments increased by only 2 percent, from 355 in 1973 to 363 in 1990.[4] Because of this disparity between available FDA resources and the increasing volume of food imports, we and others have been concerned for many years that FDA's limited inspection and testing cannot ensure that contaminated imports are not entering the United States. Historically, FDA has been able to test only a small percentage of all imported shipments for chemical contamination—currently this rate is about 1 percent. Inadequate resources is a primary reason that the agency has not tested a larger percentage of imported foods, according to FDA officials.

Limitations in U.S. Testing of Imported Products

Imported products are not tested for all the compounds of concern that may leave residues in these products. FDA and USDA are often unable to obtain the data they need to direct their testing to those compounds that are used in exporting countries. In addition, federal agencies sometimes

[4]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

limit their import testing to compounds that are of domestic concern only in the United States.

Agencies Cannot Obtain Exporting Countries' Chemical-Use Information

U.S. agencies cannot direct their limited testing resources to the commodity/chemical combinations of greatest concern. This happens because exporting nations may use chemicals that the United States has not registered for use on food or for which it has not established a tolerance. For example, we reported in 1993 that 58 food-use pesticides had Mexican tolerances for some commodities but no comparable U.S. tolerances and that 17 pesticides had food-use tolerances in Mexico but not in the United States.[5] To obtain exporting countries' pesticide usage data, FDA relies on a variety of information sources, including trade and professional journals, commercial market data, informal contacts with exporting governments, and the results of its own residue testing. In its comments on a draft of this report, FDA stated that for the past several years it has purchased worldwide pesticide usage data and conducted other intelligence-gathering activities. As a result, FDA is directing its testing to those commodities/chemicals of greatest concern. However, according to a September 1993 report from the Keystone Center,[6] this information has not been of much value to FDA in targeting its pesticide testing. The Keystone Center report recommended that FDA pursue additional avenues to collect better information on exporting countries' pesticide use, to help improve the targeting of FDA's enforcement efforts for imported foods.

To overcome the lack of data on pesticide use in foreign countries, the Congress required FDA to collect pesticide usage data through cooperative agreements with exporting countries under the Pesticide Monitoring Improvements Act. Despite FDA's efforts, the agency has been unable to obtain these data. FDA contacted 37 high-volume exporting countries to obtain their pesticide-use data; however, only 9 complete responses were returned to FDA. According to FDA's Strategic Manager for Pesticides and Chemical Contaminants, the agency was unable to use much of the information provided because it either was not what FDA had asked for, was of questionable accuracy, or was in a foreign language. This official told us that the response also reflected the exporting countries' lack of reliable and sophisticated systems to collect this information and/or a

[5]Pesticides: U.S. and Mexican Fruit and Vegetable Pesticide Programs Differ (GAO/T-RCED-93-9, Feb. 18, 1993).

[6]The Keystone Center, a nonprofit organization, published a report in September 1993 that summarizes the discussions that took place during a meeting it held on food safety and pesticides.

perception that such data collection activities were an attempt by the United States to erect nontariff trade barriers. FDA has had more success in obtaining pesticide usage data as well as ensuring compliance with U.S. standards when it has worked directly with exporting governments in a bilateral manner, which is less formal than the PMIA's memorandum-of-understanding requirements.

USDA has similar problems in obtaining information on the chemicals used in exporting countries that could result in residues in meat. For example, we and USDA's OIG have raised concerns about USDA's lack of information on drugs that have been approved for use in exporting countries but that may have been banned or are not approved for use in the United States. In 1989, USDA's OIG reported that four out of five countries that it reviewed had approved animal drugs not approved for use in the United States. Similarly, in 1992, although our review was not comprehensive, we found at least seven drugs that were approved for food-producing animals in Canada but not the United States. These drugs represent varying degrees of potential risk to human health and safety.[7]

Exporting Countries' Chemical Use May Not Be Reflected in U.S. Import Testing

U.S. agencies may not test some imported products for those chemicals that are used in exporting countries but not in the United States. Instead, some U.S. import testing programs test imports only for chemicals used in the United States. For example, although meat and poultry can be imported into the United States only from countries that meet U.S. standards, these countries may be using pesticides or animal drugs not approved or banned in the United States. Because USDA's equivalency determination does not include a review of chemicals approved and used in the exporting country but not in the United States, a country may be eligible to export products to the United States that contain residues of unapproved or banned compounds. However, under the FFDCA, FMIA, and PPIA, any residue of a compound not approved or banned in the United States is considered an adulteration and cannot enter the food supply. As a result, meat and poultry containing such residues are considered adulterated and if detected must be condemned. However, we reported this year that USDA's import inspection program tests only for chemicals monitored under the U.S. domestic meat inspection program and does not test for compounds used in exporting countries.[8] Even when USDA was

[7]Food Safety and Quality: USDA Improves Inspection Program for Canadian Meat, but Some Concerns Remain (GAO/RCED-92-260, Aug. 26, 1992).

[8]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994).

aware of potential chemical contamination problems in exporting countries, it did not modify its import testing program to reflect these concerns.

According to FSIS officials, testing imported meat and poultry for compound residues other than those tested for domestically would cause international trade problems. If USDA rejected imports, then exporting countries might also reject U.S. products that contain compounds approved in the United States but not in other countries. While we agree that foreign trade concerns may be legitimate, several facts remain: (1) U.S. food safety laws do not allow such unapproved or banned chemical residues in meat and poultry and (2) other countries have disallowed U.S. meat exports because U.S. producers use chemicals not approved in these countries.

Similarly, in its 1991 study of seafood safety, the National Academy of Sciences reported that many countries were using animal drugs in aquaculture that were not approved in the United States. The report stated that chloramphenicol, an animal drug banned in the United States because it has been found to cause cancer, was being used in foreign shrimp production. However, FDA was not testing foreign or domestic aquaculture products for drug residues at that time and had no information on the levels of these residues entering the food supply. This practice could have widespread consequences because imported cultured seafood accounts for a growing percentage of the total seafood consumed in the United States. For example, over 140 million pounds of cultured shrimp are imported from China and Ecuador, which do not regulate the use of chemotherapeutic agents in cultured seafood. Similarly, more than 40 million pounds of cultured salmon are imported annually from countries that lack tolerance levels for residues. FDA did not begin testing imported and domestic cultured shrimp for chloramphenicol until fiscal years 1992 and 1993, respectively. According to FDA, the agency is restricted in its testing of animal drugs in aquaculture because of inadequate detection methods. FDA is developing additional test methods for drug residues in aquaculture that will allow the agency to expand its drug testing in this area.

Inadequate Authority Impedes FDA's Enforcement Efforts Against Violative Food Imports

Contaminated imported foods that are regulated by FDA may be more likely to enter the food supply than are those foods regulated by USDA. The difference occurs because FDA's authorities are not as strong as USDA's in the areas of enforcement and deterrents.

The FFDCA does not provide FDA with enforcement authorities that are as powerful as those authorities directing USDA's enforcement efforts. For example, FDA must rely on voluntary agreements with exporting countries to comply with U.S. food standards, while USDA has the authority to review and certify that an exporting country's meat inspection system is equivalent to the U.S. system, before that country can ship products to the United States.

In addition, importers retain possession of an imported shipment if FDA decides to conduct residue testing of the shipment. Consequently, adulterated products, especially perishable products like fruits and vegetables, may be shipped to their destination and may be consumed before the results of the tests are known. In 1992, we reported that 60 percent of perishable foods and 38 percent of nonperishable foods that FDA found adulterated with illegal pesticides were released into U.S. markets and not returned to the Customs Service for destruction or reexport, as required by FDA's regulations. On the other hand, USDA must inspect and approve every imported shipment of meat and poultry before it is released for distribution. Therefore, each shipment is held by the Customs Service until it is transferred to a USDA-approved facility for inspection.

Finally, FDA has no control over rejected shipments and must depend on the Customs Service to ensure that rejected shipments were properly reexported or destroyed. But when USDA finds an unacceptable imported meat shipment, it immediately places that shipment in a controlled area, and rejected goods are released only to a bonded carrier for reexport or destruction.

FDA lacks the authority to fine importers who distribute adulterated food shipments. As a result, FDA cannot effectively deter illegal distribution or prevent future occurrences. FDA must rely on a bond agreement between the Customs Service and the importer as its principal deterrent. The bond agreement requires the importer to pay all duties, taxes, and charges; to retain control over the shipment; and to properly dispose of the shipment if it is found to be unacceptable. The bond amount is based on the value of the imported shipment and may be assessed at up to three times the value

of the shipment. However, even a tripled bond value is often far less than the price of the goods in U.S. markets. Moreover, when the importer does not comply with the bond agreement, the collection of damages by the Customs Service is often uneven and uncertain. In 1992, we reported that the Customs Service assessed damages for only 27 percent of improper distribution cases in the four districts that we reviewed. No damages were assessed for 73 percent of the cases because (1) the importer had no bond, (2) the Customs Service had already released the bond, and (3) FDA had made errors, such as not communicating test results promptly.

Because FDA lacks civil penalty authority and must rely on the importer's bond agreement with the Customs Service, it has been unable to provide an adequate economic disincentive to the distribution of adulterated imports for a long time. Moreover, illegal distribution of adulterated imports is concentrated in a small number of repeat offenders.[9] We reported in 1992 that in fiscal years 1988 through 1990, importers at four locations had distributed 336 (34 percent) of the 989 shipments found adulterated with pesticides. Although this rate was lower than the rates of 50 percent and 45 percent that we found in 1979 and 1988, respectively, it indicated that adulterated imports continue to be distributed to American consumers.

In its comments on a draft of this report, FDA disagreed with our statements that the agency lacks adequate deterrent authority for imported products. FDA stated that it tests for far more chemicals than USDA does and has the authority to detain products offered for import, deny entry, or require reconditioning prior to entry. While we agree that FDA tests more products than USDA, this testing is FDA's primary assurance that imported products are safe. USDA's testing of imported meat and poultry at the port of entry is only a secondary level of assurance because USDA has mechanisms in place to ensure product quality in the country of origin. Moreover, while FDA's detention authority is a powerful tool, it alone is not adequate. FDA must still rely on the Customs Service to ensure that enforcement actions have been taken against violators. As we have reported in the past, this often does not happen.

[9]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

Conclusions and Recommendations

Conclusions

Ensuring the safety of the food supply becomes a greater challenge each year as the number of chemicals in use continues to expand and as additional environmental contaminants become concerns. While federal agencies have improved their assessment and oversight of risk, these efforts have not, or cannot, overcome five basic structural weaknesses in the food safety system:

- A fragmented federal effort to identify chemicals that pose a risk to human health, which results in inconsistent assessments of chemical risks.
- A legal and regulatory infrastructure that permits the use of unapproved chemicals in food.
- A resource-intensive and inefficient compliance monitoring system that by itself cannot detect all chemicals of concern.
- An enforcement system that does not adequately deter or penalize violators.
- An import inspection system that cannot ensure that foods with unapproved or banned compounds are not entering the United States.

Although risk assessment is inherently difficult, the fragmented agency structure for assessing risk exacerbates this problem. Because FDA, EPA, and USDA have different food safety responsibilities, their priorities for the data that should be collected, their methods for analyzing these data, and their conclusions about risk levels often do not coincide. Although each agency's effort is hampered by a lack of sufficient resources, the fragmented structure sometimes results in gaps and duplication that the agencies can ill afford.

Even if completely reliable information were available, the basic laws and regulations that govern chemicals in food do not support the agencies' efforts to control chemical risks. This occurs because these laws and regulations, established in response to emerging concerns, do not always work in concert with each other. As a result, a chemical not allowed under one act may be permitted under another act because different agencies are allowed to apply different risk standards. Equally important, federal laws do not require the agencies to regularly reevaluate approved chemicals against current scientific standards. Finally, while these laws do address the risks posed by pesticide and animal drug residues in food, they do not address the critical risk posed by environmental contaminants in food.

The federal approach to monitoring chemicals in food—end-product testing—is ineffective because it is essentially reactive. This approach tries to catch problems after they have occurred because it is

resource-intensive. Reliance on this approach requires an ever-increasing amount of resources both to test food for all of the commodity/chemical combinations of concern and to develop all the multi-residue tests needed to detect these residues. Newer approaches to ensure food safety—such as HACCP—recognize these difficulties and seek to build safeguards into food production. Under such an approach, end-product testing becomes a secondary rather than the primary method of ensuring that unsafe levels of chemical residues and environmental contaminants do not remain in food products. While the benefits of HACCP-based systems are generally recognized, implementing such systems is a daunting task that will require extensive support from the federal government, the private sector, and consumers. In addition, federal enforcement efforts do not provide the backup that is necessary to ensure compliance with federal food safety standards when violations occur.

Finally, U.S. federal agencies have even less leverage in addressing these problems in imported foods. Consequently, chemicals that are a concern because they are used in exporting countries, but not in the United States, may be entering the domestic food supply.

Recommendations to the Congress

To overcome the fundamental weaknesses in the federal government's programs for monitoring chemical residues and environmental contaminants in food, the Congress should, at a minimum:

- Enact a uniform set of food safety laws that include consistent standards for chemical residues and contaminants in food and provide the federal agencies with the authorities needed to effectively carry out their oversight responsibilities.
- Revise the nature of the federal government's role for ensuring food safety by moving it away from end-product testing to preventing contamination from occurring. Under such an approach, the government would, among other things, (1) continue to approve chemicals and set tolerances; (2) oversee a mandatory, HACCP-based, industry-run food safety assurance program; and (3) assist industry in developing adequate test methods.

In addition, we believe that the Congress should consider the feasibility of requiring that all food eligible for import to the United States—not just meat and poultry—be produced under equivalent food safety systems.

We also believe that the problems associated with the current fragmented system cannot be solved by individual agencies' efforts to respond to

internal and external critics. Instead, these problems can be best addressed by a complete restructuring of the federal food safety system for chemical residues and environmental contaminants. As we have stated in other reports and testimonies,[1] food safety would be better assured if the Congress created a single food safety agency responsible for carrying out the requirements of cohesive food safety laws.

Agency Comments and Our Evaluation

We sought and received comments on a draft of this report from the Environmental Protection Agency, the Food and Drug Administration, the Department of Agriculture, and the Department of Commerce. USDA generally agreed with the conclusions and recommendations presented in this report. Commerce did not fully agree with our conclusions and stated that better interagency coordination can rectify the deficiencies of the current system. However, Commerce did agree with our recommendations. Although EPA generally concurred with the report's conclusions and findings, it did not agree that a single food safety agency was needed to overcome the problems mentioned in the report. EPA believes that an interagency council with working groups can resolve these issues. We disagree with EPA that an interagency council can resolve the structural weaknesses that we have identified. While this council may be used as an interim measure to improve communication between agencies, we have seen little evidence to suggest that interagency working groups have been effective in overcoming problems in the past. We therefore continue to believe that a single food safety agency is the best approach. All three agencies provided us with additional technical comments that have been incorporated, as appropriate, throughout the report. (Apps. IV, VI, and VII contain the full text of comments received from these agencies and our response.)

The fourth agency that commented on a draft of this report, FDA, did not concur with our conclusions and recommendations. FDA believes that this report is based on outdated information and opinions and perpetuates the public's misperception that the food supply may be unsafe. We disagree with FDA's observations about this report. While it is true that this report reiterates many of GAO's and others' previously reported positions, the deficiencies identified in this report were compiled largely from reports that were issued during the last 4 years. Every effort was also made to obtain and use the most current program-specific information available

[1]Food 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 Food Safety System Needed (GAO/T-RCED-94-233, May 25, 1994); Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993).

from the agencies—either for fiscal year 1992 or 1993. Moreover, the purpose of this report was to identify the structural and systemic weaknesses in the federal legal and regulatory structure for monitoring chemicals in food that have persisted over the past 2 decades, and not to comment on the safety of specific chemicals or foods. The deficiencies we have highlighted continue to exist today, despite federal agencies' efforts to improve their programs. Many of these problems are the result of the very laws that provide the framework for the food safety system. These problems can never be completely addressed by the agencies responsible for monitoring food and ultimately have to be addressed by the Congress. FDA also provided us with technical comments that have been incorporated throughout the report, as appropriate. (See app. V for the full text of FDA's comments and our response.)

We also contacted five organizations that represent various sectors of the food production and marketing industry for their views on the current federal system to monitor chemicals in food. Officials that we spoke to at these organizations included the Senior Vice President for Regulatory Affairs, American Meat Institute; the Vice President of Technology and Science, Food Marketing Institute; the Technical Adviser, National Broiler Council; the Executive Vice President, National Fisheries Institute; and the Senior Vice President, National Food Processors Association. Officials from these organizations told us that monitoring chemicals in food should generally be an industry responsibility. These officials provided us with numerous examples of how the food industry has developed and implemented many HACCP-based programs, although the federal government did not require it to do so. They generally believed that the current system is adequate and did not think that any major changes were necessary to better ensure the safety of the food supply. While the industry officials concurred with our conclusions and recommendation on the need to have industry-implemented HACCP programs, we disagree with their comments that this should be solely an industry responsibility with little federal government involvement. We believe that without federal government oversight, consumers have no assurance that the food industry has implemented effective HACCP plans that will adequately ensure food safety.

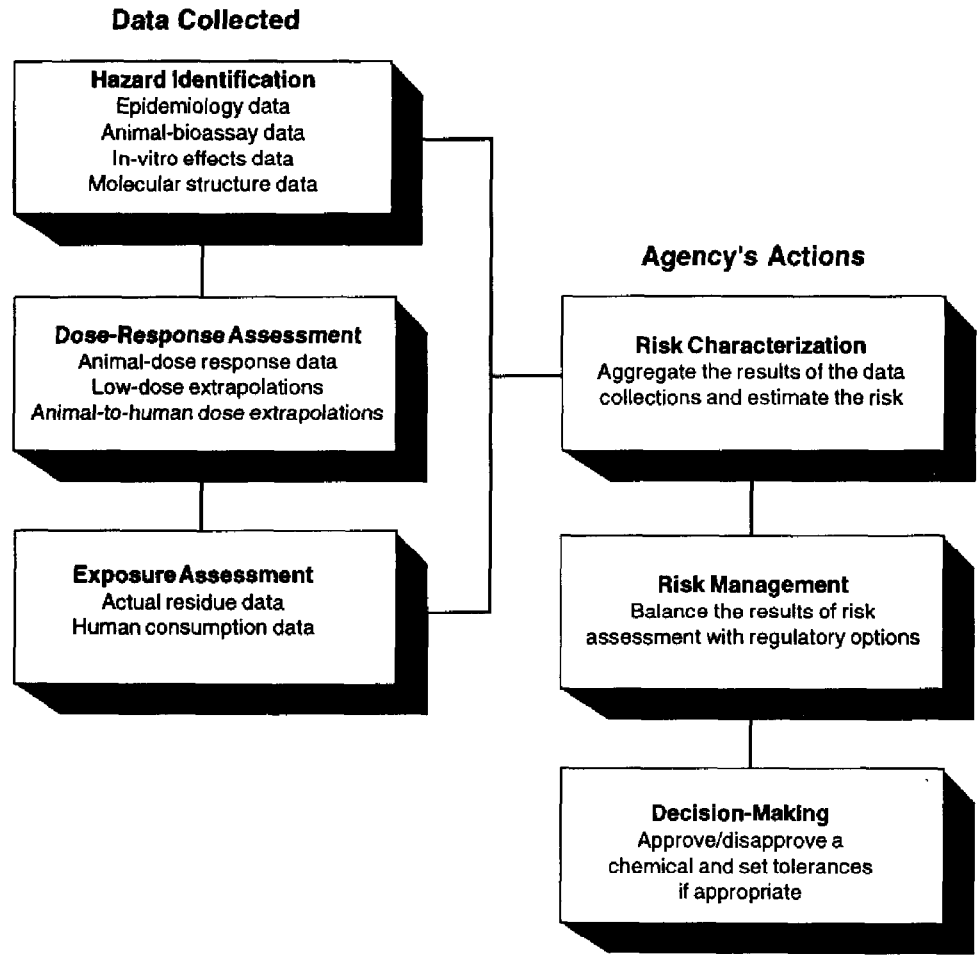
Risk Assessment Process

Risk assessment is a relatively new discipline; federal agencies did not start conducting regular risk assessments until the late 1970s. In 1983, the National Academy of Sciences (NAS) published a risk assessment paradigm,[1] which is generally accepted by federal agencies as a valuable approach to conducting risk assessments. The NAS paradigm defines four fields of analysis of risk assessment: (1) hazard identification—the determination of whether a particular chemical is or is not causally linked to a particular health effect; (2) dose-response assessment—the determination of the relationship between the magnitude of exposure and the probability of occurrence of the health effects in question; (3) exposure assessment—the determination of the extent of human exposure before or after the application of regulatory controls; and (4) risk characterization—the description of the nature and magnitude of human risk, including the attendant uncertainty, based on an analysis of the first three fields.

Each phase of the risk assessment process relies on a different set of information, and each consists of a number of decision points when inferences must be made from available evidence on the risks to human health. The inferences that an agency makes are based on both scientific judgment and policy choices. The final conclusions of the risk assessment process are ultimately based on the data, analysis, and inferences made during each of the four phases. Figure I.1 shows the process and data applied at every step for chemicals used on food.

[1]Risk Assessment in the Federal Government: Managing the Process, (National Research Council, National Academy Press, Washington, D.C., 1983).

Figure I.1: The Risk Assessment and Agency Decision-Making Processes



Even under the best conditions, risk assessment decisions are fraught with scientific uncertainty because of inherent limitations in knowledge and methodologies. These limitations result in uncertain estimates of risk even with the most complete, accurate, and reliable data. Some limitations occur because ethical considerations prevent deliberate human experimentation with potentially dangerous chemicals; therefore, the current methodology used to determine chemical risk is based on the extrapolation of animal studies to humans. However, projection from animal studies is an uncertain process at best because (1) interspecies differences must be considered when extrapolating results from animals to humans; (2) higher doses are used in animal tests than humans are expected to ingest and therefore these results must be extrapolated to lower doses that correspond to anticipated human exposure levels; (3) susceptibility to toxic effects varies from individual to individual; and (4) there may be a need to extrapolate from the route of exposure used in the laboratory experiment to a different, more likely route of human exposure. Consequently, risk assessors must rely on numerous assumptions when extrapolating animal studies to humans. One agency official told us that the risk assessment process is more art than science and does not guarantee the same results every time.

Additional limitations in the risk assessment process result from the lack of information on the synergistic effects of separate chemical substances. Generally, agencies do not determine whether the simultaneous action of separate substances produces a health effect that is greater than the sum of the individual ingredients. The potential risks to humans from multiple exposure to many different chemicals is also believed to be of some concern. It is conceivable that relatively safe chemicals may interact, even at low doses, to form a new substance that is toxic. However, federal agencies do not take these joint exposures into account when approving a chemical for use on food. According to the Environmental Protection Agency (EPA), the immense number of possible chemical residue combinations that could be ingested by people eating different diets makes this a difficult task.

Results of FDA's and USDA's Chemical Monitoring Programs

This appendix provides a list of the Food and Drug Administration's (FDA) chemical monitoring programs for fiscal year 1992 and the total number of samples that were tested and found violative under each program. This appendix also provides a list of the number of compounds tested for by the Food Safety and Inspection Service (FSIS) under its National Residue Program (NRP) for meat and poultry in calendar year 1992, the number of analyses performed, and the results of the analyses. In addition, the appendix includes the residue testing results from the Agricultural Marketing Service's (AMS) Pesticide Data Program (PDP).

Table II.1: FDA's Compliance Programs and Assignments, Fiscal Year 1992

	Domestic samples		Import samples	
Compliance program/assignment	**Analyzed**	**Violative**	**Analyzed**	**Violative**
Pesticides and industrial chemicals in domestic foods	7,784	180		
Pesticides in Mexican produce			2,653	173
Pesticides and industrial chemicals in aquaculture products	210	2		
Incidence and level monitoring for pesticide residues in domestic/imported pears	[a]	[a]	[a]	[a]
Incidence and level monitoring for pesticide residues in domestic/imported tomatoes	[a]	[a]	[a]	[a]
Pesticides in imported cocoa products			38	1
Chemical contaminants in bottom-dwelling seafood from Massachusetts Bay	107	4		
Pesticides and industrial chemicals in imported foods			6,118	269
Survey of imported tiger shrimp for chloramphenicol			49	2
Methylmercury in fresh/frozen shark and swordfish	83/36	29/8	31/70	2/21
Total	**8,220**	**223**	**8,959**	**468**

[a]These two assignments were issued in June 1992. Because it was late in the fiscal year, FDA did not include the samples taken for these programs.

Table II.2: FSIS' Testing Results for Chemicals in Meat and Poultry, Calendar Year 1992

	Domestic samples[a]		Import samples	
Chemical tested for	**Analyzed**	**Violative**	**Analyzed**	**Violative**
Antibiotics and sulfanomides	356,534	4,647	9,420	7
Arsenic	1,180	4	744	0
Benzimidazoles	2,627	0	1,765	0
Carbadox	650	0	342	0
Carbamates	1,092	0	12	0
Chlorinated hydrocarbons & organophosphates	7,329	10	3,683	0
Clenbuterol	1	0	0	0
Diethylstilbestrol	10	0	12	0
Halofuginone	623	1	16	0
Ivermectin	3,273	9	1,823	0
Nitroimidazoles	0	0	30	0
Pyrethrins	663	0	390	1
Zeranol	8	0	11	0
Total	**373,990**	**4,671**	**18,248**	**8**

[a]The number of samples analyzed and found violative for each compound includes samples analyzed under all three NRP programs—surveillance, monitoring, and individual enforcement testing.

Table II.3: Results of AMS' Statistically Based Residue Testing for Pesticides in Fruits and Vegetables, Calendar Year 1992

Commodity	Number of pesticides detected	Number of samples analyzed	Number of samples with positive residues	Number of samples that were violative
Apples	25	567[a]	502	4
Bananas	4	564[a]	209	5
Celery	21	508	409	17
Green beans	24	466[a]	279	22
Grapefruit	9	567	260	0
Grapes	21	552	381	5
Lettuce	19	565	201	5
Oranges	11	569	329	0
Peaches	22	360	307	4
Broccoli	7	153	54	0
Carrots	10	153	88	1
Potatoes	16	568	404	0
Total	**49[b]**	**5,592**	**3,423**	**63**

[a]An additional 158 samples were tested for benomyl/thiabendazole only: 51 samples of apples, 51 samples of bananas, and 56 samples of green beans.

[b]This number represents the total number of different pesticides detected.

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Researching Health Risks (Office of Technology Assessment, Report No. OTA-BBS-571, Nov. 1993).

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

23 AUG 1994

OFFICE OF
ADMINISTRATION
AND RESOURCES
MANAGEMENT

Mr. John W. Harman
Director, Food and Agriculture Issues
Resources, Community and Economic Development Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Harman:

See comment 1.

I appreciate the opportunity to review and comment on the GAO draft report entitled Food Safety: Changes Needed to Minimize Unsafe Chemical Residues (GAO/RCED-94-192). Under separate cover, EPA staff provided GAO with detailed comments for consideration when preparing the final report.

Now on p. 4.

We agree with the report's recommendation to Congress on page 6 for better oversight authorities and suggest expanding the recommendation to include human tissue monitoring programs that may yield data on dietary exposure. However, we strongly disagree with GAO's recommendation that Congress create a single food safety agency (page 6). Trying to reconfigure the responsibilities of the Food and Drug Administration, the Department of Agriculture and the Environmental Protection Agency into a consolidated agency would cause more confusion and could require large public expenditures with no real benefits. A better alternative would be an interagency council with work groups to focus on specific problems, such as those raised by GAO, through cross-agency coordination and cooperation.

See comment 2.

Again, thank you for the opportunity to comment on the draft report. I look forward to receiving the final report.

Sincerely,

for Jonathan Z. Cannon
Assistant Administrator
and Chief Financial Officer

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The following are GAO's comments on the Environmental Protection Agency's letter dated August 23, 1994.

GAO Comments

1. We have modified the report on the basis of the technical comments that we received from EPA, as appropriate.

2. While we agree with EPA that establishing a single food safety agency is no small task, we believe that this is the preferred approach to effectively ensure the safety of the food supply. We disagree with EPA's suggestion that an interagency council with working groups can resolve the issues we have raised in this report. An interagency council, by itself, cannot eliminate the inefficiencies caused by fragmentation or eliminate the problems that result from the inconsistent legal patchwork that undergirds the current food safety system. Moreover, the persistent nature of the problems we have identified and the limited evidence of successful past attempts at setting up interagency bodies raises questions about the feasibility of this approach. During our review, we found examples of interagency working groups that had been set up in the past to improve coordination and cooperation between agencies, but which either lapsed into inaction because of a lack of commitment or resources by the agencies involved or just became forums to facilitate the exchange of information between agencies. Interagency groups worked effectively only when they were established to respond to urgent and life-threatening situations. As we have stated in this and past reports, the preferred approach for better ensuring food safety would be to create a single food safety agency and revise the food safety laws to make them uniform and consistent.

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

Memorandum

Date AUG 5 1994

From Associate Commissioner for Legislative Affairs, HFW-1

Subject Food and Drug Administration Comments on the GAO Draft Report Entitled: Food Safety: Changes Needed to Minimize Unsafe Chemical Residues

To John Harmon

Attached are FDA's comments on the GAO draft report.

Diane T. Thompson for
Diane E. Thompson

Attachment

Food and Drug Administration Comments on the GAO Draft Report Entitled: FOOD SAFETY: Changes Needed to Minimize Unsafe Chemical Residues

We have reviewed the draft report and generally find that it restates previous GAO positions that do not necessarily sustain the conclusions and recommendations in the report. Much of the text is composed of outdated information/opinions. The regulatory agencies have made progress with respect to chemical residues in food, which is not reflected in the draft report. This perpetuates the public's misperception that the food supply may be unsafe. We believe the report would be of more use to the Congress and to the American consumers if it presented a balanced perspective regarding the relative risks to which the public is exposed.

The report would also be more useful and accurate if it were rewritten to clearly separate the various substances into the appropriate categories (e.g., pesticides, drug residues, environmental contaminants) and to separate the responsibilities of each of the regulatory agencies from those of the other agencies. Also, a clearer discussion of the significance of tolerances, illegal residues, unacceptable risk, etc., would facilitate consumer understanding regarding which chemical residues/contaminants may be hazardous versus those that are not hazardous. As the report is currently written, one could conclude that all residues are equally hazardous, which is not the case.

The report suggests (page 10 and elsewhere) that residues at any level in excess of tolerance usually are hazardous. There is no scientific basis for such a conclusion; therefore there is no real basis for the conclusions and recommendations made in the draft report. Occasional above-tolerance levels of pesticides or drugs, or the presence of a pesticide in a commodity for which a tolerance has not been established do not necessarily present serious health hazards to consumers. Safety factors are usually built into established tolerances to assure that the public is protected.

See comment 1.

Additionally, pesticides, animal drugs, and food additives, by definition are not categorized as chemical contaminants, since they are intentionally added to food for specific reasons. Only chemicals that are not intentionally added to foods are called "chemical contaminants." Over-tolerance residues of pesticides or drugs are "illegal" or "non-permitted" residues.

See comment 2.

The report indicts all federal chemical residue programs (page 23). However, there is nothing in the draft that supports such an indictment, gives insight into why or how the federal monitoring system is failing to provide assurance that the food supply is unsafe, or substantiates the claim of "...widespread

Now on p. 20.

See comment 1.

recognition that the federal system to monitor chemical residues in food has been unable to provide adequate assurance that the food supply is safe...."

Recommendation:

To overcome the fundamental weaknesses in the federal government's programs for monitoring chemical residues in food the Congress should, at a minimum:

> Revise the nature of the federal government's role for ensuring food safety by moving away from end-product testing to preventing the contamination from occurring. This can be accomplished by shifting the burden of ensuring food safety to the food producers and processors. Under this approach, the government would, among other things, (1) continue to approve chemicals and set tolerances; (2) oversee a mandatory, HACCP-based, industry-run food safety assurance program; and (3) assist industry in developing adequate test methods.

FDA Comment:

This reflects a misunderstanding of the Federal Food, Drug, and Cosmetic Act if this recommendation is directed toward FDA's programs, which is unclear. Since enactment in 1938, the FFDCA has placed the burden of producing a safe, non-violative product on the food producer, not the government. FDA's role is to ascertain whether or not the industry is doing its job and to take regulatory action sufficient to bring about compliance with the law and regulations when noncompliance is determined to have occurred. To this end, FDA has promulgated regulations and guidelines for use by the food producing industry, instituted a HACCP quality control system for certain foods, begun expansion of the HACCP requirements to other food commodities such as seafood, inspected food producing operations, held workshops and educational programs for food producers, taken appropriate action (which ranges from educational activities through warning letters, injunctions and seizures to criminal prosecutions when warranted by the circumstances), and sampled and analyzed products. End-product testing does not now nor was it ever intended to detect and stop all violative foods from entering commerce. It is one instrument that FDA has employed to ascertain that the industry is doing its job.

Moreover, as GAO is aware, FDA has required HACCP-type quality control for certain potentially high-risk products for many years, low-acid canned foods and infant formula being prime examples. FDA is also seeking public comment on the feasibility and desirability of requiring HACCP-type manufacturing controls for all foods. The report should acknowledge FDA's leadership in this arena.

See comment 3.

2

Recommendation

In addition, we believe that the Congress should consider the feasibility of requiring that all food eligible for import to the United States--not just meat and poultry--be produced under equivalent food safety systems.

FDA Comment

While this is a recommendation to the Congress that does not require FDA comment or concurrence, we would like to point out that it would be virtually impossible to impose on other countries. Field-grown crops such as fruits and vegetables present totally different challenges from slaughter operations, which generally are done at a central location that can be continuously inspected. Neither the U.S. nor any other country is likely to have the resources to monitor food production in the way that a slaughter operation can be monitored. Furthermore, the Congress has not imposed such a system upon the domestic producers. Insofar as FDA's requirements are concerned, imported products are required to meet the same safety standards that are required of domestic products.

See comment 4.

Technical Comments

In addition to the above, FDA has the following technical comments:

1. Overall: The report commingles all substances under the general word, "chemicals." This needs to be corrected. It is confusing and often worded incorrectly with respect to at least some of the specific residues that may occur, i.e., pesticides, environmental contaminants, animal drugs, industrial chemicals, etc. All are treated differently by the specific statutes and therefore, must be treated differently by the agencies.

See comment 2.

2. Page 2, line 8: Change to read, "...for and used in various aspects of food production."

See comment 5.

3. Page 2, line 9 and throughout the report: Technically, the term "residues" refers to residual chemicals present after intentional application, e.g., pesticides and drugs. Environmental contaminants are not "residues", but should be called "food borne chemical contaminants." This is more than a technicality. The residues and chemical contaminants are specifically treated differently under the statutes in recognition that some are preventable and others are not. This very important distinction is lost throughout the report.

See comment 6.

3

See comment 6.

Now on p. 2.
See comment 7.

Now on p. 2.
See comment 8.

See comment 9.

Now on p. 3.
See comment 10.

See comment 10.

Now on p. 4.

See comment 11.

Now on p. 4.
See comment 12.

4. Page 2, line 25: Change to read, "...considered illegal only..."

5. Page 3, line 34: The Environmental Protection Agency does not monitor foods for "residues" of any kind. Please delete them from the list.

6. Page 3, line 36: The statement as written is true for drugs, pesticides, and food additives. It is not true for environmental contaminants or industrial chemicals.

7. Page 3, lines 49 through 53: If we correctly read the intent of this statement, it is speculative and not substantiated by the rest of the report. Is there documentation to support this contention? If so, it should be cited in the report. Another reading of the sentence could be that the existence of risks from chemicals in food is questionable? is this the intended meaning? Perhaps the appropriate term is "unacceptable risk".

8. Page 4, lines 88-92: It should be noted that some, if not most, of the industrial chemicals have a very small (even vanishingly small) potential for entering the food supply.

9. Page 4, lines 97-98: No system will ever be able to guarantee that it can "...detect and prevent all contaminated food products from entering the food supply..." It should be noted that the food producers have the primary responsibility for producing safe food. The Federal programs act as checks to determine whether the producers are meeting their obligations and to impose corrective action when necessary.

10. Page 5, lines 108-110: The report should acknowledge that FDA has led the effort to institute the HACCP program in food-producing operations. Some such programs have been in place for quite some time, and others are being initiated, e.g., seafood HACCP and possibly all food products.

11. Page 5, lines 130-131: Item (2) is not true with respect to FDA's pesticide residue monitoring program. The statement should be qualified to indicate specifically which import programs are being indicted.

12. Page 10, second paragraph: This paragraph needs to be re-written. As we state above, pesticides, animal drugs, and food additives, by definition in the governing statutes, are not correctly categorized as chemical contaminants. Only chemicals that are not intentionally added to foods are called "chemical contaminants." Over tolerance residues of pesticides or animal drugs are technically called as "illegal" or "non-permitted." The second sentence of the

paragraph is not correct. As indicated above, not all chemicals are required to have established tolerances. This sentence should be changed to read, "...on raw or processed foods, or if no tolerance has been established (for a variety of reasons.)"

The fourth sentence is also incorrect. Occasional occurrences of above-tolerance levels do not necessarily present serious health hazards to consumers. Safety factors are usually built into tolerances to provide a cushion of safety even when the tolerance is exceeded.

See comment 13.

13. Page 11, second paragraph, second sentence: Delete. This sentence makes a comparison that is unnecessary and is misleading.

See comment 14.

14. Page 11, last paragraph, second sentence: Of the three chemicals listed, only selenium is an essential nutrient at any level. The other two should be deleted from this discussion. Furthermore, with some exceptions (notably, methyl mercury), chemicals usually are diluted, not concentrated in the environment. Finally, these substances do not become highly toxic. They are already highly toxic.

See comment 14.

15. Page 12, main paragraph, third sentence: This is not correct for environmental contaminants such as lead, mercury, aflatoxins and others. These substances are not approved for use in food.

See comment 15.

16. Page 12, main paragraph, fourth sentence: Change to read, "...food supply for the presence of illegal residues and contaminants..."

See comment 15.

17. Page 14, page 17,and elsewhere: FDA has responsibility for shell eggs. USDA has responsibility for egg products. This needs to be clarified in the chart on page 14 and in the text where references are made to the responsibilities of the respective agencies.

Now on pp. 13 and 15.

18. Page 16, second full paragraph, first sentence: Add, "(4) monitors a wide variety of food for contaminants."

See comment 16.

19. Page 16, second full paragraph, third and fourth sentences: Change to read, "FDA is responsible for developing and overseeing the regulation and enforcement of the food safety, quality, and labeling requirements of the FFDCA. Relevant FDA activities include developing analytical methods for measuring residues in foods, determining the incidence and level of occurrence of pesticides and chemical contaminants in food, carrying out field-monitoring programs

Now on p. 15.

See comment 17.

Now on p. 15.

5

See comment 18.

See comment 19.

Now on p. 20.

See comment 20.

Now on p. 25.
See comment 21.

Now on p. 25.

See comment 22.

Now on p. 26.

for selected contaminants, and taking regulatory action as appropriate."

20. Page 18, second full paragraph, fourth sentence: This is incorrect. NASS does not monitor residues. AMS analyzes food for pesticide residues for the purpose of providing such information to EPA, not to monitor residues in the food supply.

21. Page 23, Objective, Scope, and Methodology paragraph: The report does not substantiate the sweeping statement that there is widespread recognition that the federal system for monitoring residues in food have been unable to provide adequate assurance that the food supply is safe. The statement begs the question of what would be adequate assurance. As GAO has been told, FDA's pesticide monitoring program clearly shows that there are very few incidences of illegal pesticide residues in the food tested by the agency. Furthermore, contrary to the often asserted position that all pesticides pose equal risks to the consumer, FDA's program is directed toward the pesticides that are most likely to result in residues. Scientists familiar with pesticide chemistry are well aware that, for many different reasons, not all pesticides will produce a residue when applied to food. As was mentioned early in the draft report, there are other, potentially more serious threats to the food supply than chemical residues. By perpetuating the unfounded concerns that have lead to the current regulatory imbalance among the various potential food safety issues, this report will only help to further skew resource allocations toward "perceived" problems rather than real ones.

22. Page 29, second full paragraph, fifth sentence: Delete. This is outdated information. FDA has not said that the PDP duplicates FDA's efforts for quite some time.

23. Page 30, top, partial paragraph: FDA did not implement sampling and testing under the pilot effort "...without first comparing its surveillance residue data with the PDP residue data..." We suggest that the evaluators contact FDA for further input to this discussion.

24. Page 30, Inadequate Federal Data Management Practices Further Limit Data's Usefulness: This paragraph is not correct with respect to FDA's pesticide data management. The Pesticide Monitoring Improvements Act directed FDA to provide data to the Congress and others. This has required the agency to develop a data management system to facilitate meeting the requirements of the Act. FDA has invested its time and resources heavily toward meeting this need and can now provide all data users with appropriate information. We

6

See comment 23.

suggest further discussions between FDA and the evaluators with respect to this section of the draft report to assure that it is current.

Now on p. 28.
See comment 24.

25. Page 33, first paragraph, third sentence: Proposed pesticide legislation addresses this problem.

Now on p. 28.

26. Page 33, first paragraph, last sentence: The meaning of this sentence is unclear. The FFDCA authorizes FDA to regulate environmental contaminants of food, and we have taken steps to do so. The law does provide a very specific standard and FDA adheres to that standard in regulating environmental contaminants.

See comment 25.

Now on p. 28.

27. Page 33, second paragraph: The report should include examples of "at least one agency , operating under one act, considers allowable, but which another agency, operating under different legislation, may not consider allowable." The third sentence of this paragraph does not seem to be connected to the first part of the paragraph and should be deleted.

See comment 26.

Now on p. 28.

28. Page 34, first full paragraph, last two sentences: This is incorrect. The FFDCA allows FDA to consider both benefits and risks when approving an animal drug, but economic considerations are not permitted. Furthermore, EPA sets tolerances for pesticides; FDA enforces the tolerances. With respect to industrial and environmental contaminants, the FFDCA does permit "unavoidable" levels in food so long as they are not unsafe. We suggest that the evaluators contact FDA for a more in-depth discussion of the issue. We also suggest that concrete examples of GAO's hypothesis be provided, if there are any.

See comment 27.

Now on p. 29.

29. Page 35, first full paragraph, last sentence: The report should recognize that there are legitimate differences and concerns between the two agencies that make it not only desirable, but necessary that both agencies address the issues of contamination of fish. The report dismisses these legitimate differences much too readily.

See comment 28.

Now on p. 30.

30. Page 35, second full paragraph and last, partial paragraph: The legislation now before Congress addresses these points. It should be noted that much of this page and the following few pages merely reiterate previously-known information that is currently being addressed by the agencies and by the Congress. This should be stated in the report.

See comment 29.

Now on p. 34.

31. Page 42, first full paragraph: This draft, along with much of the previous work done by GAO with respect to drug residues, fails to acknowledge the legitimate and compelling concerns about the humane treatment of sick animals that

See comment 30.

Now on p. 35.

See comment 31.

Now on p. 36.
See comment 32.

Now on p. 37.

often require treatment when no drug has been approved for use with the particular species or disease. FDA recognizes this need and has provided for it through the extra-label use policy. It should further be noted that animal drug manufacturers often do not have a viable commercial interest in pursuing approval of a new drug for use in a minor species because sales would not be sufficient for the drug sponsor to recoup its investment, let alone make a profit.

32. Page 43, first full paragraph: This paragraph needs to be significantly revised. The first sentence should be changed to read, "Although FDA ranks some environmental contaminants, such as lead and mercury, as being of significant safety concern, at least as important as pesticides residues,..." The second sentence is incorrect as written. FDA officials told GAO that nobody "sponsors" data requirements for environmental contaminants, meaning that no firm is required to submit data to the agency to support a product marketing application. The agency must gather data for itself, a costly and time-consuming activity, particularly if FDA were required to gather such data for all possible chemicals. While it is true that the FFDCA does not specifically state that FDA is required to set tolerances for environmental contaminants, FDA has done so when it is in the best interest of consumers. An example is the tolerance for polychlorinated biphenyls in fish. It is more difficult to establish tolerances for the environmental contaminants because there are no commercial sponsors seeking approval of a product labelled "environmental contaminant".

33. Page 43, second paragraph, first sentence. Delete, "and lead."

34. Page 45, first paragraph, second sentence: Delete. This sentence is based upon an unfounded conclusion that the federal efforts to test the food supply for unsafe residues are not working. From all the evidence we have, the system employed by FDA is, indeed, effective. The incidences of illegal residues of pesticides and of animal drugs are declining. The agency has worked extensively with food producers, processors, veterinarians, and state and local governments to educate them with respect to their responsibilities and how to produce a compliant product. We have also worked extensively with foreign governments, both to train their producers and regulators, and to acquire information about pesticides and animal drugs used in other countries. An appraisal of the results would clearly show that these efforts have been successful. As an example, the Agency issues annual reports that describe the results of FDA's pesticide programs. These results clearly show that the incidence of illegal "unsafe" pesticide residues is

8

See comment 33.

Now on p. 37.
See comment 34.

Now on p. 37.

See comment 35.

Now on p. 37.
See comment 36.

Now on p. 38.

See comment 37.

Now on p. 40.

See comment 38.

Now on page 40.
See comment 38.

extremely low. Furthermore, dietary exposures to pesticide residues, which is perhaps the more important issue, are significantly below safety standards set by EPA and the World Health Organization.

35. Page 45, last paragraph, first sentence: Add at the end, "at the retail level."

36. Page 46: An over-all comment on this page is required. The report juxtaposes two entirely different activities in such a way as to be misleading. We understand that the two agencies keep statistics in different ways, which in fairness, would require that they not be presented together as though they are comparable. However, comparable data are available. As previous GAO reports have noted, FDA's pesticide testing program employs multiresidue methods which, on average, recover between 150 and 200 pesticides per test. Calculating conservatively, (12,000 samples times 150 tests) FDA runs approximately 2 million tests per year. FDA will be happy to discuss this further with the evaluators.

37. Page 46, first paragraph, second sentence: Change to read, "...food through (1) surveillance monitoring--used when there is no reason to suspect a problem, and (2) compliance monitoring--used for commodities where..."

38. Page 46, last paragraph: The first sentence is incorrect with respect to pesticides. For the past several years, FDA has purchased world-wide pesticide usage data in addition to conducting other intelligence-gathering activities. The statement in this report possibly would have been true a decade ago, but is no longer true. It should be noted that the statements on page 46 also contradict those on page 47, where the report acknowledges that usage data is currently available to the agency.

39. Page 49, second paragraph: Change to read, "...While pesticide/drug registrants/sponsors must provide an analytical method for their compound, these methods are single-residue methods which are impractical for surveillance or routine use by the federal agencies. Generally, the federal agencies use multiresidue methods which can detect several substances with one test and are thus more cost effective than single residue methods. Federal agencies must develop the multiresidue methods because the sponsors cannot be required to do so. However, the agencies are constrained in their multiresidue test development..."

40. Page 49, last paragraph, third sentence: Delete, "...because some of the tests detect the same pesticides."

9

Now on p. 41.
See comment 39.

Now on p. 41.
See comment 40.

Now on p. 41.
See comment 41.

Now on p. 42.
See comment 42.

Now on p. 45.

See comment 43.

Now on p. 45.
See comment 44.

Now on p. 49.
See comment 45.

Now on p. 51.
See comment 46.

Now on p. 51.
See comment 46.

Now on p. 52.
See comment 47.

41. Page 50, last paragraph: It should be noted that the agencies are currently coordinating their efforts to develop test methods for pesticides.

42. Page 51, first paragraph: Change the third sentence to read, "Newer pesticides are comprised of more chemically diverse compounds which are not as amenable to multiresidue methods as are older pesticides. They also degrade more quickly, which results in less residue in food."

43. Page 51, second paragraph, last sentence: For pesticides, FDA acknowledges that there may be low levels of residues in the food, but the risks are low or non-existent.

44. Page 51, last paragraph, last full sentence: This sentence should reflect that FDA's surveillance testing is largely random, while compliance testing is targeted.

45. Page 56, first full paragraph, second sentence: This sentence implies that the government has had the primary responsibility for ensuring that food is safe. This is incorrect. The producer has always had the responsibility for ensuring a safe product. The day-to-day testing has always been the producer's responsibility for foods other than meat and poultry. The HACCP program formalizes this understanding and requires that the producers have in place a quality control program that will help to ensure that safety is built into their products throughout the manufacturing process. This avoids relying on the "end-product" testing that this draft report faults. FDA does not delegate its responsibilities to the regulated industry.

46. Page 57, first line: insert the word, "industry" before the word records.

47. Page 61, first paragraph, fifth sentence: FDA does test imported foods for pesticides used in the exporting country that are not approved for use in the U.S.

48. Page 64, first paragraph: This information, which apparently was taken from a GAO report issued 15 years ago, is outdated. As we have stated elsewhere, we do have information about the pesticides used in foreign countries and we do direct testing to those commodity/chemicals of greatest concern. We have done this for quite some time.

49. Page 64, last paragraph, third sentence: Change to read, "FDA contacted 37 high-volume..."

50. Page 65, second line: Insert after "for" the words, ", was of questionable accuracy..."

10

Now on p. 54.

51. Page 67, Inadequate Authority Impedes FDA's Enforcement Efforts Against Violative Food Imports, first paragraph: The first sentence reaches questionable conclusions without foundation. Imported products regulated by FDA probably are no more likely to be contaminated than those regulated by USDA. FDA tests for far more chemicals than does USDA, and is therefore more likely to detect an illegal residue. The second sentence is in error. FDA's deterrent authorities for imported products is sufficient to keep contaminated products from entering the country. FDA has complete authority to detain products offered for import, deny entry, or require reconditioning prior to entry. However, the resources the agency has to devote to imported food are limited, as are resources for domestically produced foods.

See comment 48.

Now on p. 65.

52. Page 80, last column: Delete this column. The PDP is not intended to determine whether samples are violative and should not be linked with such a determination. Until a product has been determined by FDA to be violative, it is not so considered.

See comment 49.

There are numerous other statements in the report that should also be clarified, deleted, or modified to be more accurate. FDA will be happy to provide further assistance to GAO regarding these points.

The following are GAO's comments on the Food and Drug Administration's letter dated August 5, 1994.

GAO Comments

1. We disagree with the agency's statement that the information contained in the report is outdated and does not support the conclusions and recommendations. Although findings from over 90 GAO and other investigations conducted over the past 20 years provide the basis for much of this report, the issues highlighted in this report were largely compiled from reports issued in the last 4 years. Every effort was made to update the data and use only the most current program-specific information available from the agencies—for either fiscal year 1992 or 1993. In its written comments, FDA did not provide us with any concrete examples of where we had used only outdated information to support the conclusions of this report. We also disagree with FDA's comment that the report does not reflect the progress made by regulatory agencies. Throughout the report, we have provided relevant examples of actions taken by federal agencies to improve their programs.

Furthermore, while we recognize that all chemicals do not pose the same level of risk, the intent of this report was not to address chemical-specific issues or comment on the overall safety of the food supply. It was also not the purpose of this report to "indict" all federal programs, as FDA asserts. Instead, the objectives of this review were to identify specific structural and systemic weaknesses that hamper the effectiveness of the current federal food monitoring system. Many of these weaknesses have persisted for over 2 decades, despite the agencies' efforts to take corrective actions. The persistence of these problems, as we point out in the report, is indicative of fundamental weaknesses in the legal and regulatory framework, which can only be overcome by congressional actions.

2. We have modified the report, as appropriate, to clarify the differences between chemical residues and environmental contaminants.

3. GAO does not misunderstand the provisions of the FFDCA, as FDA asserts. While we agree that the FFDCA places responsibility for food safety on the industry, the law does not include requirements for a HACCP-based monitoring system, as we have recommended to the Congress. We believe that the Congress should amend the laws, including the FFDCA, FMIA, and PPIA, to implement such a requirement.

Moreover, while we agree that FDA has been a key federal player in the implementation of federal HACCP-based programs, we disagree with FDA's assertion that it has been a leader in this area. We believe that the food industry itself has taken the lead in developing and implementing HACCP-based programs. A 20-year gap has occurred between FDA's first implementation of a HACCP-based program for low-acid canned foods and the 1994 proposal for a HACCP seafood program. However, in the interim many sectors of the food industry have developed and implemented HACCP-based systems as part of their food production processes, without any mandatory requirements by the federal government or FDA. Moreover, FDA's statement that it requires a HACCP-based program for infant formula is incorrect. According to an official in FDA's Division of Programs and Enforcement Policy, Office of Special Nutritionals, the current infant formula regulations are not HACCP-based. No change was made to the report on the basis of FDA's comments on this issue.

4. We disagree with FDA's comment that it is "virtually impossible" to require that all imported foods, not just meat and poultry, be produced under equivalent food safety systems. Because we recognize the differences in monitoring imported fruits and vegetables versus meat and poultry, we have not suggested that the solutions to ensure their safety must be identical, as FDA states. Rather, we believe that given the unique problems of these types of foods, other solutions are possible. For example, if FDA is seeking HACCP-based systems for all domestic foods, as stated in its comments on this report, then FDA will also have to require that imported products be produced under HACCP-based systems. By implementing this requirement, FDA is, in effect, ensuring that imported foods are being produced under equivalent food safety systems. Otherwise, imported products will not meet U.S. food safety standards.

5. We have modified the report to reflect FDA's comment.

6. We have modified the report to clarify this difference.

7. We disagree with FDA's comment that EPA is not a primary federal agency responsible for monitoring chemicals in food. For this report, we have defined the term "monitoring" in a much broader sense than FDA has interpreted it; we include as part of this definition all activities conducted by federal agencies to approve chemicals for use in food; test food products for the presence of illegal chemicals; enforce compliance with U.S. standards; and perform research and development. In this context, EPA is a primary federal agency responsible for monitoring chemicals in

food because, among other things, it ensures that only safe pesticides are approved for and used on food and sets water quality standards that affect drinking water and fish.

8. Changes made to the report under comment 6 should clarify this statement.

9. We have modified the report to reflect FDA's comment.

10. We have modified the report to reflect FDA's comment.

11. See comment 3. We made no changes to the report on the basis of FDA's comment on this issue.

12. This statement is a generalization of the facts reported in chapter 5 of the report. The first part of the statement is valid for all import programs, and we have qualified the second part of the sentence because it applies only to some import programs.

13. See comment 6. We have also modified the report to include FDA's other comments.

14. We have modified the report to reflect FDA's comment.

15. We have modified the report to reflect FDA's comment.

16. We have modified the report to reflect FDA's comment.

17. We have not changed the report because these facts are already stated in chapter 1.

18. We have modified the report to reflect FDA's comment.

19. We disagree with FDA's statement that NASS and AMS do not have a role in monitoring the food supply for illegal residues. As we have explained in the report and in comment 7, our definition of monitoring also includes the activities conducted by NASS and AMS. In this context, NASS' pesticide usage data collection activities and AMS' pesticide residue data collection and testing of egg products for chemicals are relevant federal monitoring activities. We have made no change to the report on the basis of FDA's comment on this issue.

20. We disagree with FDA's comment that our statement on the widespread recognition of problems with the current system is unsubstantiated. As we point out in this report, GAO and other organizations have been reporting for over 20 years on numerous program-specific problems that continue to limit the effectiveness of the current system. We also disagree with FDA's comment that this report perpetuates "unfounded" concerns and will lead to further regulatory imbalances and skewed resource allocation toward perceived rather than real problems. As we have stated in this report and in past reports, the imbalances in the current regulatory system are primarily the result of the fragmented legal structure. This fragmentation has resulted in the division of responsibility among multiple federal agencies, which in turn has resulted in both gaps and duplication in federal food safety monitoring activities. Furthermore, in this report as in past reports, we continue to emphasize the need for a uniform food safety system that is risk-based and under which resources are allocated according to the greatest risk. No changes were made to the report on the basis of FDA's comments on this issue.

21. We disagree with FDA's new position that there is no duplication between USDA's PDP and FDA's residue programs. Since no changes have occurred in either agency's program, we do not believe that the duplication has been eliminated. We have modified the report to reflect this comment.

22. We have made no change to the report on the basis of FDA's comment because, during our review, FDA could not provide us with any evidence that the pilot program was started after the agency had first compared the results of USDA's statistically based data program with FDA's nonstatistical sampling program. Any comparisons that were made after the pilot program was implemented do not change this fact.

23. We disagree with FDA's comment that the section on Inadequate Data Management Practices is incorrect. This section does not discuss FDA's pesticide data management system, as asserted by the agency. Instead, it reviews deficiencies in other specifically mentioned data bases. The requirements of the Pesticide Monitoring Improvements Act and FDA's fulfillment of these requirements are also discussed in detail in chapter 5 of this report. No change was made to the report on the basis of FDA's comment.

24. We recognize that the proposed legislation addresses this concern and have referred to it, where appropriate, throughout chapter 3. No change was made to the report on the basis of FDA's comment.

25. We disagree with FDA's comment that the FFDCA provides a specific standard to regulate environmental contaminants. As stated in the report, although FDA may set tolerance levels for environmental contaminants under the food safety provisions of the FFDCA, it is not required to do so and, as a result, has established few tolerances for these chemicals. We have modified the report to clarify this issue.

26. We have made no changes to the report in response to FDA's comment because this paragraph in the report is an introductory paragraph. Greater detail and the examples suggested by FDA are included in the relevant sections following the introductory paragraph.

27. We have modified the report to reflect FDA's comment.

28. We have made no changes to the report in response to FDA's comment because we believe that we have adequately identified the differences in EPA's and FDA's legislative responsibilities in both chapters 1 and 3. Furthermore, the purpose of this paragraph in the report is to highlight the duplication between two agencies providing similar kinds of information to the states. We recognize that both agencies have different responsibilities for ensuring the safety of fish, but we do not believe that these differences justify the lack of a unified effort when the agencies are providing information to the states.

29. We agree that this section of the report is a reiteration of GAO's past positions on the issue, and we discuss the proposed legislation at the end of this section, as it applies to these concerns. However, until action is taken by the Congress on the proposed legislation or any other bill that addresses these concerns, we believe that these issues will continue to be relevant. No change was made to the report on the basis of FDA's comment.

30. We disagree with FDA that this report and past reports have not acknowledged that the intent of the extra-label drug use policy is to provide for the emergency and rare use of unapproved animal drugs to treat sick animals. Past GAO reports, and this one in chapter 4, have all recognized the need for an extra-label drug use policy. However, our concern has been and continues to be with FDA's inability to prevent the

widespread misuse of this policy by both veterinarians and farmers. No changes were made to the report on the basis of FDA's comment.

31. We recognize the problems that FDA faces in collecting the data needed to support the establishment of tolerances for environmental contaminants and have modified the report to include these concerns. However, the purpose of this section of the report is to identify how the lack of a specific legal requirement to set tolerances for environmental contaminants has resulted in few tolerances for these contaminants and that agencies generally respond to such hazards only in life-threatening situations.

32. We have modified the report to reflect FDA's comment.

33. We disagree with FDA's comment that our conclusion about the inability of federal agencies to test the food supply for unsafe residues is unfounded. Chapter 4 of this report summarizes significant deficiencies that continue to exist in the various government programs in place to ensure that the food supply complies with federal standards. We believe that as long as the federal government continues to rely primarily on end-product testing as the means of enforcing compliance with federal standards, federal enforcement activities will continue to be inadequate and inefficient. While it is true that FDA's testing results show a low level of illegal residue violations for pesticides, these results may not represent the true incidence of residues in the total food supply because they are not statistically valid. Moreover, we do not believe that low violation rates should justify the continuation of the existing monitoring system that catches problems at the end of the production process. To better ensure the safety of the food supply, federal agencies should move toward HACCP-based approaches that emphasize building safety into the whole production process. No changes were made to the report on the basis of FDA's comment.

34. We have modified the report to reflect FDA's comment.

35. We disagree with FDA's comment that the report unfairly compares FDA's and USDA's statistics. We have presented the facts in the same manner that the agencies report the results of their testing programs to the Congress and the public. In addition, the report notes that these results are not comparable. We believe that FDA's attempt to estimate a comparable number of pesticide analyses conducted every year is misleading as well as inaccurate. According to data provided to us by FDA, the six

multi-residue methods that are used by the agency's pesticide residue program individually can detect 13, 19, 24, 102, 128, and 258 pesticides, respectively. Without identifying how many of the 12,000 samples were tested by each of these methods, it is not possible to estimate the number of comparable pesticide analyses that FDA performed. As we have reported in the past, most samples are not tested for pesticides using all six multi-residue methods. Moreover, about 8 percent of FDA's samples are tested using single-residue or selective multi-residue methods, which are capable of detecting only one or a few selected compounds. No changes were made to the report on the basis of FDA's comment.

36. We have modified the report to reflect FDA's comment.

37. We have not made any changes to the report in response to FDA's comment because the focus of this section is on domestic pesticide usage data. A discussion of FDA's import pesticide usage data is included in chapter 5 of the report.

38. We have modified the report to reflect FDA's comment.

39. We have made no change to the report on the basis of this comment because we do not believe that the level of coordination that currently exists addresses the concerns that we have highlighted in the report. Although the officials that we spoke to were aware of test method development activities ongoing in other agencies, we found no evidence to suggest that they were cooperating in a manner that would result in the more efficient use of resources and improve the federal government's test method development efforts.

40. We have modified the report to reflect FDA's comment.

41. We have made no change to the report on the basis of FDA's comment because this discussion focuses on the lack of statistically valid data and on the limitations in using these data to project the general safety of the food supply.

42. We have included this information in the report.

43. We have modified the report to reflect FDA's comment.

44. We have modified the report to reflect FDA's comment.

45. We have not modified the report on the basis of FDA's comment because we believe that we have adequately qualified our statement. The report states that some import programs do not test for chemicals used in foreign countries, and we have provided details on the programs we are referring to.

46. We have modified the report on the basis of FDA's comment. However, while the report recognizes that FDA has multiple sources of information on foreign pesticide use, we also note that a 1993 report from the Keystone Center, a nonprofit organization, specifically states that these data sources have not been of much value to FDA in targeting its import pesticide testing and recommends that the agency pursue alternative sources of information.

47. We have modified the report to reflect FDA's comment.

48. We disagree with FDA's comment that our conclusion about FDA's inability to take adequate enforcement action against violative imports is unfounded. We have recognized in this report and in past reports that FDA needs not only additional resources to inspect and test imports, but also greater enforcement authorities. While we agree that FDA's detention authority is a very powerful enforcement tool, it alone is not adequate, because FDA must still rely on the Customs Service to ensure that enforcement actions have been taken against violative imports. As we have reported in the past, enforcement often does not happen for a variety of reasons, including poor coordination and differing priorities between the agencies. Moreover, while FDA may test for a greater number of chemicals than USDA, this testing is FDA's primary assurance that imported foods meet U.S. standards. USDA, on the other hand, relies on testing products at the port of entry only as a secondary control, because it has other mechanisms in place in the country of origin to ensure the safety of imported meat and poultry.

49. No changes were made to the report on the basis of FDA's comment. The data that we have provided in appendix II appear as they were reported by USDA. Under the USDA program, a violation occurs when a residue is found that exceeds the tolerance levels set by EPA, or when a residue is found for which there is no tolerance for a particular crop. We believe that this is consistent with the requirements of the FFDCA. FDA's comment on the USDA's role under the PDP and FDA's role in determining whether a product is violative or not, raises questions about duplication and lack of cooperation and coordination between federal agencies. We

believe that FDA's comment provides another example of the unnecessary problems that exist and the confusion that arises from the fragmentation of responsibility among numerous agencies under the current system.

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

August 29, 1994

Mr. John W. Harman
Director, Food and Agriculture Issues
Resources, Community, and Economic
Development Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Harman:

Thank you for the opportunity to comment on your draft report RCED-94-192, FOOD SAFETY: Changes Needed to Minimize Unsafe Chemical Residues. We have enclosed detailed suggestions for clarifying or correcting portions of the report.

With regard to your observations concerning the number of agencies involved in the existing residue program, USDA will continue to take advantage of every opportunity to work with other agencies to ensure a coordinated Federal approach to assessing risk and taking actions on residue violations.

We look forward to GAO's final conclusions and recommendations that can improve the consistency of methodology and legal and regulatory approaches.

Sincerely,

Patricia Jensen
Acting Assistant Secretary
Marketing and Inspection Services

Enclosures

Now on p. 3.

See comment 1.

Now on p. 4.

See comment 2.

See comment 3.

Now on p. 10.

See comment 4.

Now on p. 15.

See comment 5.

Now on p. 16.
See comment 6.

Now on p. 25.

**Comments on GAO's Draft Report
"FOOD SAFETY: Changes Needed to Minimize Unsafe Chemical Residues" (RCED-94-192)**

Page 4, Line 88, after "compounds." - add the following:

Also, limits of detection for various chemicals differ among agencies based upon sophistication of methods and testing equipment, and improved methodology results in lower limits of detection. A further concern is the error due to sampling, which in many cases may exceed the error in chemical analysis.

Page 5, Line 131, after "concern." - add the following:

In addition, the short shelf life of perishable and semi-perishable foods precludes testing before consumption of the products.

Page 10, Paragraph 1, Line 10 after "concern." - add the following:

Many consumers are also under the impression that the entire commercial food supply is tested by the federal government prior to appearing in the marketplace.

Page 11, Paragraph 3, Line 9, after "concern." - add the following:

Moreover, there are naturally occurring toxins in the environment such as aflatoxin caused by mold growth.

Page 17, Paragraph 3:

The report occasionally refers to AMS' responsibilities for testing eggs "Several agencies within USDA have programs that monitor chemical residues in foods--primarily meat, poultry, and eggs"). It should be clarified that AMS only tests egg products; the wholesomeness and testing of shell eggs is the Food and Drug Administration's (FDA) responsibility.

Page 18, Paragraph 2, End of Paragraph - add the following:

AMS also monitors, through Memorandums of Understanding with FDA, aflatoxin residues in peanuts, imported pistachio Brazil nuts.

Page 29:

There is no duplication of effort between the AMS and FDA pesticide residue testing programs as stated by FDA to GAO. FDA, at the Pesticide Data Program (PDP) meeting of the Executive Steering Committee on February 1, 1994, attempted to emphasize the differences in mission and objectives of both programs.

The linking or merging of these programs as may be suggested by FDA, after PDP has been established and is now fully operational, would not result in any efficiencies.

PDP is a federally sponsored state-operated program, where 85 percent of the appropriation is directly allocated to the states. The sampling program, pesticide detection requirements, reporting criteria, and data quality specifications are designed specifically for dietary risk assessment in the reregistration and special review of pesticides. The program's objective is to provide national inferences based on the data collected in the nine participating states. The standard operating procedures parallel the Environmental Protection Agency's Good Laboratory Practices Guidelines.

A document describing the significant differences between the FDA and AMS programs is enclosed.

See comment 7.

Page 46, Paragraph 2:

Now on p. 37.
See comment 8.

The NRP consists of monitoring, surveillance, exploratory, and individual enforcement testing programs.

Page 48, Paragraph 3:

Now on p. 39.

The "list of 367 potential compounds" is a compendium based on a 1979 GAO report and suggestions from consumer groups, industry, other regulatory agencies and the scientific literature. It is an historical list.

There is overemphasis on the significance of the 367 compounds in this list. The list is compounds that have been considered. There is tremendous duplication throughout the list of the same compounds but in different formulations. An example of this is arsenic. At least seven different formulations of arsenic exist in the list.

Multi-residue tests which are currently in use by FSIS will pick up many of the compounds in the list that are not ranked. Since FSIS can already detect the presence of these compounds, the Agency does not want to waste resources to rank them. For example, we have a multi-residue test that will determine the presence of members of the beta lactam family. Amoxicillin and cloxacillin are members of this family that are on the list and not ranked.

Some of the compounds on the list such as follicle stimulating hormone are naturally synthesized in the body of animals and humans. They are also formulated by companies to treat different conditions in animals. It is impossible to develop a test to differentiate between naturally occurring and the administered types. It would not be worthwhile to rank these compounds.

Some of the compounds on the list which were of concern at the time the list was developed are now not of concern because of various reasons. For example many of the compounds in the list we now know will not cause residues in animals consequently we do not waste time ranking them. An example of this is most non-chlorinated organophosphates such as malathion. We feel that we have ranked and tested for most of the compounds on this list which are of public health concern. The compounds of public health interest will vary from year to year depending on current scientific information.

It is unreasonable to test for everything which could get into meat since it would be extremely costly. Some compounds are not only unlikely to occur or, if they do occur they would be in non-toxic concentrations.

The report appears to focus too heavily on the relationship between the availability of a multi-residue method (MRM) and whether a low ranking compound is in the NRP. Since MRM's are usually based on some important common chemical feature, the existence of an MRM permits the NRP to include additional (and lower CES-ranked) compounds in monitoring or surveillance programs. That is, information on these additional compounds is obtained at virtually no additional cost because they are isolated and detected by the same method as is used for a compound with a high CES ranking.

"FSIS' criteria requires that compounds with no violations for the past 3 years be rotated out of the plan" is an incorrect statement. The correct statement should be "Whenever there are no violative results after 1 to 3 years of testing, the compound is a candidate to be cycled out."

See comment 9.

Now on p. 42.

Page 51, Paragraph 2, Line 2, after "results." - add the following:

See comment 10.

In some cases insufficient sample size and improper sample preparation can contribute errors to results that far exceed the error in chemical testing.

Now on p. 42.

Page 52, Paragraph 2:

A distinction should be made between random and representative samples. Random sampling is not always the sole determining factor. The samples must also be representative of the lot.

Geographical and/or seasonal patterns in use of compound does not affect the validity of the sample design of the domestic monitoring program, given that the sample design is based on an objective of detection with a certain level of confidence, not maximizing the probability of detection.

For each slaughter class/compound pair a determination has been made as to the level of confidence desired and the level of detection desired. The sample size is based on these parameters. Usually the goal is to be at least 95 percent confident of detecting a violative residue in the sample if 1 percent or more of the species population is truly violative. These parameters will differ for some of the species/compound pairs, depending upon certain factors. For example, for some of the minor species, economic burden on the limited number of plants may be a consideration. This does affect the level of detection and/or the confidence level for such species/compound pairs. This design is intentional, so that limited resources can be placed into major areas of concern.

A design that would sample all species and compounds at the same "rate" is not necessary for the program to be statistically "valid." Indeed, such a design would not meet the current statistical objective of the domestic monitoring program.

See comment 11.

Now on p. 42.

Page 53, Paragraph 1:

The domestic monitoring sampling program is designed to do the following for each of specific species/compounds pairs: to detect (with a predetermined level of confidence) in the specific species the presence (at predetermined levels) of the specific residue. The sampling was NOT designed to provide an overall estimate of the national level of all chemical residues occurring in the meat and poultry supply. Nor was the sampling designed to provide estimates for individual species/compound pairs with specified levels of precision.

Within a slaughter class/pair, the results of the sampling may be considered as representative of that entire population for the compound in question, since the sample selection procedure is designed to approximate the selection of a simple random sample of animals.

Adjustments in the sample selection process are made for those species where it is felt that variation in slaughter due to season warrants this adjustment. The purpose of this adjustment is to equalize the probability of selection of samples over the year.

However, sample sizes are distributed evenly throughout the year for species whose seasonal production do not differ greatly. This could cause a slight bias; however, this possibility must be balanced against such concerns as stabilizing laboratory workloads and scheduling the generation and distribution of forms.

In the Domestic Residue Data Book - National Residue Program 1992 the data presented in the results section do not show rates. The

number of tests and violatives are listed by residue grouping and species/production class. Totals are shown by residue grouping, and a cumulative total section is also presented in the report. The residue and cumulative totals should be used only as an indication of work load and should not be used to derive overall violation rates. This data should not be summed over either species or residues to arrive at an "overall" violation rate.

Species violation rates across residues should not be combined even if the sample numbers were the same for species. Also, an overall violation rate (across species and residues) can not be calculated and then compared to previous years.

On Page iii of the Domestic Residue Data Book - National Residue Program 1992, FSIS does indicate an overall sample violation rate and compares it with the sample rates of the previous 2 years.

This rate is not presented as a statistical estimate of a population violation rate; however, it should be omitted, since it appears that it is being interpreted as such.

As pointed out in the GAO report, overall comparisons across years using monitoring results would not be valid for a number of reasons. Monitoring was not designed to estimate rates. It was designed to detect problems in populations. Another reason would be that the compounds, as well as species, may change from year to year.

In summary, violation rates for each slaughter class/compound pair could be calculated if sample sizes were adequate and confidence intervals were presented. This would produce statistically valid estimates of the corresponding population rates. These individual rates could be compared across species, residues or years. For example, the violation rate for sulfonamides in 1992 market hogs could be presented as 0.9 percent +/- the confidence interval for sows. However, although it is valid to make statistical comparisons using these individual rates, the sample sizes might not be sufficient to detect small differences at low prevalence levels.

The Monitoring Program is designed to identify the existence of potential residue problems in populations without expending the necessary resources to measure actual rates. For example, it makes little difference whether one or two violations are found in a slaughter class with a sample size of 300. What is critical is that the large population this sample represents would appear to have violations exceeding 1 percent.

See comment 11.

Now on p. 43.

See comment 12.

Page 53, Paragraph 2, Sentence 2:

Suggest changing "does not" to "may not." It can be one of the preventative measures, if testing is done prior to consumption of the food.

Now on p. 65.
See comment 13.

Page 80, Table II. 3:

A revised table is enclosed.

AUG 6 1993

**MAJOR DIFFERENCES BETWEEN
RESIDUE TESTING PROGRAMS OF
FOOD AND DRUG ADMINISTRATION (FDA) AND
AGRICULTURAL MARKETING SERVICE'S (AMS')
PESTICIDE DATA PROGRAM (PDP)**

o	**Mission:**	FDA's programs are oriented primarily toward regulatory enforcement of pesticide residue tolerances. PDP provides comprehensive data for use by the Environmental Protection Agency (EPA) to conduct dietary risk assessments, address pesticide reregistration issues, and complete the special review of specific pesticides.
o	**Commodities:**	FDA covers a wide range of commodities. PDP focuses on high consumption fresh fruits and vegetables.
o	**Sampling:**	FDA uses targeted, non-random sampling of products to have better opportunities to detect violations. (A recent special sampling program for tomatoes and pears was statistically based.) PDP uses statistically-based, random sampling procedures to provide objective, comprehensive residue data from which statistical inferences can be made.
o	**Sampling Locations:**	FDA collects samples of domestic product as close as possible to the point of production and collects samples of imported product at the point of entry into U.S. commerce. Emphasis is placed on imported product. PDP collects samples close to the consumer level at terminal markets and chain store distribution centers. Domestic and imported product is sampled as available in the distribution channels.
o	**Number of Samples:**	FDA's number of samples per commodity varies, and can be quite small. PDP's number of samples requested per commodity is 720 per year.

o	**Laboratory Methodology:**	FDA uses primarily traditional, multiresidue methods with some use of single residue methods for pesticides not covered by the former methods. PDP uses state-of-the-art, highly sensitive multiresidue methods, with special attention to single residue methods for specific requests of EPA. (Single residue methods are complex and very resource intensive.) Participating State laboratories use similar instrumentation, have received identical training on the methods, and adhere to common standard operating procedures.
o	**Laboratory Controls:**	FDA carries out limited laboratory quality control and quality assurance procedures. PDP has an extensive laboratory quality control and quality assurance system. Approximately 35 percent of the samples analyzed are for quality control purposes. A quarterly check sample program is carried out to determine the consistency of results among laboratories participating in the program.
o	**Confirmation of Results:**	FDA confirms all results that are violative. PDP confirms all detectable results.
o	**Good Laboratory Practices (GLPs):**	FDA does not require adherence to GLPs. PDP laboratories are in compliance with GLPs, where appropriate.
o	**On-site Reviews:**	We do not have specific information regarding FDA's review of its testing program. PDP conducts periodic on-site reviews of sampling and laboratory operations to ensure compliance with standard operating procedures.
o	**Reports of Findings:**	FDA publishes an annual overview of its residue testing results. PDP publishes detailed, comprehensive reports of its findings. (Annual report for 1991; semiannual report for first half of 1992. Annual reports will be published in the future.) All violative results are reported to FDA by participating States and AMS.

DRAFT

APPENDIX II APPENDIX II

Table II.3: Results of AMS' Statistically Based Residue Testing for Pesticides in Fruits and Vegetables, Calendar Year 1992

Commodity	Number of pesticides detected	Number of samples analyzed	Number of samples with positive residues	Number of Samples that were Violative
Apples	25	567[a]	502	4
Bananas	4	564[a]	209	5
Celery	21	508	409	~~20~~ 17
Green beans	24	466[a]	279	~~22~~ 22
Grapefruit	9	567	260	0
Grapes	21	552	381	5
Lettuce	19	565	201	~~5~~ 5
Oranges	11	569	329	0
Peaches	22	360	307	~~4~~ 4
Broccoli	7	153	54	
Carrots	10	153	88	1
Potatoes	16	568	404	0
Total	49[b]	5,592	3,423	63

~~[a]An additional 51 samples of samples were tested for benomyl/thiabendazole only.~~

[b]This represents the total number of different pesticides detected.

[a] An additional 158 samples were tested benomyl/thiabendazole only; 51 samples of apples, 51 samples of bananas, and 56 samples of green beans.

80

DRAFT

The following are GAO's comments on the U.S. Department of Agriculture's letter dated August 29, 1994.

GAO Comments

1. We agree with USDA's statement and believe that the fragmentation of responsibility among various agencies has largely contributed to these problems. However, these concerns are more relevant to our discussion in chapter 4 on the ineffectiveness of end-product testing for ensuring compliance with federal standards. No changes were made to the report on the basis of USDA's comment.

2. We agree with USDA's statement and have included this information in chapter 5, where we discuss imported products in greater detail.

3. While we agree with USDA's comment that many consumers may be under the impression that the federal government tests the entire food supply, we have not seen any research or studies that have actually shown this to be a fact. We have therefore not included this statement in the report.

4. While we agree with USDA's statement, we have not included this information in the report because naturally occurring toxins were not included within the scope of this review.

5. We have modified the report to clarify this point.

6. We have not included this information in the report because naturally occurring toxins were not part of our review.

7. Although FDA has apparently changed its position on whether USDA's Pesticide Data Program duplicates its own programs, we still question the need for two separate federal programs in the area of pesticide residue monitoring. We have modified the report to reflect these changes.

8. We have included this information in the report.

9. In our report entitled Food Safety: USDA's Role Under The National Residue Program Should Be Reevaluated (GAO/RCED-94-168, Sept. 26, 1994), we discuss in greater detail many of the issues that USDA raises in its comments. As we stated in that report, the list of 367 compounds is significant because it provides the basis for establishing priorities and allocating resources for the National Residue Program. If this list contains

duplicative and/or historical data, we believe that FSIS should quickly update it so that it can provide meaningful information for making program decisions. We have made no change to the report on the basis of USDA's comment about the relation between multi-residue tests and low-ranked compounds. This relationship is not the focus of the report. Rather, the report focuses on how the lack of adequate multi-residue methods has impeded federal efforts to detect all compounds of concern. Because of this deficiency, the current system, which relies on end-product testing, cannot adequately ensure the safety of the food supply. We have modified the report to clarify the criteria used by USDA when it makes decisions to rotate chemicals out of the plan.

10. We have made no changes to the report on the basis of USDA's comment because the purpose of this section is to discuss how the lack of statistically based data prohibits extrapolations of the incidence of chemicals to the whole food supply.

11. In our report entitled Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994), we discuss in greater detail many of the issues that USDA raises in its comments. As we stated in that report, the flaws that we found in USDA's sampling plan could result in biases that would affect the statistical validity of the sample results. Moreover, we stated that we were concerned that the manner in which FSIS was reporting information on violations implied an overall violation estimate that the sampling plan is not designed to report. As a result, no changes were made to the report on the basis of USDA's comment.

12. We disagree with USDA's suggested change to the report. End-product testing, by itself, does not prevent contamination from occurring. We agree with USDA that while end-product testing may be one of the preventive measures if done prior to consumption, by itself it cannot prevent problems. We have made no changes to the report on the basis of USDA's comment.

13. We have modified the report to reflect USDA's revised data.

Comments From the U.S. Department of Commerce/ National Oceanic and Atmospheric Administration

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

THE SECRETARY OF COMMERCE
Washington, D.C. 20230

AUG 26 1994

Mr. John W. Harman
Director, Food and Agriculture
Issues, Resources, Community,
and Economic Development Division
General Accounting Office
Washington, D.C. 20548

Dear Mr. Harman:

Enclosed is a copy of the Department of Commerce's reply to the General Accounting Office draft report: Food Safety: Changes Needed to Minimize Unsafe Chemical Residues (GAO/RCED-94-192).

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

Sincerely,

Ronald H. Brown

Enclosure

U.S. DEPARTMENT OF COMMERCE

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

COMMENTS ON DRAFT GAO REPORT ENTITLED

"Food Safety: Changes Needed to Minimize Unsafe Chemical Residues"

GAO/RCED-94-192

July 6, 1994

COMMENTS:

NOAA generally agrees with the findings and conclusions of the subject draft report. Numerous examples are cited throughout the report to support the GAO finding that federal agency efforts to improve risk assessment and oversight have not overcome five basic structural weaknesses in the food safety system. These weaknesses noted by GAO are:

-- A fragmented federal effort to identify chemicals that pose a risk to human health and that results in inconsistent assessments of chemical risks.

-- An uncoordinated legal and regulatory infrastructure that permits potentially unsafe chemicals to enter the food supply.

-- A resource-intensive and inefficient compliance monitoring system that by itself cannot detect all chemicals of concern in the food supply.

-- An enforcement system that does not adequately deter or penalize violators.

-- An import inspection system that is unable to prevent potentially hazardous residues of unapproved or banned compounds from entering the U.S. food supply.

However, NOAA does not fully agree with GAO's conclusion that the responsible federal agencies will not be able to rectify these deficiencies under the constraints of the current legal and regulatory infrastructure. NOAA believes that it is possible for federal agencies to improve their coordination and harmonize approaches to the problem of chemical contaminants in foods under the existing authorities. A framework for interagency coordination in planning and executing activities of the responsible agencies is needed.

The report is very well-prepared and clearly presented. However, use of the term "chemical residues" in the title and throughout the report is misleading in the case of environmental contaminants such as mercury. These contaminants are not residues per se, but enter the food supply through their natural occurrence in the environment, as opposed to those chemicals (pesticides and drugs) added or applied for some purpose. While this distinction is recognized in the discussion at the bottom of page 11, the text on page 10 and elsewhere continues to include environmental contaminants as "residues."

See comment 1.

NOAA also recommends the following "editorial" changes:

Now on p. 4.

P. 5, Lines 103-114 of the Executive Summary:
Why not identify the "new approach" specifically as the Hazard Analysis Critical Control Point (HACCP) system? HACCP is well-recognized, and is referred to by name in the discussion beginning on page 53.

See comment 2.
Now on p. 43.

Now on p. 18.

P. 20, under National Marine Fisheries Service:

Line 1 - Insert between "(NMFS)" and "within": "of the National Oceanic and Atmospheric Administration".

See comment 3.

Line 9 - Revise sentence to read: "NMFS also administers a Product Quality and Safety (PQS) Research Program that conducts research on issues affecting the optimum use of living marine resources."

Now on p. 36.
See comment 4.

P. 43, Line 13 - Reference is made to "heavy metals and lead." Lead is a heavy metal.

Now on p. 44.

P. 55, under Federal Government Making Slow Progress...

Line 6 - Replace the word "seafood" after "voluntary" with "fee-for-service."

See comment 5.

Line 10 - Delete ", which is" after the word "program"; otherwise, it sounds like this is NMFS' only inspection program. NMFS continues to offer other, non-HACCP-based services, which were in place before July 1992.

Now on p. 46.
See comment 6.

P. 58, Line 7 - There should be a footnoted citation of the National Academy of Sciences' seafood safety report to be consistent with the other publication references. The NAS report is included in the appended list of documents cited by GAO (page 86, sixth citation).

Now on p. 71.

RECOMMENDATION:

Enact a uniform set of food safety laws that include consistent standards for chemical contaminants in food, and provide the federal agencies with the authorities needed to effectively carry out their oversight responsibilities.

RESPONSE:

NOAA concurs that consistent standards are needed, and that federal agencies should be given the authorities needed to effectively carry out their oversight responsibilities. NOAA has taken actions to address the lack of data needed in order for regulatory agencies to set consistent standards. The National Marine Fisheries Service (NMFS) of NOAA is developing a Seafood Contaminants Risk Information System that will incorporate data on contaminants in seafood as well as consumption data. Eventually, the database could be accessed by other federal agencies for use in risk analysis and standards setting activities.

Now on pp. 23-25.

See comment 7.

Regarding the need for consumption data mentioned in the report, particularly on pages 27-29, NOAA has funded a study to develop models for collecting seafood consumption data for use in risk analysis. Two models are being developed, one for a national survey of fish consumption by the general population, and one that could be targeted to specific subpopulations, geographic regions, or species of fish. The project is scheduled for completion in August 1994. The actual conduct of consumption surveys using the models is a longer term effort that will require substantial resources.

In addition, research is currently ongoing in NMFS to determine the toxic form of chemicals in fish, so that more precise risk assessments can be made.

RECOMMENDATION:

Revise the nature of the federal government's role for ensuring food safety by moving away from end-product testing to preventing the contamination from occurring. This can be accomplished by shifting the burden of ensuring food safety to the food producers and processors. Under this approach, the government would, among other things, (1) continue to approve chemicals and set tolerances; (2) oversee a mandatory, HACCP-based, industry-run food safety assurance program; and (3) assist industry in developing adequate test methods.

RESPONSE:

NOAA concurs that end product testing is not sufficient to protect the public health, and that the Hazard Analysis Critical Control Point (HACCP) system is the most effective means of ensuring food safety with respect to all hazards, including chemical contaminants. HACCP is a preventive system of controls that has been endorsed and adopted worldwide, by groups such as the Codex Alimentarius Commission and the European Union.

The report recognizes that NOAA has had a HACCP-based voluntary inspection program in effect since July 1992. As of May 1994, 23 firms are participating in this program. Furthermore, NOAA has conducted training in HACCP principles since October 1992, resulting in the certification of 1310 individuals from various U.S. industry segments and 394 individuals from government and industry in other countries. NOAA has also supported the development by the Food and Drug Administration (FDA) of a mandatory HACCP-based program for seafood.

Regarding test method development, NOAA believes that for HACCP to be effective, industry must be equipped with the analytical tools to monitor critical control points in their operations. Through its Product Quality and Safety (PQS) Program, NOAA/NMFS conducts research to develop methods to detect contaminants in seafood products, including efforts to develop rapid tests that could be used onsite at

various stages, such as harvesting and processing. Research results are shared with the industry as part of NOAA's industry assistance responsibilities.

"RECOMMENDATION":

In addition, we believe that the Congress should consider the feasibility of requiring that all food eligible for import to the United States--not just meat and poultry--be produced under equivalent food safety systems.

RESPONSE:

This was not clearly identified as a recommendation in the report, but rather as an additional issue to be considered. NOAA concurs that this is important in ensuring not only food safety, but also a "level playing field" between domestic and imported products in the marketplace. NOAA believes that this issue should be raised to a recommendation by the GAO.

"RECOMMENDATION":

We also believe that the problems associated with the current fragmented system cannot be solved by individual agencies' efforts to respond to internal and external critics. Instead, these problems can be best addressed by a complete restructuring of the federal food safety system for chemical residues. As we have stated in other reports and testimonies, food safety would be better assured if the Congress created a single food safety agency responsible for carrying out the requirements of cohesive food safety laws.

RESPONSE:

This item was also not stated as a specific recommendation, but rather appears to be a statement of the opinion of the report's authors. NOAA does not disagree with the concept of a single food safety agency. While the report deals with the problem of chemical contamination, a single food safety agency would have responsibility for all food safety concerns, including microbial, viral, and physical contaminants as well.

The following are GAO's comments on the Department of Commerce's letter dated August 26, 1994.

GAO Comments

1. We have modified the report to address this concern and no longer use the term chemical residues to include environmental contaminants, as appropriate.

2. We have included this information in the report to reflect Commerce's comment.

3. We have modified the report to reflect Commerce's comment.

4. We have modified the report to reflect Commerce's comment.

5. We have modified the report to reflect Commerce's comment.

6. We have added this information to the report.

7. We have included this information in the report.

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