FOREWORD

Federal food safety regulation, the responsibility of several agencies, is a complex system of laws enacted over a period of almost 80 years to address specific needs. The Congress and the administration have been considering amendments to food safety statutes, but because the U.S. food supply is changing from staple foods to highly processed foods and real Federal dollars going to food safety programs are declining, the ability of food regulation programs to efficiently and effectively protect the U.S. public may be diminished in the future.

We made this study to assist policymakers in analyzing the need for food regulation changes by synthesizing material from past studies by congressional committees, a presidential project, congressional agencies, other study groups, and GAO, published between 1972 and 1981. In addition, we performed work at the Food Safety and Inspection Service, U.S. Department of Agriculture; the Food and Drug Administration, U.S. Department of Health and Human Services; and the Environmental Protection Agency to determine if these agencies had acted on past recommendations. The study provides an overview of food safety regulation problems identified by GAO and other groups and catalogs major Federal food safety programs and their costs. It discusses past recommendations for statutory, organizational, and administrative changes by GAO and others and what, if any, changes resulted. Issues that remain to be addressed are also presented.

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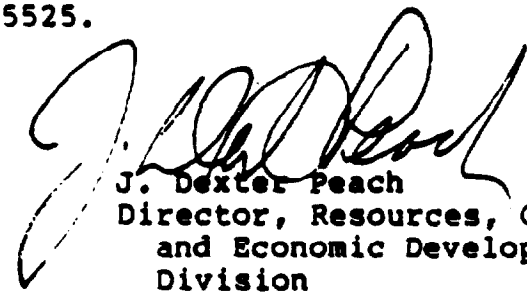

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STUDY BY THE STAFF OF THE
U.S. GENERAL ACCOUNTING OFFICE

MONITORING AND ENFORCING FOOD SAFETY--AN OVERVIEW OF PAST STUDIES

D I G E S T

Studies of food safety regulation by GAO and others published between 1972 and 1981 found that improvements could be made both in authorizing legislation and in program administration. Responsible Federal agencies have made some improvements, but issues remain to be addressed if Federal programs are to keep pace with the changing nature of the U.S. food supply and declining real Federal dollars going to food safety programs.

U.S. consumers rely on an array of federally administered programs to assure the safety of a food supply that increasingly consists of complex factory-produced foods. Although immediate deaths or illnesses directly related to consuming adulterated food are rare, long-term cumulative effects of food contamination--by toxic chemicals, for example--on health are unknown. While it is generally believed that Federal food regulation provides adequate public protection, past studies showed the Federal regulatory process is not working as well as it could.

GAO conducted this study to bring together the views of past studies by groups outside GAO about needed food safety statutory and organizational changes (see ch. 2), as well as to provide an overview of past GAO reports on food safety program administration and to update the status of agencies' program improvements (see ch. 3). The study also presents issues that remain to be addressed. (See ch. 4.)

THE FEDERAL FOOD REGULATORY STRUCTURE

The major Federal agencies involved in regulating the safety of U.S.-produced and imported food are the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service and the Department of Health and Human Services' Food and Drug Administration (FDA). The Environmental Protection Agency regulates pesticides which can contaminate food. Those agencies estimated that programs related to food safety would cost approximately $436 million and 12,500 staff years in fiscal year 1982.

Real food safety program dollars have declined. Between fiscal year 1977, when the Congressional Research Service catalogued USDA and FDA costs, and fiscal year 1982, real dollars devoted to most programs dropped--in some FDA programs by over 25 percent. (See app. II, p. 68.)

The agencies administer programs that

--set standards for what processed food should contain;

--approve additives, animal drugs, or pesticides before their marketing or use;

--set tolerances or levels for acceptable amounts of chemical residues in food;

--inspect food and food producing facilities including testing food for illegal residues;

--determine what information food labels should contain and what packaging is acceptable; and

--monitor State and local inspection and enforcement programs.

PAST STUDIES IDENTIFIED OPPORTUNITIES TO IMPROVE THE OVERALL REGULATORY PROCESS

Federal food safety regulation is complex. The food regulation process was characterized in 1977 by the Senate Committee on Governmental Affairs as often duplicative, sometimes contradictory, undeniably costly, and unduly complex. Over the years, the overall food regulation process has been studied by congressional committees, a presidential project, congressional agencies, and other groups outside of GAO.

Changes suggested by past study groups to correct problems in Federal food regulation included consolidating programs in one agency, amending food regulation statutes to make them consistent and to increase agencies' authorities, and increasing the use of interagency agreements and standing interagency coordinating committees. (See p. 16.)

Legislative changes to the Federal Food, Drug, and Cosmetic Act of 1938, the Federal Meat Inspection Act, and the Poultry and Egg Products Inspection Acts were discussed during

the 97th Congress. The changes, among other things, provided for risk assessment of substances added to foods. The Reagan administration's Subcabinet Council Working Group on Food Safety also suggested changes targeted at increasing the credibility, consistency, and efficiency of Federal food regulation. (See p. 20.)

To date, organizational or legislative changes responding to study recommendations have not been made, although the agencies have taken some steps to address specific problems. Recent proposals by the Congress and the administration to amend food safety statutes have not addressed all issues raised in past studies, such as inconsistent monitoring and enforcement authorities. (See p. 18.)

GAO IDENTIFIED OPPORTUNITIES TO IMPROVE PROGRAM ADMINISTRATION

Both USDA and FDA have experienced problems in preventing public distribution of adulterated food. GAO found that many times agencies did not

--have sufficient data to identify their regulatory scope or critical problem areas requiring attention (see p. 27),

--manage agency staff efficiently and effectively (see p. 36),

--investigate violators' corrective action effectively, and

--have criteria to guide decisions about proceeding with enforcement against violators. (See p. 40.)

Agencies' efforts to improve food regulation have been constrained in the past by scientific considerations such as the slow development of adequate methods of analyzing residues in food, and by the lack of good industry quality-assurance practices. (See p. 51.)

Although the agencies have made some changes in food safety program administration which GAO recommended in the past, the following issues remain to be addressed:

--How adequate are food regulatory agencies' management data systems? Recommendations calling for improved data have been met in

some cases by agency resistance when the data have been costly to obtain and are viewed by management as being of little importance to certain programs.

--How well are food regulatory agencies managing their staffs? GAO's followup suggests continuing problems with staff shortages and inefficient procedures.

--How well are agencies following up on repeat violators? Agencies have paid attention to the need for better recordkeeping, but tracking the source of problems remains difficult and interagency coordination remains complex.

--How effective are existing enforcement options in obtaining corrective action or deterring violations? Agencies still pursue the mildest enforcement options, and evidence exists of growing reliance on food industry volunteerism because of Federal resource constraints and changing regulatory philosophies.

CHAPTER 1

INTRODUCTION

Although it is generally recognized that the U.S. food supply is one of the world's safest and that Federal food safety regulation provides adequate public protection, the Congress and the administration are considering changes to food safety statutes targeted at increasing regulatory credibility, consistency, and efficiency.

We and other study groups in the past have identified the need for improving food safety regulation. Food production and marketing are growing in technological complexity. At the same time, real Federal dollars devoted to food safety regulation are declining. These forces may limit the ability of Federal food safety regulation to continue to adequately protect the U.S. public. For that reason, we conducted this study to bring together the views of past studies about needed food safety changes, as well as to provide an overview of our past food safety reports. The study defines an agenda of issues which merit further exploration.

FOOD PRODUCTION INCREASINGLY COMPLEX

The first major Federal laws designed to regulate food adulteration[1] were enacted in 1906. At that time, the production and marketing of food were relatively simple. People bought food produced and sold by a local farmer, or from a local commercial food handler. Food processing, such as smoking meat or canning produce, was still done in the home. As food processing increasingly was transferred to the factory and food was shipped to market for longer distances, the nature of the food sold changed from staple foods to factory-processed ones. Manufacturers relied on the addition of chemical preservatives and colors to retain and simulate freshness, prolonging the food's shelf-life. New products proliferated, particularly after World War II. In 1969, for the first time, the dollar volume sales of processed food exceeded those of unprocessed foods.

Since World War II, farm products increasingly have been processed, fortified, and otherwise commercially converted into food products. About 60 percent of food products' supermarket cost comes from processing.

THE FEDERAL FOOD REGULATORY STRUCTURE

Food industry analysts assert that the future holds increasing food production complexity. Federal efforts to ensure safe food must prove equal to the challenge of sophisticated food

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[1]Adulterated food is food that is unsafe, filthy, unfit for food, or debased by inferior substitutes or by other means.

processing technology. The Federal Government is involved in food regulation through programs that

--set standards for what processed foods should contain;

--approve additives, animals drugs, or pesticides before their marketing or use;

--set tolerances or levels for acceptable amounts of chemical residues in food;

--inspect food and food producing facilities, including testing food for illegal residues;

--determine what information labels should contain and what packaging is acceptable; and

--monitor State and local inspection programs for food retail and service establishments.

Government food regulation has three different purposes:

(1) To regulate economic aspects of food marketing, such as substitution of cheaper ingredients, like water for milk, or labeling for contents.

(2) To regulate the esthetic quality of food, such as preventing use of filthy raw materials like insect-infested wheat for flour production or filth from dirty machinery.

(3) To regulate food safety so that foods consumed do not endanger the public health.

The major agencies involved in regulating the U.S. food supply are the Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS), under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.); and the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and

the Public Health Service Act (42 U.S.C. 201 et seq.).[2] The Environmental Protection Agency (EPA) also affects food regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

In fiscal year 1982, those agencies estimated that programs related to food safety would cost approximately 12,500 staff years and $436 million. Appendix I contains information, by agency, on food regulatory programs and estimated costs for fiscal year 1982. Appendix II contains information, by program, about how food safety program dollars have changed since fiscal year 1977, when the Congressional Research Service catalogued program costs.[3] Real dollars devoted to food safety programs generally have fallen by over 25 percent in most programs. FDA program budgets appear to have been affected by budget constraints more than USDA program budgets have.

USDA food regulation activities

Meat and poultry inspection

USDA's meat and poultry inspection programs, currently administered by FSIS, are the largest Federal food safety programs in terms of required resources. In fiscal year 1982, USDA allocated 9,324 positions and $308 million to these efforts, which represents 97 percent of its funds committed to food regulation. As of December 1982, FSIS was responsible for inspecting 543 slaughter plants, 5,127 processing plants, and 1,534 combination slaughter and processing plants.

The Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) require the Secretary of Agriculture to inspect the slaughter of livestock and poultry and the processing of meat and poultry products shipped interstate or to foreign markets. The primary objective of these laws is to ensure that meat and poultry products

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[2]Various agencies in USDA have been responsible for meat and poultry inspection activities over the years. These have included the Consumer and Marketing Service established in Feb. 1965; the Animal and Plant Health Inspection Service established in Apr. 1972; the Food Safety and Quality Service established in Mar. 1977; and effective June 17, 1981, FSIS. We will refer to the agency in this report by its current name, FSIS. In May 1980 the Department of Health, Education and Welfare was abolished and FDA became part of the new Department of Health and Human Services. We will use HHS throughout this report to denote FDA's parent organization.

[3]"Food Testing and Inspection Programs of the U.S. Department of Agriculture and the Food and Drug Administration," Congressional Research Service, June 6, 1977.

distributed to consumers are produced under sanitary conditions, are wholesome, are not adulterated, and are properly marked, labeled, and packaged. Plant managers are primarily responsible for meeting these requirements. To do business, plants subject to the acts must first receive approval from FSIS that the plants' facilities, equipment, and operating procedures meet inspection program requirements.

FSIS may detain products suspected of being contaminated or condemn adulterated products. It may also withdraw or suspend inspection in cases where unsanitary conditions result in an adulterated product, the plant fails to destroy condemned products, or plant personnel assault or intimidate inspectors. Because plants cannot operate without inspection, withdrawals of inspection are severe actions which are costly to the plants.

The Meat Act requires inspection before slaughter of each animal, whereas the Poultry Act requires ante-mortem inspection only to the extent considered necessary by the Secretary of Agriculture. Both acts require inspection of each carcass after slaughter. The Meat Act also requires inspection of all processed meat products prepared for commerce. The Poultry Act authorizes, but does not require, inspection of all processed poultry products. The acts do not prescribe the specific method or frequency of processing inspection, but all products are subject to inspection as often as deemed necessary.

USDA has determined that, to achieve the degree of control and supervision intended by the Meat and Poultry Acts, most processing plants need to be inspected at least daily, even though an inspector may spend only a few hours each day at a plant.

Although FDA has primary responsibility for approving the use of substances identified as food additives, such as chemical preservatives, USDA has the additional responsibility to determine whether an FDA-approved additive may be used in meat and poultry products. This responsibility includes (1) determining that the approved additive will serve a useful purpose and (2) establishing a minimum amount of the additive necessary to achieve that purpose. USDA also restricts and monitors the use of approved additives to assure that requirements for safe use are met.

FSIS meat and poultry inspection programs include a residue testing and evaluation program. Meat and poultry products which

contain residues at levels above tolerances or action levels[4] set by EPA or FDA, under programs discussed below, are considered adulterated. FSIS laboratories provide laboratory services for sample analysis.

If the laboratory analysis indicates that residues are present in raw meat or poultry at levels in excess of tolerance, USDA refers the case to FDA for investigation. If illegal pesticide residues are found, the case is also referred to EPA. FDA and EPA inspectors investigate at the grower level to determine the cause of the residue problem and to take regulatory action, if warranted.

FDA food regulation activities

Food processing inspection

The Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 et seq.) gives FDA regulatory authority over foods that are received or shipped in interstate commerce, except for meat and poultry products which are subject to USDA continuous inspection. FDA and USDA share jurisdiction over eggs and egg products. Under FFDCA, the manufacturer has prime responsibility for assuring that food is not adulterated.

As of October 1, 1982, FDA's active inventory of food establishments subject to inspection included about 64,000 food-processing plants, storage facilities, and repacking and relabeling plants.[5] In fiscal year 1982, FDA planned to devote 960 staff years to food sanitation and quality control at a cost of $38 million.

When adulterated products or unsanitary plant conditions that may cause adulteration are found, FDA can initiate one or more of the following legal actions through the Department of Justice:

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[4]A tolerance specifies the level of a contaminant that will make a food adulterated. Tolerances are adopted through prescribed formal rulemaking procedures and any factual determinations will be sustained on review if supported by substantial evidence in the rulemaking record. An action level is an informal judgment about the level of a contaminant to which consumers may be safely exposed. It is an administrative guideline denoting when regulatory enforcement action will be initiated.

[5]For planning purposes, FDA has categorized its inventory of food establishments as active, inactive, or auxiliary. Inactive establishments are those not in operation during specific periods, such as fruit canneries which close after the harvest season. Auxiliary establishments are those which are out of business, are no longer engaged in activities subject to FDA inspection, have moved outside one FDA district's boundaries, or are only marginally regulated.

--Prosecute an individual who violates provisions of FFDCA.

--Enjoin a plant or individual to perform or not perform some act.

--Seize any food that is adulterated or misbranded when introduced into, or while in, interstate commerce.

For minor infractions, FDA can issue to the violator a written notice or warning to correct the conditions. Also, although recall is not specifically provided for under FFDCA, FDA permits firms to voluntarily recall products alleged to be in violation of the act. FDA may also request firms to recall products.

FDA inspects food plants on a random, unannounced basis. The frequency of FDA's inspections depends on a plant's past record of compliance and the hazards related to the processing activity. Plants producing high-risk foods, such as low-acid canned foods, may be inspected about once a year, whereas plants producing low-risk foods, such as breakfast cereals, may be inspected less frequently. On the average, FDA planned to inspect food-processing plants once every 5 to 6 years in 1982, compared to once every 6 to 7 years in 1977.

Regulation of imported foods

FDA, assisted by the U.S. Customs Service, is also responsible for ensuring the safety of foods imported into the United States, except for foods falling under USDA jurisdiction. Under FFDCA, FDA ensures that imported products subject to its regulation

--have not been manufactured, processed, or packed under unsanitary conditions;

--are not restricted for sale in the country in which they were produced or from which they were exported; or

--are not otherwise adulterated or misbranded.

Foods must be safe, pure, and wholesome. In addition, the misbranding provisions of the act require that products be accurately labeled.

Regulation of additives, animal drugs, and contaminants

FDA also is responsible for regulating food and color additives, animal drugs, and environmental and chemical contaminants and enforcing pesticide tolerances set by EPA. These substances may appear in food by direct or indirect addition. In fiscal year 1982, FDA planned to expend 853 staff years and $34 million on food additive and chemical contaminant regulation and 407 staff

years and $18 million on programs related to the safety of animal-derived human food. (See app. I, p. 59.)

FDA ensures that chemical residues in food (other than meat, poultry, and egg products, which are USDA regulated) and animal feed are within safe levels. It also regulates the use of animal drugs and intentional additives in food by approving their use before they are marketed and sets tolerances or action levels for contaminants that are unavoidably present in food or feeds.

FDA's Bureau of Foods is responsible for developing regulations, performing safety evaluations, and administering other provisions of FFDCA relating to food additives and other substances used in food.

FDA's Bureau of Veterinary Medicine is responsible for reviewing applications which are submitted to demonstrate the safety and effectiveness of new animal drugs. The Bureau also reviews data submitted by animal drug sponsors to demonstrate the safety of any drug-related residues in food.

EPA regulation of pesticides and toxic substances

EPA regulates pesticides and toxic substances which may contaminate food.[6] The legal authorities for pesticide regulation within the United States are the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and FFDCA. EPA (1) registers pesticides for distribution, sale, and use in the United States and cancels the registration of or otherwise regulates pesticides that the Administrator concludes cause unreasonable adverse effects on the environment and (2) sets tolerances for levels of pesticides that might remain in food, feed, and livestock from intentional use. EPA may establish a withdrawal period during which time the pesticide may not be administered.

A pesticide produced solely for export is not required to be registered with EPA and may be exported regardless of its U.S. regulatory status or the appropriateness of its intended use. Under FFDCA, any food product containing residues of a pesticide for which a tolerance has not been established or containing residues in excess of established tolerances is adulterated. If a pesticide remains in or on food, FFDCA requires that pesticide manufacturers, or other petitioners, apply to EPA for a tolerance--the maximum residue allowed in or on food for that pesticide.

The task of enforcing tolerances--usually by sampling food--belongs to FDA and USDA. FDA enforces tolerances on general food commodities and USDA handles meat, poultry, and egg products.

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[6]EPA sets tolerances for pesticide residues in food; FDA and USDA enforce the tolerances. The presence of most toxic substances as environmental food contaminants is regulated by USDA or FDA.

State departments of agriculture generally are now responsible for enforcement actions against pesticide violators, although EPA still can prosecute or levy a civil money penalty against an applicator who is using a pesticide in a manner inconsistent with its labeling.

EPA also controls the manufacturing, processing, distribution, use, and disposal of chemical substances and mixtures covered by the Toxic Substances Control Act (15 U.S.C. 2601 et seq.) which the Administrator concludes present unreasonable risks to health or the environment. The introduction of most chemical substances into food as environmental contaminants which are not regulated as drugs, pesticides, or food additives is regulated by EPA under the Toxic Substances Control Act. EPA's Office of Pesticide Programs carries out most of EPA's pesticide regulatory responsibilities.

OBJECTIVES, SCOPE, AND METHODOLOGY

Our objective in this study was to provide an overview of major food safety regulation studies and to determine the status of Government actions on recommended changes by (1) gathering information on recurrent, common Federal food safety administrative problems that we identified in past reports published between 1972 and 1981 and determining what, if any, actions have been taken by the responsible agencies to address the problems and (2) analyzing food safety regulation studies published during 1976 to 1981 by other groups and determining if study recommendations had resulted in statutory or organizational changes. We also determined the cost of Federal food regulation.

After reviewing our reports and studies by outside groups (see apps. III and IV, pp. 69 and 72), we limited the scope of our followup work to determining whether USDA, FDA, and EPA implemented recommendations related to the ability of USDA and FDA to keep adulterated food and food products from being marketed. (EPA has no authority to monitor the food supply's safety.) We also determined the status of recommendations to the Congress for statutory changes.

To define issues involving the overall Federal food safety process, we reviewed studies by the Congressional Research Service; the Senate Committee on Agriculture, Nutrition, and Forestry; the Committee for a Study on Saccharin and Food Safety Policy, National Academy of Sciences; the President's Reorganization Project; the Senate Committee on Governmental Affairs; and the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce. To determine the status of Government action on recommendations, we obtained the views of individuals concerned with food safety regulation in public interest groups and in scientific and industry organizations.

Because in the past we had performed agency program evaluations which had resulted in many reports and studies about

specific food safety programs, we reviewed our past reports and noted where different programs encountered difficulties which shared a common cause. We thus were able to classify findings in our past reports according to whether the problem's cause concerned (1) management information, (2) staff management, (3) enforcement, (4) scientific considerations, or (5) industry capability.

To determine the status of agencies' actions to effect recommended changes, we obtained and reviewed pertinent documents at the headquarters of USDA, FDA, and EPA and at our audit sites in those agencies, including (1) our files of department and agency responses to recommendations, (2) department and agency followup files, and (3) department and agency internal management reports, publications, and policy and procedural manuals. We also interviewed agency officials at the Washington, D.C., headquarters offices of FSIS, FDA, and EPA. We also determined the status of our recommendations to the Congress (see app. V, on p. 73).

We did not perform detailed audit work at agency field offices to evaluate whether agency policy and procedural changes were effective. Except for obtaining formal agency comments, our review was done in accordance with generally accepted government auditing standards. We performed the work on-site between January and November 1982 and contacted agency personnel after November 1982 to ensure that our work remained current.

To determine the cost of agency food regulation programs, we asked the agencies to furnish information about programs, enabling legislation, authorized positions and budget authority, and administering organization for fiscal year 1982. So that we could compare costs and see program changes, we employed the format used in the June 6, 1977, report by the Congressional Research Service, "Food Testing and Inspection Programs of the U.S. Department of Agriculture and the Food and Drug Administration."

CHAPTER 2

OPPORTUNITIES TO IMPROVE THE OVERALL REGULATORY PROCESS

It is generally believed that Federal food safety regulation provides adequate protection for the U.S. public, although we believe that comprehensive information to support that belief does not exist. Immediate deaths or illnesses directly related to consumption of adulterated food are rare. Long-term exposure to foods containing illegal amounts of chemicals or other contaminants may potentially harm the U.S. public, but cumulative effects are unknown.

However, the process by which the Federal Government regulates food safety does not work as well as it could. This chapter discusses studies by congressional committees, a presidential task force, and other groups which identified Federal food regulation issues and recommended changes to improve regulatory efficiency and effectiveness.

One major problem identified was that no consistent expression of overall Federal policy exists for food safety regulation. Existing statutes were enacted over a long period of time in response to a variety of needs. The studies noted that duplication of effort and regulatory gaps had resulted. Agencies' enabling legislation mandated different regulatory approaches.

In our update we found that (1) past studies' recommendations for statutory or organizational changes have not resulted in corrective action, although the agencies have taken some steps to address specific problems, and (2) bills have been introduced but not enacted by the Congress. The agencies continue to point to the need for statutory change as one reason for their lack of progress in improving some operations, but organizational changes are not seen as an option for improvement.

FEDERAL FOOD REGULATION IS FRAGMENTED

Federal food safety regulation is fragmented, encompassing myriad statutes administered by several agencies. The Congressional Research Service (CRS), in its 1981 report entitled "Food Safety Policy Issues," identified as a primary concern

> "The fragmentation of regulatory activity [which] prevents a cohesive, coordinated Federal food safety policy, contributing to numerous conflicts between State and Federal policies, and among the Federal agencies."

Earlier, the National Academy of Sciences, in its 1979 report, "Food Safety Policy: Scientific and Societal Considerations," concluded that FFDCA was "complicated, inflexible, and inconsistent

in implementation," and that food safety policy merited thorough periodic review.

Federal food laws represent a succession of provisions dealing with food safety enacted by the Congress over a period of almost 80 years. Appendix VI (see p. 78) contains a chronology of legislation which, although not comprehensive, illustrates the myriad statutes which affect Federal food regulation. Since 1906, at least 36 statutes have been enacted which concern Federal food regulation. The pace of legislation has increased over time. Between 1900 and 1960, 20 acts were passed, while between 1960 and 1980, 17 acts were passed.

The major agencies concerned with regulating food--FDA and USDA--regulate for the most part under disparate statutes using significantly different regulatory approaches, as discussed in chapter 1. The Senate Committee on Governmental Affairs in "Regulatory Organization," Vol. V, Study on Federal Regulation (Dec. 1977), concluded that

> "Divided responsibility * * * for food regulation has created a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex * * *. There is currently no systematic or rational overall approach to federal food regulation."

No agreed-upon definition of food "safety" exists. The application of the term is defined case-by-case, generally through litigation. CRS concluded in 1981 that standard definitions of terms were lacking, presumably because of a lack of consensus among policymakers.

PAST STUDIES FOUND REGULATORY OVERLAP AND GAPS

Past studies identified problems in agency duplication of effort and regulatory gaps. Regulatory duplication, or overlap, occurs when duplicate requirements result from separate statutes that have similar objectives. Regulatory gaps occur when legislative authority is not sufficiently clear and complete.

Overlapping food regulation

FDA and USDA administer food safety programs with overlapping jurisdictions. The President's Reorganization Project, conducted under the Carter administration, in its December 19, 1978, "Food and Nutrition Study Final Report," pointed out instances of duplicate inspections. For example, USDA and FDA sometimes inspect the same plants at the same time in about 2,100 food manufacturing firms. One example of duplication given by the Senate Committee on Governmental Affairs in 1977 was of a soup manufacturer who produces both vegetable and vegetable-beef canned soups. USDA inspectors must monitor the processing of the vegetable-beef soup, while FDA inspectors have jurisdiction over the vegetable soup.

Both agencies check similar sanitation requirements, although the USDA inspector is in the plant daily while the FDA inspector may visit only once every several years.

We found, as discussed below, that duplication of plant inspections by USDA and FDA apparently does not present great problems either to the industry or to the agencies.

Study suggests overlap not greatest business concern

In a 1981 report[1] we said that regulatory overlap, including overlapping food regulation, was not a major problem to the firms we surveyed, compared to other issues like excessive paperwork. Firms surveyed also did not report that overlap placed an economic burden on them, although they found it difficult to make specific cost estimates.

Firms we surveyed did not mention duplicative USDA/FDA food establishment inspections as a problem. Of 52 examples of regulatory conflict and overlap described by the 50 companies we surveyed, 14 examples concerned food regulation. Most problems companies cited involved overlapping jurisdiction in premarket approvals and labeling and packaging standards. No instances of overlapping USDA/FDA establishment inspections were cited.

Outside experts in food and nutrition whom we contacted during our followup did not believe regulatory overlap was a major problem in food safety regulation.

Agencies do not believe inspection overlap is a problem

Agency officials do not believe food inspection overlap is a problem. USDA officials point out that as a practical matter no inspection overlap of food manufacturers exists between FDA and USDA because FDA investigators may visit a facility only once every several years. USDA inspectors are in plants daily.

We were unable to determine the number of food manufacturers currently falling under both USDA and FDA jurisdiction. The 2,100 plants cited above by the Reorganization Project were arrived at as a result of a one-time FDA/USDA project to determine the number of joint facilities. We were told by officials involved in the original project that since that project, FDA and USDA have not redetermined the number of joint plants.

As a result of that project, USDA and FDA negotiated an interagency agreement, FDA number 225-79-2401, approved June 1981, covering joint FDA/FSIS inspection activities. The agreement

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[1]"Gains and Shortcomings in Resolving Regulatory Conflicts and Overlaps" (PAD-81-76, June 23, 1981).

calls for, among other things, the agencies to "minimize duplication of inspectional effort through an exchange of information for work planning * * *."

Past studies found regulatory gaps existed

The Senate Governmental Affairs Committee pointed out in 1977 that where agencies share responsibilities, often there were areas of insufficiently clear and complete authority to do the task, resulting in a serious problem "falling between the cracks." The report stated:

> "* * * where regulatory authority has been imprecisely--or concurrently--allocated, the result has been confusion and uncertainty as to the limits of each agency's jurisdiction and an unrealistic demand for close cooperation between agencies which proceed under substantially different statutory direction and philosophies of regulation. Sometimes uncertainty has led to an excess of deference and the failure of either agency to act effectively in the face of a regulatory need."

The committee found that jurisdiction over a food product might change depending upon where the product was located in the food marketing chain. For example, FDA had authority over live animals intended for the food supply. USDA assumed jurisdiction once the animal reached the slaughterhouse and retained jurisdiction over the meat as it was processed, for example, into canned beef stew. Once the beef stew was sent to a retail store, USDA and FDA shared jurisdiction, although only FDA had authority to inspect the retail premises.

One instance of a regulatory gap cited by the committee concerned insufficient regulation of low-acid canned meat or poultry products. Although FDA had issued stringent restrictions in 1973 on the processing of low-acid foods which have a high risk of botulism contamination, USDA did not follow suit for products under its jurisdiction until 1976.

Regulation of toxic contaminants at the grower level, on the farm, was a regulatory gap cited in 1978 by the President's Reorganization Project. The Project's report pointed out that FDA, EPA, and USDA each had partial responsibility for keeping toxic contaminants out of the food supply. The report concluded that coordination of effort was difficult and that no agency had sufficient resources directed to keeping illegal residues out of foods at the farm level.

As discussed in chapter 3, we found in our update that little improvement has been made in strengthening FDA residue enforcement activities in raw meat and poultry although residues in raw meat and poultry detected by USDA have dropped (see p. 47). Also, USDA initiated a program in 1982 directed at educating farmers about

how to raise livestock and poultry so as to avoid illegal residues. This program, the Residue Avoidance Program, is a joint FSIS/Cooperative Extension Service effort and is voluntary on the part of producers and industry groups.

FDA, USDA, and EPA are negotiating a revised interagency agreement covering illegal residues in food which is intended to clarify enforcement procedures and improve coordination. The revised agreement is expected to be issued by the summer of 1983, according to a USDA official.

REGULATORY APPROACHES ARE DIFFERENT

Agencies responsible for keeping adulterated food from the marketplace have substantially different statutorily required approaches to monitoring and enforcement. The Senate Governmental Affairs Committee in 1977 found that different regulatory approaches were historical, rather than based on a scientific or health basis. The committee concluded that different inspection approaches were unjustified by differing health risks presented by meat and non-meat products. An example of differing approaches required by statutes occurs in in-plant food inspection.

Monitoring food processing and enforcing regulations--separate approaches

FDA and USDA are required to inspect food-processing facilities--such as slaughterhouses, canneries, and warehouses--to ensure that foods are not adulterated or misbranded. The agencies' approaches to inspection and enforcement are very different. The following chart summarizes differences in USDA and FDA in-plant monitoring.

Food Inspection

USDA	FDA
Continuous daily inspection of meat and poultry slaughterhouses and processors.	Intermittent plant inspection based upon product/producer history and risk.
Product must have USDA stamp of approval before entering interstate commerce.	No prior approval required before entry into interstate commerce.
Facility construction plans must be reviewed and approved by USDA.	Food producers are not required to notify FDA of their operations.
Statutory right to examine plant records.	Little authority to examine plant records, except for manufacturers of infant formulas or pursuant to a warrant or court order.
Responsible in 1982 for about 7,200 meat and poultry slaughterhouses and processors.	Responsible in 1982 for about 64,000 active food establishments.

Primary Source: "Regulatory Organization," Vol. V, Study on Federal Regulation, Senate Committee on Governmental Affairs, Dec. 1977.

Within their respective jurisdictions USDA and FDA have statutorily authorized enforcement authorities that also differ markedly. As outlined in chapter 1, FDA cannot administratively (1) withhold inspection, as can USDA, (2) condemn or detain domestic products, as can USDA, or (3) require product recalls. FDA product seizures or injunctions, as well as criminal prosecutions, must be pursued through the Department of Justice. Recalls of adulterated products are pursued voluntarily by food producers, sometimes at FDA's request.

Although USDA also litigates its cases through the Department of Justice, it has additional administrative remedies it can pursue. USDA may detain or condemn adulterated products and may suspend or withdraw its inspection, effectively stopping production in the plant. USDA may also detain products in distribution for up to 20 days until the product is destroyed or brought into compliance. Products in distribution which are not brought into compliance are subject to judicial seizure. USDA may also request voluntary product recalls.

CHANGES SUGGESTED TO IMPROVE REGULATION

Past studies have suggested organizational and statutory changes to Federal regulation of food safety to address issues such as regulatory overlaps and gaps and inconsistent monitoring and enforcement. Studies also pointed to interagency agreements and standing interagency coordinating committees as useful tools to improve regulatory efficiency.

Consolidation of regulatory functions

Studies of Federal food regulation performed since the Hoover Commission study in the 1950's have recommended that regulatory functions be consolidated in one agency. The recent studies by the Senate Governmental Affairs Committee and the President's Reorganization Project both recommended placing food regulatory functions in one agency. The committee recommended consolidation in FDA, and the Reorganization Project recommended placement in a reorganized USDA.[2] It appears that such a consolidating reorganization will not take place.

Statutory changes recommended to improve regulation

Studies have recommended legislative changes to make food safety laws consistent, to more closely align FDA's and USDA's inspection procedures, and to allow more efficient and effective food production monitoring. The Senate Governmental Affairs Committee recommended the phasing-out of USDA continuous inspection in meat processing facilities to increase inspection efficiency, as did a USDA consultant report.[3]

The Senate committee also concluded that FDA's triennial or quadrennial inspections of processing facilities could not assure that the food processing industry performed within legal requirements. The committee recommended that the Congress authorize additional funds for FDA inspections and that the Congress review all food regulatory authority to ensure that FDA would have appropriate and adequate directives for its enforcement efforts.

The President's Reorganization Project's 1978 Food and Nutrition Study recommended the following changes to both USDA and FDA food monitoring and enforcement programs so that regulation of all

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[2]The Project recommended that USDA be reorganized into separate functions concerning agricultural promotion and consumer protection to alleviate the perception that USDA is biased toward agricultural rather than consumer interests.

[3]"A Study of the Federal Meat and Poultry Inspection System," Booz, Allen, and Hamilton, Inc., June 1977.

foods would be consistent and programs would be efficient and effective:

--The intensity of inspectional coverage should be varied in accordance with food safety risks.

--FDA should have access to plant records.

--Agencies should require food processors to set up quality-assurance programs that meet regulatory requirements.

--Agencies should have authority to detain products.

--Agencies should have authority to assess civil penalities for violations of the laws and regulations.

--USDA should have authority to quarantine livestock and poultry containing illegal levels of chemical residues.

--Agencies should have authority to prohibit chronic violators of the food inspection laws from engaging in commercial food transactions.

Changes would have required amendments to FFDCA and to the Meat and Poultry Products Inspection Acts. The Project concluded that

> "* * * unification, accompanied by legislation to standardize regulatory approaches, powers, and penalties, could not only provide an environment for correcting longstanding problems, but also significantly reduce Federal expenditures."

In March 1979, a National Academy of Sciences Committee for a Study on Saccharin and Food Safety Policy issued a report[4] which recommended that changes in food safety statutes be made to foster a consistent regulatory system that

--exerted continuous pressure for reduction in the overall risk from substances permitted in the food supply,

--was comprehensive and applied to all food substances equitably regardless of their route of entry into food,

--distinguished among risk levels and assigned priorities among categories of risk,

--allowed a variety of regulatory and educational approaches in response to risks posed by food substances,

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[4]"Food Safety Policy: Scientific and Societal Considerations," Part 2, Mar. 1979, National Academy of Sciences.

--allowed FDA the discretion to make judgments using expert analysis of scientific information and informed public opinion,

--provided for greater scientific and other support for FDA, and

--encouraged the fullest expression of public opinion.

STATUS OF CHANGES RECOMMENDED IN THE REGULATORY PROCESS

As of July 1983, no action had been taken on past recommendations for organizational or legislative change, although the agencies have taken some steps to address specific problems.

Individuals within the Government and without expressed their belief that little urgency exists for substantially changing Federal food regulation because the public perceives the process to be working adequately. We did not find any evidence that the way the Federal Government regulates food safety does not protect the public overall. Neither FDA nor USDA employs program performance indicators about how well Federal food safety programs are working. Agency officials also expressed their belief that statistics on food-related deaths or illnesses are unreliable indicators because physicians or medical examiners may misdiagnose cases. As long as major food-related disasters do not occur, experts believe that major statutory or organizational changes will not be made.

Legislative initiatives not successful

Past reports which have recommended statutory changes have resulted in the introduction of bills, but none have been enacted; thus, the issues which changes would have addressed still are outstanding.

Several unsuccessful attempts have been made to pass legislation to improve FDA surveillance. Legislation was introduced in the 95th Congress to, among other things, allow FDA the authority to inspect records and take photographs during its factory inspections. The Senate Committee on Agriculture, Nutrition, and Forestry's 1979 report, "Food Safety: Where Are We?," reported that two bills introduced in the 95th Congress would have required that: (1) food processors register with FDA, (2) food processors notify the FDA when products become adulterated or when they recall products because of violations, (3) to help in monitoring recalls, products carry codes with the place and date of manufacture, and (4) FDA have access to records.

A bill (H.R. 7035) was introduced in the 96th Congress to allow FDA authority for administrative detention of food and feed

commodities suspected of containing illegal pesticide or industrial chemical residues. The proposal, which had resulted from a comprehensive internal FDA study of pesticide and industrial chemical regulation,[5] was not considered by the Congress.

Another FDA proposal to provide for civil penalties for FFDCA violations, including the marketing of food and feed products containing pesticide or industrial chemical residues, was submitted in fiscal year 1980 by FDA to HHS for consideration.

According to FDA, no further action on any of these proposals is contemplated as of July 1983.

Although the Senate Governmental Affairs Committee in 1977 recommended that the Congress appropriate more funds for FDA food establishment inspections, resources devoted by FDA to food manufacturing inspection actually decreased. In fiscal year 1977, FDA planned to spend $36 million and devote 1,162 staff years to food sanitation control. In fiscal year 1982, FDA planned to devote 960 staff years, a 17 percent decrease from 1977, and about $38 million to food sanitation and quality control. When we converted FDA's 1977 planned expenditures into 1982 dollars, we found that FDA dollars devoted to food sanitation had dropped almost 27 percent in real terms from 1977 to 1982. FDA planned to inspect most food establishments once every 5 to 6 years in 1982, compared to once every 6 to 7 years in 1977.

In 1974, FDA initiated a study to determine the food establishment inspection coverage necessary to provide an adequate level of consumer protection. The study's 1976 report entitled "Domestic Food Establishment Inspectional Strategy" stated that the estimated 1975 staff resource level was insufficient to provide an adequate level of protection and that approximately 1,200 additional positions would be required, representing a 71 percent increase above the fiscal year 1975 base level of 1,689 staff years.[6] The staff years required represented the total resources needed to implement an adequate inspection strategy, including, for example, semi-annual inspections of high-risk food establishments. According to an FDA official, the inspection strategy developed by the study group was controversial and was never fully implemented because FDA realized that additional positions would not be available and because FDA's inspection strategy changed.

FDA last formally measured the effectiveness of its food sanitation and quality control program in 1976. The evaluation has not been repeated because of resource constraints, according to an FDA official.

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[5]"FDA Monitoring Programs for Pesticide and Industrial Chemical Residues in Food," FDA, June 1979.

[6]Positions included FDA regional operations staff, Bureau of Foods staff, and other staff such as attorneys.

USDA's enabling statutes also have not been changed. In December 1980, the outgoing Carter administration submitted a legislative proposal, introduced in the Senate as S. 3256, which would have authorized USDA to quarantine animals having excessive levels of chemical residues and would have required growers to place identification tags on animals before marketing them. Although USDA had determined at that time that quarantine and tagging authority were the most cost-effective means of improving meat and poultry residue regulation, USDA commented on the report in March 1981 that "the proposal would impose significant new costs on industry during a time of economic crisis."

In the spring of 1982, USDA proposed legislation enabling the Secretary to choose which meat and poultry processing plants needed fulltime inspectors on the basis of the plant's history of compliance, internal quality control systems, and other factors. However, the legislation (S. 2348 and H.R. 6062) was not acted on during the 97th Congress.

The National Academy of Sciences' 1979 proposal for a revision of food safety laws was considered in a May 1979 hearing before the Subcommittee on Health and Scientific Research, Senate Committee on Labor and Human Resources. Individuals who testified acknowledged that food safety law is complex, but some noted that suggested overall revisions to the current system were impractical. Objections generally brought out were that (1) the state of scientific knowledge was insufficient to support FDA categorization of the health risk of substances added to food, (2) the benefits of added substances would be difficult to determine, and (3) changes would have placed the burden of proof in determining safety on FDA rather than the industry. No statutory changes yet have resulted from the Academy report, although, as discussed below, the dialog about needed revisions has continued.

Recent proposals not intended to be comprehensive

We found in our followup that three food safety bills, a congressional committee draft food safety bill, and administration issue papers focused dialog on the need for statutory changes during the 97th Congress. Proposals discussed by congressional staff and department and agency officials arose because of concern about the need for changes in FFDCA's Delaney Clause. The clause requires FDA to ban food additives which are found to cause cancer when ingested by humans or animals or are found, after appropriate tests which evaluate the safety of food additives, to induce cancer in humans or animals.

The proposals were not intended to be comprehensive. Issues raised in past studies by us and by others, such as inconsistent monitoring and enforcement authorities, were not all addressed.

The first bills introduced in the 97th Congress, the proposed Food Safety Amendments of 1981 (S. 1442 and H.R. 4014 introduced

in June 1981), would have amended FFDCA, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. The purpose of the bills was, among other things, "to provide for assessment of risks to health presented by substances present in food." In our December 1981 report[7] we said that the idea of risk assessment is a controversial and complicated procedure aimed at determining the relationship between the incidence of cancer in animals and the potential for cancer in humans. The bills also provided for weighing the risks of using food substances against the benefits gained by their use.

Another bill, H.R. 5491, introduced in February 1982, would have revised FFDCA's provisions for food additives and provided for assessing the nature and extent of risks associated with food substances and for weighing risks and benefits in food safety decisions.

Hearings were not held on those bills, and in April 1982, a further food safety proposal was issued to the Congress for discussion purposes by the Senate Committee on Labor and Human Resources. The proposal, a staff working draft food safety bill, reflected a blending of the first three bills, but the proposal was never introduced.

In response to congressional reform proposals and as part of a move to reform Federal regulation in the area of pure food and drugs, the Reagan administration in 1980 chartered a Subcabinet Council Working Group on Food Safety to review the need for changes in food safety statutes. The group's purpose is to contribute to formulation of an administration food safety policy. Members of the Working Group are the Assistant Secretary of Agriculture for Marketing and Inspection Services; the FDA Commissioner; the FSIS Administrator; the EPA Deputy Administrator; and the Assistant Secretary for Health, HHS.

In September 1982, the Group published issue papers reflecting its position on 17 food safety topics, which were intended to form the foundation for its final recommendations to the Cabinet Council on Human Resources. The Group's purpose in proposing changes was to increase the credibility, consistency, and efficiency of Federal food regulation. One of the principles adopted by the Group in its deliberations was that Federal statutes on food safety should be consistent and nonduplicative. The Group also agreed with the need for incorporating a definition of "safe" into FFDCA and for weighing food substance risks and benefits, as proposed by bills during the 97th Congress.

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[7]"Regulation of Cancer-Causing Food Additives--Time for a Change?" (HRD-82-3, Dec. 11, 1981, p. 16).

Interagency agreements as coordination tools

The use of interagency agreements or memorandums of understanding to clarify and coordinate related agency food regulation activities was cited by past studies as a useful practice. Memorandums can be useful coordination tools but may not be sufficient to address areas where organizational or statutory changes were considered to be needed. Memorandums generally concern narrow topics and are not always kept current.

Agencies involved in regulating food coordinate their concurrent jurisdictions through memorandums of understanding which are interagency agreements defining areas of potential overlap and providing guidelines. A 1977 CRS report, "Food Testing and Inspection Programs of the U.S. Department of Agriculture and the Food and Drug Administration," concluded that cooperation between the two agencies was sound and that the small number and recent dates of the memorandums of understanding indicated good relations. The Senate Governmental Affairs Committee suggested in its 1977 report that increased use of cooperative agreements would provide structure to "ad hoc case-by-case" coordination.

Memorandums generally concern narrow, discrete topics rather than broad areas of jurisdictional overlap. For example, of the 13 memorandums approved by USDA and FDA that were identified by CRS in 1977, 9 deal with individual products or commodities--dry milk products; imported dates; imported raisins; pistachio nuts; brazil nuts; peanuts; industrial fishery products intended for animal feed use; grain, rice, and pulses; and egg products. An FSIS official commented that memorandums must be fairly narrow in scope if agencies are ever to come to agreement on policy and procedures.

We found that agencies have negotiated additional agreements since CRS issued its report in 1977. One additional memorandum between FSIS and FDA has been approved since 1977 covering joint FDA/FSIS food processing plant inspection activities. The memorandum was negotiated in 1979 in response to our 1975 survey disclosing inspectional overlap in meat processing plants. The memorandum was updated in 1981 to reflect new agency responsibilities under the Infant Formula Act of 1980.

FSIS also negotiated a memorandum with EPA covering pesticide residues in animal feeds and meat and poultry, dated August 17, 1977. The latter memorandum and a 1975 USDA/FDA agreement on food and chemical residues are being reviewed jointly by staff of FSIS, FDA, and EPA for the purpose of combining them into one tripartite agreement. Although USDA had indicated in its response to our

1979 report[8] about residues in raw meat and poultry that the memorandums would be reviewed, the Deputy Administrator for Science, FSIS, commented that negotiations are taking a long time because three agencies are trying to agree on procedures which all three can implement.

Agencies have not always updated older interagency agreements to reflect changes. An agreement to which USDA's Animal and Plant Health Inspection Service initially was a party has not been changed, although FSIS currently performs the functions mentioned. Agreements to which USDA's Food Safety and Quality Service was a party have not been updated to reflect its 1981 reorganization into FSIS. Functions performed by the older Food Safety and Quality Service were transferred to the USDA Agricultural Marketing Service. FDA officials commented that they did not believe it was critically important to reissue a memorandum to reflect organizational changes because the agreement remains operative.

Interagency committees

Although long-term interagency planning and coordination committees had been suggested as one means of increasing food safety regulation effectiveness, long-term committees have not been established. As an interim reform to consolidating food safety regulation in one agency, the Senate Committee on Governmental Affairs suggested that USDA and FDA form continuous, long-range planning committees and devise a regular procedure for coordinating their enforcement activities to ameliorate "ad hoc, case-by-case" coordination.

One entity which served for a time as a forum for agency interaction on matters concerning overlapping jurisdiction was the Interagency Regulatory Liaison Group (IRLG). IRLG was formed in 1977 by the heads of four agencies--the Consumer Product Safety Commission, EPA, FDA, and the Occupational Safety and Health Administration. FSIS was later invited to join the group. IRLG was formed to enable the agencies to work closely together in areas of common interest and responsibility, by sharing information, avoiding duplication, and establishing consistent policies.

The group's charter was for 4 years; in 1981, when the charter would have had to be renewed, IRLG was disbanded. Some of its functions were transferred to the Office of Science and Technology Policy, Office of Scientific Advisors to the President.

Interagency coordination is once again on an ad hoc, case-by-case basis, but FSIS and FDA officials commented that interagency coordination is good and that IRLG is not missed. Several

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

commented that IRLG added little more than another level of bureaucracy to the process. Joint working-level committees are working on specific technical problems in the agencies. For example, an interagency group advises FSIS about chemicals which should be included in its annual meat and poultry residue monitoring effort. One FDA official, however, observed that committees formed to address specific technical problems are narrowly focused. Broad issues such as making sure agencies share sufficient, useful, and compatible data are not addressed by such committees.

CHAPTER 3

OPPORTUNITIES TO IMPROVE PROGRAM ADMINISTRATION

Although Federal food protection statutes were enacted to assure the U.S. public of an unadulterated food supply, we reported in the past that products which violated the statutes reached the public. This chapter discusses our reports related to problems the agencies experienced in keeping adulterated food from distribution to the public. Some problems occurred because agencies lacked sufficient authority, as discussed in chapter 2. However, we also found in the past that violative food and food products continued to be marketed because agencies many times

--did not have sufficient data to identify their regulatory scope or critical problem areas requiring attention,

--did not manage agency staff resources efficiently and effectively,

--did not follow up on industry violators effectively, and

--did not have criteria to guide decisions about proceeding with enforcement against violators.

In addition, we have reported that agencies' management problems were made more difficult to address because of scientific constraints such as the slowness of developing faster, more accurate detection methods for food residues. Also, some food manufacturers had been slow to improve their own quality-assurance practices.

Although it is doubtful that any means exists for FDA and USDA to ensure completely that only unadulterated food is marketed, we found in our update that issues which we identified in the past remain to be addressed by the agencies. Also, the agencies appear to be placing emphasis on voluntary food industry compliance efforts, as we note in the remainder of this chapter, because of resource constraints and changing regulatory philosophies.

REPORTS FOUND AGENCIES WERE UNABLE TO KEEP ADULTERATED PRODUCTS FROM MARKETS

A series of our reports said that USDA and FDA were unable to keep all food products which violated food protection statutes from being marketed. Adulterated products continued to reach consumers whether produced in the United States or imported.

--In 1972, we estimated that about 40 percent of 4,500 food manufacturers regulated by FDA and included in the scope of our review operated under insanitary conditions.[1]

--By 1976, results of an FDA compliance program showed a drop in violative firms from about 15.6 percent of 1,528 firms inspected in 1974 to only 8.5 percent of 1,778 firms inspected in 1976.[2]

--In 1977, we found that some meat and poultry processing plants under USDA inspection continued to have repetitive sanitation defects, although improvements were noted.[3]

--In 1977, our review of imports, including food, regulated by FDA found that only about 17 percent of the entries of the various FDA-regulated products imported during fiscal year 1975 were inspected. Ninety percent of the dollar value of all FDA-regulated imports was food products. FDA records showed that imported [illegible]

FDA's information on regulatory scope

FDA is responsible for regulating all U.S.-produced and imported food except, generally, meat, poultry, and egg products which are subject to USDA continuous inspection. Effectively fulfilling this mandate requires good information for workload planning and other uses. We reported in the past that FDA information about its regulatory scope was inadequate. FDA has worked to improve its information but further improvements could be made.

FDA's official establishment inventory

In the past, we identified a need for improvement in FDA's official establishment inventory. FDA maintains the establishment inventory, which includes U.S. food processing firms, to determine which firms it must inspect, among other uses.[9] However, FDA cannot control the completeness of its inventory because it has difficulty determining which firms fall under its jurisdiction. FDA has no legal authority to require food establishments to register with it. We found that the establishment inventory in the six FDA districts we included in our review was not complete or accurate.[10]

We reported in 1978[11] that FDA had taken steps to improve the establishment inventory resulting in an establishment inventory which one FDA official estimated was 90 percent accurate. This action represented progress by FDA. Further improvements would have required food processors to register with FDA, necessitating statutory change.

Update

FDA actions have responded to our concerns. On October 1, 1982, FDA's establishment inventory active file contained about 64,000 food establishments. The Associate Director for Compliance, Bureau of Foods, believes that the inventory is sufficient for FDA's purpose. The inventory is used to plan field staffing levels. He stated that inspection resources must be concentrated on large firms with a significant market share or on firms producing high-risk products and that those firms would be included in the inventory.

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[9]FDA's official establishment inventory lists food plants subject to FDA regulation and includes data such as types of products produced, annual sales volume, and inspection results. The inventory is divided into files of active and auxiliary food establishments.

[10]"Dimensions of Insanitary Conditions in the Food Manufacturing Industry" (B-164031(2), Apr. 18, 1972).

[11]Letter to the Commissioner, Food and Drug Administration, Apr. 11, 1978.

Each FDA district is responsible for the accuracy and completeness of its own establishment inventory. An FDA Field Management Directive, "Official Establishment Inventory and Maintenance Procedures," dated May 14, 1982, sets out systematic procedures for FDA headquarters and district offices to follow in assuring accuracy of inventory data.

Although it has begun to implement procedures to ensure its inventory's accuracy, assurance of completeness is ad hoc. FDA has no systematic procedure to ensure the inventory's completeness, and food processors do not have to register with FDA. Information updating the inventory may be received from FDA inspectors who notice establishment changes in the course of their duties, from State agencies which inspect food establishments, and from the food industry itself.

FDA's imported-product data

In 1977, we identified a need to improve FDA's information about products imported into the United States.[12] We found most imported products subject to FDA regulation were not inspected, partly because FDA lacked sufficient specific information about volume, type, and quality of entering products to effectively plan coverage. Only 17 percent of imports subject to FDA inspection during fiscal year 1975 were inspected. Ninety percent of the dollar value of all FDA-regulated imports at that time was food products. We recommended that FDA establish a system to provide comprehensive information on specific imported products, showing the volume imported, the volume inspected, and the inspection results.

Commenting on the report, HHS stated that FDA proposed to develop an imported product information system providing volume of products imported, those inspected by FDA, and inspection results.

Update

FDA reassessed its proposal for developing an imported product information system. FDA determined that it would not expand its import data system because

--the data was not needed to carry out existing import enforcement activities and

--the system would be too expensive.

According to the Deputy Executive Director of Regional Operations, the proposed system would cost about $1 million to develop,

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[12]"Food and Drug Administration's Program for Regulating Imported Products Needs Improving" (HRD-77-72, July 5, 1977).

and FDA does not have the resources for it. FDA currently inspects imports not by a statistical sampling scheme but by known problem areas--district staff determine from past personal experience, media and Government reports about foreign agriculture, and other districts' inspection results where import problems are likely to occur.

FDA's data on pesticides

In a 1979 report[13] we pointed out that lack of information about pesticide practices of and pesticides used in other countries hampered FDA efforts to keep imported food containing toxic residues from entering U.S. markets. Many other countries used pesticides banned for U.S. use. Unless FDA knew which pesticide residues were likely to be present in imported food, it could not effectively determine which tests to conduct for safety and purity. We recommended that FDA obtain data about foreign pesticide usage as a basis for determining what pesticide residue analyses to perform. HHS agreed with the recommendation, with the reservation that there were limits to anticipating what residues might be present.

In December 1980, we reported[14] on progress FDA had made in getting better information. FDA indicated that it had restructured its pesticide monitoring program for imported foods, partly on the basis of better pesticide use data.

Update

FDA reported to the House Committee on Appropriations in March 1982 that it would not allocate investigational resources to determine what pesticides are used on imported food because of cost, practical difficulties in acquiring and using the data, and potential adverse consequences to U.S. international trade relations. As we reported in 1980, FDA continues to rely on foreign governments' voluntarily providing lists of pesticides approved for agricultural use and on the recommended pesticide tolerances of an international committee.

FDA's data on domestic pesticide use

FDA also should have adequate, accurate information on pesticide use within the United States. A 1978 USDA report estimated that U.S. farmers used 65 percent of all pesticides produced. FDA is responsible for ensuring that all food marketed in the United States, except generally meat, poultry, and egg products which are USDA continuously inspected, meets FFDCA's residue requirements. FDA needs pesticide usage data to structure its monitoring

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[13]"Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential" (CED-79-43, June 22, 1979).

[14]"Further Federal Action Needed To Detect and Control Environmental Contamination of Food" (CED-81-19, Dec. 31, 1980).

programs. However, in 1980, we found that EPA pesticide usage data were not comprehensive and sometimes were not accurate. We reported[15] that data on agricultural pesticide use f rnished to EPA by USDA could produce inaccurate estimates of a pesticide's total volume and that USDA data usually were not current. We concluded that other EPA sources of information about agricultural pesticide use were of limited value. We recommended improvements in EPA pesticide data collection.

In December 1980, EPA responded that although it could not afford to develop a pesticide use data base which would meet the highest standards, it was taking steps to improve the quality of the data available. EPA reported having begun a pesticide usage survey program in cooperation with USDA, the States, the Bureau of the Census, other agencies, the pesticide producers, and user groups. It planned to repeat surveys every 3 to 5 years.

Update

Our concerns have not yet been addressed completely. According to the Chief, Economic Analysis Branch, Office of Pesticide Programs, EPA, budget constraints and procurement delays have impeded progress of the pesticide usage surveys. As of November 1982, no usage survey had been completed. An interagency pesticide usage data planning group is responsible for coordinating data needs among EPA, FDA, USDA, Bureau of the Census, State regulatory agencies, and State universities. USDA is the lead agency for crop and livestock pesticide usage data.

FDA reported in March 1982 to the House Committee on Appropriations that it has allocated investigational resources to obtain information about pesticides used on domestic crops. FDA emphasized, however, that it cannot rely solely on usage data to guide its pesticide residue sampling. Accidents or environmental contamination may also result in food contaminated with pesticides.

In response to an internal review of FDA pesticide and industrial chemical residue programs, FDA developed a Surveillance Index designed to reflect the relative potential health risk of residues that may occur in domestic and imported food and feed commodities. Information from the Surveillance Index determines (1) what pesticides will be sampled under FDA routine surveillance programs and (2) which will be the object of special surveys. As of October 1982, FDA's Bureau of Foods had developed Surveillance Index documents on 110 pesticides. FDA estimates that 280 pesticides have food uses or the potential to contaminate food.

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[15]Letter Report to the Administrator, EPA, "Need for Comprehensive Pesticide Use Data" (CED-80-145, Sept. 30, 1980).

USDA's data on consumer exposure to residues in raw meat and poultry

We stated in a 1979 report[16] that USDA's national meat and poultry monitoring program for violative residues of animal drugs, pesticides, and environmental contaminants did not provide adequate data on the extent to which consumers were exposed to potentially harmful residues. We stated that an accurate estimate of total public exposure to violative residues was important so that USDA and FDA could reliably determine the extent of the residue problem. We recommended that the Secretary of Agriculture revise the methods used to compute residue violation rates to more accurately reflect the extent to which consumers were exposed to residues in raw meat and poultry.

USDA took exception to this recommendation, stating that its monitoring program was not represented or intended as an estimate of total public exposure.

Update

Because it disagreed with us, USDA has not responded to our concerns. USDA's national residue monitoring program still is not useful as an index of consumer exposure to illegal residues in raw meat and poultry. FSIS officials told us that they believe that such an index is not needed, because sampling under the national residue monitoring program is directed to critical problem areas already. A working-level interagency group with representatives from FSIS, FDA, EPA, and the USDA Cooperative Extension Service meets periodically to determine what substances are to be tested for in the monitoring program based on estimates about where residues are most likely to occur and previous program experience.

Agencies' information on repeat violators

An important part of any regulatory program is record-keeping. Records must be kept about producers, inspection results, and violations and their frequency so that agencies can concentrate limited resources on firms, processes, and products most likely to present significant problems. Our reports of Federal food regulation documented deficiencies in agencies' ability to track repeat violators or products which represented critical problem areas, and our update showed this still to be an issue in raw meat and poultry residue regulation.

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

Data on USDA-inspected plants

In a 1981 survey of FSIS-inspected meat and poultry slaughter plants, we found that inspection program supervisors at times did not document adequately the results of their required monthly plant review.[17] Lack of documentation, we concluded, weakened FSIS monitoring of plant compliance with inspection program requirements. Documentation should provide a record of compliance trends and deficiencies in need of followup. We recommended that the Administrator, FSIS, instruct plant inspectors on the need to document all deficiencies found during sanitation inspection and emphasize to supervisors that deficiency records need to be kept.

Update

USDA has responded to our concerns by outlining specific actions underway to strengthen sanitation program recordkeeping. USDA reported that work-unit meetings between inspectors and supervisors were being used increasingly to enhance awareness of recordkeeping responsibilities. FSIS also implemented an establishment review and evaluation reporting system for use by supervisors in conducting plant and inspection reviews to assist in documenting sanitation deficiencies. FSIS developed new forms, the establishment review and evaluation report and worksheet, for use in documenting review results. According to USDA, the information from such reviews and documents will allow regions to identify slaughter establishments requiring additional inspection effort and those continually failing to comply.

Data on repeat residue violators

In April 1979, we reported that lack of data about repeat violators impeded effective regulation of raw meat and poultry that contained potentially harmful residues of animal drugs, pesticides, or environmental contaminants.[18] We stated that FDA could not develop case histories from data furnished it by USDA sufficient to take strong regulatory action against growers who marketed animals found to contain illegal residues. Animals sampled for residues by USDA were taken at random, making it unlikely that a grower would be sampled frequently enough to develop a criminal case or injunction. We also found that USDA's required pretest for identified growers with previous residue violations was easily avoided by shipping animals to an auction house or to a different slaughterhouse so that little likelihood existed of adequate followup data from that source.

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[17]"Improving Sanitation and Federal Inspection at Slaughter Plants: How To Get Better Results for the Inspection Dollar" (CED-81-118, July 30, 1981).

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

Some steps we recommended to improve followup of violative growers required legislative change. We recommended that the Congress amend the

--Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize USDA to (1) quarantine animals from a violative grower and (2) require growers to place an identification tag on animals;

--Federal Food, Drug, and Cosmetic Act to make misuse of animal drugs illegal and to authorize the use of civil penalties for residue violations; and

--Federal Insecticide, Fungicide, and Rodenticide Act to better enable EPA to identify the possible misuse of pesticides.

We also recommended that the Secretary of Agriculture develop (1) a sampling program designed to enable FDA to develop case histories on violative growers and (2) a more effective pretest system to prevent growers from shipping additional violative animals.

Although it agreed in 1979 with the need for better data for FDA to use in developing case histories, USDA believed significant improvements were not possible at the time given USDA's authority and limited resources.

Update

We found little progress in the agencies' obtaining adequate data for regulatory action against meat and poultry producers who repeatedly market animals having excessive levels of animal drugs, pesticides, or environmental contaminants. As discussed in chapter 2, no statutory changes have occurred. USDA's residue monitoring program remains a random sampling of animals presented for USDA inspection. FSIS officials emphasize that the monitoring program is not an enforcement program and thus is not designed to screen for repeat violators.

According to the Director, Residue Evaluation and Planning Division, FSIS, case files in the USDA regions show that recent USDA experience is that once an illegal residue is discovered, USDA can trace owners of violative poultry in every case, while owners of violative livestock can be traced in 70 percent of the cases. FSIS procedures require "possible repeat violator" to be stamped on case reports when they are referred to FDA. However, according to the Associate Director for Surveillance and Compliance, FDA's Bureau of Veterinary Medicine, determining which USDA-referred illegal residue cases concern repeat violators is strictly by chance. Although some improvements have been made in data collection about residues of pesticides or toxic chemicals, the official believes it fair to say that no changes have occurred in FDA's followup of repeat violators of residue tolerances in raw meat and poultry since our 1979 report. As discussed on page 41,

FDA now has guidance about when violative residue findings are to be followed up.

In our 1979 report, we also concluded that USDA's voluntary program of pretesting animals suspected of violating residue levels was an ineffective followup tool in residue regulation. In response to our report, USDA said that it should follow up on all pretest cases and that it planned to shift resources into that activity. We found that 54.5 percent of growers between 1974 and 1976 voluntarily submitted animals for pretest.

In following up, we were unable to determine if USDA had responded to our concerns, if the rate of voluntary pretest compliance had improved, or if USDA's pretest followup had improved because information about pretesting is kept at the USDA regional level. FSIS headquarters officials whom we interviewed said they believed that the pretest requirement can still be avoided by marketing through middlemen.

Data on repeat import violations

We concluded in a June 1979 report[19] that FDA inspectors responsible for sampling for illegal pesticide residues in food products imported into the United States were handicapped because they often were not aware of previous importer violations. FDA headquarters did not notify inspectors of all violations detected at other points of entry. Thus, inspectors were not alerted to shipments which should have been detained for residue testing. We recommended that FDA take steps to provide inspectors with results of all violative laboratory analyses so that importers and products found repeatedly in violation could be identified and prevented from entering the U.S. market before FDA analyses were completed.

In response, FDA reported it had already initiated a change in procedure to provide its districts with lists of products found violative, and other needed information.

Update

FDA has responded to our concerns. FDA districts currently have three sources of information about importer violations: ad hoc import alerts about specific importer problems that occur; weekly detention lists which provide aggregate data on the shipper, the country of origin, the importer, and the reason for the violation, from all points of entry by commodity; and an annual summary of import program results. According to the FDA Compliance Program Guidance Manual for import foods in fiscal year 1982, these data, among other sources, are to be used by FDA districts

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[19]"Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential" (CED-79-43, June 22, 1979).

in determining imported products to be examined. Also, as discussed on page 46, FDA may also require a shipper/grower of fresh produce who has a history of pesticide residue violations to certify that his or her goods are in compliance.

REPORTS FOUND AGENCIES HAD NOT MANAGED STAFFS ADEQUATELY

Regulating food safety is a complex, technical, and labor-intensive undertaking. To make the best use of increasingly limited resources, agencies need to make effective use of personnel to assure maximum productivity, plan adequately for staff requirements to meet workloads, and ensure that employees are adequately trained and are performing well. We have reported that personnel management problems, such as lack of effective operating procedures and poor training and supervision, have impeded effective food protection programs. The agencies have undertaken a number of initiatives to overcome these problems, but resource constraints or inefficient and ineffective procedures continue to adversely affect agencies' personnel management.

Operating procedures which affect personnel

Our past reports noted that food regulation programs could be made more effective by operating procedures which made better use of limited personnel resources. FDA and USDA have made some changes, but problems remain.

USDA's slaughter inspection procedures

In a July 1981 report[20] we stated that FSIS staff shortages limited the USDA slaughter inspection program's effectiveness. In February 1981, about 7 percent of FSIS' 5,995 authorized slaughter inspector positions were vacant because of hiring restrictions and budget constraints, although inspection duties were being performed by temporary personnel.

Staff shortages resulted in temporary reassignments of other FSIS personnel to slaughter inspection duties, which resulted in reduced supervision and monitoring and reduced inspections of processing operations, among other difficulties. We recommended some changes in inspection procedures to alleviate the shortage. For example, we recommended that procedures be changed so that USDA slaughter inspectors would spend less time examining meat carcasses for dressing defects (presence of contamination or unwholesome or inedible parts) that plants' personnel were responsible for checking.

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[20] "Improving Sanitation and Federal Inspection at Slaughter Plants: How To Get Better Results for the Inspection Dollar" (CED-81-118, July 30, 1981).

Responding to the recommendations in November 1981, USDA reported that the vacancy rate for slaughter inspector positions had increased to 9 percent since February 1981. USDA described FSIS' actions to improve management and procedural techniques, including new techniques for ante-mortem and post-mortem poultry and swine inspection and quality control and modification of traditional inspection procedures.

Update

USDA has responded to our concerns, but slaughter inspector vacancies continued to affect other FSIS functions such as supervision or processing inspection. In our followup we found that the slaughter inspector vacancy rate had dropped to 5 percent by October 1982. However, FSIS continued to fill slaughter inspector positions temporarily by reassigning FSIS personnel from other duties.

One change we recommended in 1977 in USDA operating procedures to more effectively use limited personnel resources is being partly implemented on a test basis.[21] We reported that efficiencies could be achieved in meat and poultry processing plant inspections if inspection frequency was tailored to the inspection needs of individual plants. USDA had been inspecting meat and poultry processing plants daily although it had found few or no problems in the plants' sanitary conditions, plant equipment, facilities, and processing methods. We recommended that USDA seek legislative authority to move to a system of periodic, unannounced plant inspections, coupled with required in-plant quality control systems and civil penalties for violators.

USDA has responded to our concerns. It has sought additional authority for periodic inspections, however, without mandatory quality programs or civil penalties. On April 1, 1982, a USDA legislative proposal to amend the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act was introduced in the Senate as S. 2348 and in the House as H.R. 6062. The proposed changes to USDA's meat and poultry processing inspection authority would have given the Secretary of Agriculture discretionary authority to decide how intensively processing operations must be inspected and would have permitted, according to USDA, use of inspection staff resources in slaughter plants and other areas where the need is greatest. The Congress did not act on the bills during the 97th Congress. The bill was reintroduced in the House during the 98th Congress as H.R. 2691.

In the interim, USDA has moved to a voluntary program of in-plant quality control for processing plants. As of July 7, 1983, total quality control programs had been implemented in 167 of the more than 6,500 processing and combination slaughter/processing

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[21]"A Better Way for the Department of Agriculture To Inspect Meat and Poultry Processing Plants" (CED-78-11, Dec. 9, 1977).

plants inspected by USDA. Quality control programs for 184 additional plants had been approved, but plans were awaiting implementation.

FDA's import inspection procedures

In 1977, FDA pointed to resource limitations as a factor preventing it from giving sufficient inspection coverage to imported products.[22] We recommended methods such as cooperative agreements with exporting countries ensuring that products were safe, pure, and wholesome as one means of alleviating the effects of resource limitations. FDA responded that it believed it had been sufficiently aggressive in developing cooperative certification agreements and that countries most likely to export violative products were frequently the least capable of carrying out a cooperative certification agreement.

FDA planned to improve inspection effectiveness by providing its districts with better data on potentially violative products, allowing inspectors to be alert to problems.

Update

In following up, we found that FDA had made the changes which it had planned. FDA districts now are provided with import alerts and weekly detention lists of violative products at all points of entry. The Associate Director for Compliance, Bureau of Foods, FDA, estimated that approximately 20 percent of FDA-regulated imports are now inspected and that further coverage is limited by resource constraints.

Procedures for response to contamination incidents

In a December 1980 report[23] we concluded that a 1979 incident involving contamination by polychlorinated biphenyls[24] of chickens and other food items in several Western States took USDA and FDA too long to identify and control. Contaminated products became quickly and widely dispersed through food marketing channels. We estimated that $3.5 million in costs and the human health risk could have been avoided if agencies had had better procedures to allow personnel to respond to such incidents in a more timely manner.

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[22]"Food and Drug Administration's Program for Regulating Imported Products Needs Improving" (HRD-77-72, July 5, 1977).

[23]"Further Federal Action Needed To Detect and Control Environmental Contamination of Food" (CED-81-19, Dec. 31, 1980).

[24]Polychlorinated biphenyls are toxic industrial chemicals once widely used as heat-transfer fluids and additives.

We recommended that the Secretaries of Agriculture and HHS and the Administrator of EPA clearly define which agency would assume the leadership role under the various circumstances and conditions which were anticipated. In response, USDA, EPA, and HHS generally agreed that the leadership role of the agencies involved in identifying and resolving the problems raised by food contamination incidents should be more clearly defined.

Update

The agencies have responded to our concerns although USDA, HHS, and EPA have not formally designated a lead agency through a memorandum of understanding. According to FSIS and FDA officials, a lead agency designation is not needed because the interagency system developed and implemented since 1979 works well. USDA's contamination response system ties in to FDA's and EPA's emergency response procedures. As incidents occur, the lead agency is determined, according to officials.

In the 1979 contamination incident, we found that it took 28 days for USDA to confirm a residue violation. According to the FSIS Deputy Administrator for Science, FSIS set a goal subsequently to notify a plant inspector of a confirmed contaminated residue monitoring sample within 14 calendar days, or half the time. Under USDA's new procedures, when a suspect sample is found, FSIS headquarters, the USDA contamination response system, and the USDA region are notified, usually within 11 days. According to the FSIS Deputy Administrator for Science, the in-plant USDA inspector then can begin to take action to determine the source of the problem or can detain the product if it is still in the plant.

USDA's program supervision and training

In 1981 we reported that supervision of USDA's slaughter inspection program and training of slaughter inspection personnel presented problems. Our update shows the issues still are valid.

We reported in 1981 that FSIS meat and poultry slaughter plant inspection program supervisors had rarely given plants included in our review unacceptable ratings even when conditions appeared to warrant them.[25] We concluded that FSIS needed to provide better guidance to inspection program supervisors on rating plants acceptable or unacceptable, so that ratings would be objective and uniform. We stated that overreliance on raters' judgment promoted inconsistency which might undermine assurance of slaughter plant inspection program compliance.

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[25]"Improving Sanitation and Federal Inspection at Slaughter Plants: How To Get Better Results for the Inspection Dollar" (CED-81-118, July 30, 1981).

In response to the report, USDA stated that a comprehensive establishment review and evaluation reporting system scheduled for implementation in fiscal year 1982 would provide inspection program supervisors with forms specifying objective criteria and a revised rating system for plants.

Update

Because it disagreed with the need for guidelines, USDA has not responded to our concerns. New forms in use in the USDA establishment review and evaluation reporting system allow consistency in review scope between supervisors because they provide a detailed review checklist in each of five program areas. They do not, however, provide guidelines on whether a variation in plant facilities or procedures is major or minor, nor do they indicate when a pl is to be rated unacceptable in each inspection program area overall. According to meat and poultry inspection program icials, such ratings are appropriately dgmental, and adequat uidelines are provided by existing policy and procedural dire ves.

Water system guidelines

Our 1981 report also stated that FSIS inspectors often did not know what to look for in assessing slaughter plants' water systems. We recommended that FSIS issue more detailed guidelines on inspection program requirements for slaughter plant water systems, including illustrations and descriptions of deficiencies likely to be found. Inadequate plant water systems can allow contaminated water to contact meat and poultry carcasses.

In response, USDA stated that FSIS would issue detailed guidelines during fiscal year 1982 covering detection of in-plant water supply problems associated with product contamination. USDA also stated that a cooperative program with industry was being launched to jointly arrive at solutions to minimize water system problems.

Update

USDA has responded to our concerns. FSIS hired a consultant to work with FSIS staff on water system problems, and training seminars were being held for inspection program supervisors. Also, FSIS performed a one-time review of plant water systems in the fall of 1982. The review covered 400 plants, including the 39 plants which we found to have water system problems. At the time of our followup, the FSIS Review and Evaluation Staff had completed its field work and was drafting a report.

REPORTS FOUND CORRECTIVE ACTION DIFFICULT TO OBTAIN

Agencies must have good means of ensuring corrective action on identified problems. To achieve effective corrective action,

USDA and FDA should have good followup systems and should employ available enforcement options to obtain compliance.

Our past reports have found that agencies were not always effective in obtaining corrective action. In many instances, criteria to guide agency enforcement personnel in deciding about proceeding against violators did not exist. Our update shows that past issues concerning agency followup adequacy and use of enforcement options still are valid.

Agency followup systems

Effective followup of firms repeatedly marketing unsafe food and food products requires good recordkeeping and close coordination between agencies. We reported in the past that agencies were not always effective in following up violators in the programs we reviewed. Although we found in our update that agencies had paid attention to the need for better recordkeeping, problems remain in meat and poultry residue followup, in part because regulatory responsibility is shared, and in imported produce.

Meat and poultry residue followup

In 1979, we found that although FDA and EPA were required to determine the cause of and corrective actions needed for residue violations that USDA found in raw meat and poultry, FDA generally did not do so.[26] (We did not review EPA performance in this area.) We found, for example, that during the 4-year period ended December 1976, USDA reported 3,124 residue violations to FDA for followup. FDA district offices reported investigations on only 1,161, or 37 percent, of the cases.

We recommended that the Secretary of HHS direct the FDA Commissioner to establish guidelines to ensure effective followup on residue violations referred by USDA. In response, HHS said it was considering modifications to its guidelines.

Update

FDA has responded to our concerns. However, Bureau of Veterinary Medicine (BVM) officials stated that identifying an animal's owner and tracking repeat violators are still problems, partly because FSIS still does not adequately document cases. On the other hand, the FSIS Director of Residue Evaluation and Planning stated that FSIS personnel may not believe better documentation for FDA is useful because no court cases result.

According to BVM's Associate Director for Surveillance and Compliance, FDA as a matter of policy investigates all reports of

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

animals with violative levels of pesticides or industrial chemicals whose owners can be identified. Animal drug violations would be investigated by a site visit only if a pattern of misuse were present, the residue was substantially above the established tolerance or action level, or the residue resulted from the illegal use of a banned drug or from a drug not approved for food animals.

The fiscal years 1982 and 1983 FDA Compliance Program Guidance Manual on illegal residues in meat and poultry states that FDA districts will conduct an investigation by letter, telephone contact, or on-site visit for all illegal tissue residue findings reported by USDA. Exceptions to this policy occur when residues were found only at the injection site; when residues were not specifically identified; or when residues were found in animals voluntarily submitted by producers for USDA pretest. FDA districts are not to investigate when past experience has shown the animal's owner cannot be traced.

In our update, we found that during fiscal years 1979-81, USDA referred approximately 1,500 tissue sample residue findings, not all of which were violative, to FDA. FDA stated in its fiscal year 1983 justification of appropriation estimates that in fiscal year 1981 it had performed 367 investigations and that it planned to perform 360 investigations in both fiscal years 1982 and 1983. At that rate, FDA would be investigating about one-fourth of the approximately 1,500 violations referred to it annually by USDA, compared to the 37 percent we reported earlier. As mentioned previously, determining which cases concern repeat violators is not systematic.

Commenting on this study, the Associate Director for Surveillance and Compliance, BVM, stated that, although the data are not yet complete, in fiscal year 1982 FDA followed up on an estimated 48 percent of the 2,330 violative residue reports from USDA and that further followup improvements are underway.

Histories of import violators

In 1979, we found that FDA had problems regulating imported food containing pesticide residues.[27] We found that food would probably be marketed and consumed before FDA could confirm a residue violation and recall it. Existing law and FDA procedures permitted imported products, primarily perishable foods such as produce and fresh fish, to be marketed before completion of FDA residue analysis if the product had no known history of residue violation.

We reported in 1979 that FDA also had not effectively implemented its policy that perishable food be held intact until

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[27]"Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential" (CED-79-43, June 22, 1979).

residue analyses were complete for imports with histories of violations. FDA inspectors were unaware of importer and product quality histories and were not detaining shipments pending analysis results. We recommended that the Secretary of HHS, through the Commissioner, FDA, provide for the timely completion and reporting of laboratory analyses to FDA inspectors so that they could take action to prevent the marketing of adulterated food and food suspected of being adulterated.

In commenting on the report, HHS said that a change in procedure had been initiated to provide each district with a listing of all products found violative at all points of entry, including information on the commodity, the shipper, the importer, and the violation's cause, and that it tried to always provide timely laboratory analysis.

Update

Although FDA has undertaken program improvements in its regulation of imported foods, FDA management reports show that shipments of Mexican produce containing violative pesticide residues are entering the U.S. market even though FDA has placed special emphasis on this area.

FDA's special-emphasis program for pesticide residues in Mexican produce was implemented in fiscal year 1979. Mexican produce imported into the United States was selected for emphasis because of the importance of such produce in the U.S. diet and its history of relatively high pesticide violation rates. Among other special features, the program includes increased sampling directed to problem areas determined on the basis of background information, such as peak shipping periods, and continuing FDA headquarters program evaluation and reporting. We were told that the number of shipments sampled under FDA's special-emphasis Mexican program is equal to the total number of shipments sampled from all other countries.

In fiscal year 1981, almost one-third of the Mexican produce shipments found to contain violative pesticide residues under FDA's special-emphasis program entered U.S. commerce. The chart below shows Mexican produce shipments entering commerce with illegal residues.

Fiscal year	Shipments with illegal residues	Denied entry	Recalled	Certificate required[a]	Entered commerce	
					No.	Percent
1979	106	88	2	1	16	15.1
1980	178	115	5	4	58	32.6
1981	103	64	5	6	34	33.0

[a]When FDA detects a pattern of violative produce shipments from the same shipper/grower, it may invoke a requirement for certification that the shipment complies with the law. Shipments subject to a certification requirement which are not accompanied by a certificate are detained by FDA without sampling.

Source: Internal FDA documents.

According to FDA annual reports of findings from the Mexican produce special-emphasis program, most shipments of Mexican produce entering commerce which were found to contain illegal residues were shipments sampled on a routine surveillance basis where FDA had no reason to suspect that illegal residues might be present.

Commenting on this follow-on study, FDA noted that a given violative shipment may have entered commerce before sample analysis was complete; however, the finding of an illegal residue in that shipment triggered FDA followup actions which would preclude further shipments from entering commerce until sample analysis was complete. Further, the Scientific Coordinator, Office of Regulatory Affairs, FDA, said that the levels and types of pesticide residues that FDA has found in imported food do not pose a threat to the public health.

During our followup we asked whether FDA had considered developing a rapid analysis screening test for produce pesticide residues. A rapid pesticide screening test could enable FDA to determine on-site whether a shipment should be considered suspect and held. The FDA Assistant to the Director, Division of Chemical Technology, Bureau of Foods, told us that development of such a screening test for produce pesticide residues was not feasible because of the nature of the analytical methods required.

We were unable to determine the tonnage of produce which was involved in the shipments allowed entry before presence of illegal residues was known. Sixty-three, or 58 percent, of the 108 shipments which entered from 1979 to 1981 were either peppers, strawberries, or tomatoes. USDA statistics for fiscal year 1982 showed the following tonnages of peppers, strawberries, and tomatoes imported from Mexico:

	Volume imported FY 1982 (in pounds)
Peppers	179,500,000
Strawberries	232,800,000
Tomatoes	583,700,000

Source: U.S. Imports of Fruits and Vegetables Under Plant Quarantine Regulations, Fiscal Year 1982, USDA.

Interagency violation referrals

In our 1981 report assessing domestic pesticide regulation,[28] we found that FDA referrals to EPA of pesticide residue violations in domestically produced food lacked management control. Neither agency maintained records of referrals, and neither followed up to determine the status of investigations. We recommended that FDA and EPA improve management controls over referrals and strengthen their coordination to help assure that pesticide residue violations were investigated.

FDA agreed with the recommendation and stated that it planned to more formally and systematically document its referrals to EPA of violative pesticide residues in food. It also planned to discuss with EPA the need for better methods of notifying FDA on the outcomes of pesticide misuse cases referred to EPA.

Update

FDA has responded to our concerns. FDA reviewed its procedures and as a consequence issued a Field Management Directive for regional and district offices in February 1982, which included criteria for determining when EPA referrals should be made and provided for feedback on the outcomes of the investigations.

Criteria for enforcement decisions

Agencies responsible for regulating food safety have a variety of enforcement options available to them under existing statutes, ranging in severity from oral or written warnings to product detentions, seizures and injunctions, inspection withdrawal, and criminal proceedings. FDA and USDA also may request that manufacturers voluntarily recall violative products.

Our reports have stated that the agencies generally pursued only the mildest enforcement actions against violators. Appropriate use of existing penalties for noncompliance with agency regulations is essential to effectively meeting the objectives of food safety legislation. We found in our update that agencies still

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[28]"Stronger Enforcement Needed Against Misuse of Pesticides" (CED-82-5, Oct. 15, 1981).

pursue the mildest enforcement options and in some instances have begun cooperative efforts for voluntary industry compliance. This trend toward industry volunteerism appears to be occurring because of the reality of declining Federal food safety resources, and changing regulatory philosophies.

Illegal import penalties

FDA policy and procedures permit importers to deliver perishable goods--such as perishable produce, fresh fish and seafood--before FDA has analyzed samples of shipments for adulterants if holding the shipment would cause it to spoil. FFDCA requires importers of food and food products to file a "good and sufficient" bond--a so-called redelivery bond--with U.S. Customs to pay for damages in case importers fail to return products to Customs for FDA disposition when adulteration has been confirmed by FDA analysis. In two reports[29] about FDA regulation of imports in 1977 and 1979, we found bonds were ineffectively used as enforcement tools.

In 1977, we found that redelivery bond penalties assessed against importers varied because FDA did not have uniform criteria to guide its district offices in advising Customs about how large a penalty should be imposed. Three FDA districts we reviewed varied in guidance available about penalties and in penalties imposed. Generally, penalties were small. Because import penalties should be severe enough to deter repetitive violations, we reported that we did not believe unauthorized distributions were being discouraged by the many small penalties that were assessed.

In 1979, we concluded that the redelivery bonds were totally ineffective as enforcement tools for violative importers of food products. Essentially, we concluded there was no penalty for adulterated imports, provided importers made "good faith" efforts to reclaim products. Violative food would probably be marketed and consumed before FDA confirmed a violation and thus would be impossible for the importer to recall.

We recommended automatic forfeiture of redelivery bonds for violative food products which had been marketed. In response, FDA said it would consider further inclusion of penalties--such as automatic forfeiture of redelivery bonds--in importer agreements.

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[29] "Food and Drug Administration's Program for Regulating Imported Products Needs Improving" (HRD-77-72, July 5, 1977) and "Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential" (CED-79-43, June 22, 1979).

Update

Because it disagreed with us, FDA has not responded to our concerns. In December 1980, we reported[30] that FDA, after further considering our 1979 recommendation, believed that including provisions for penalties in importer agreements would be inappropriate. FDA also stated that in fiscal year 1980 it adopted a revised import enforcement guideline that states that when FDA district offices encounter two or more violative shipments of fresh produce from the same shipper/grower, they may invoke a requirement for certification that the suspect food complies with the law. The certificate required shows the results of an independent laboratory analysis for pesticide residues. If a shipment which is under a certification requirement is presented for FDA inspection without a certificate, it is automatically detained by FDA without sampling.

We found in this followup that the revised import enforcement guidelines adopted by FDA in fiscal year 1980 refer to shipments of fresh produce only, although fresh fish and seafood are also permitted to enter pending FDA sample analysis results.[31] Since FDA adopted revised import enforcement guidelines, it has invoked certification 12 times for importers whose fresh Mexican produce shipments were determined to contain illegal pesticide residues.

In spite of this, we found, as shown on page 43, that the percent of shipments from Mexico entering U.S. commerce with illegal residues has been increasing. Also, although the concepts embodied in the special-emphasis Mexican program were to have been extended to other FDA import program areas, they have not been because of resource constraints. FDA also continues to disagree with the need for importer penalties because it believes that penalities should be directed at the shipper/grower responsible for the food's adulteration.

Animal residue enforcement

FDA regulates chemical residues in domestically produced animals by setting tolerances. Cases where excessive residues of

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[30]"Further Federal Action Needed To Detect and Control Environmental Contamination of Food" (CED-81-19, Dec. 31, 1980).

[31]FDA regulatory action procedures against imported produce with illegal pesticide residues are two-phase: (1) certification requirement, also called border closing or automatic detention, and (2) block listing. The first phase occurs when an FDA district encounters two or more shipments of violative produce from the same shipper/grower. Block listing is a regulatory action which may follow a certification requirement if FDA perceives that a pesticide problem on imported produce is widespread in a particular country. Block-listed products are detained without FDA sampling and analysis.

animal drugs, pesticides, or industrial contaminants are found in raw meat and poultry sampled by USDA are referred to FDA for regulatory action. In 1979, we found FDA generally issued information letters, the least severe regulatory alternative, to growers notifying them of excessive residues and requesting corrective action.[32] Information letters were used in lieu of stronger regulatory alternatives such as regulatory letters,[33] product seizures, grower injunction, or criminal prosecution of growers.

In response to the report's recommendations for FDA to more effectively use regulatory alternatives and to establish followup guidelines, FDA reported it was studying ways to improve its enforcement procedures and was considering modifications to its guidelines for investigation of residue violations.

Update

FDA issued guidelines for investigation followup, as mentioned on page 41. However, BVM officials stated that employing enforcement alternatives stronger than a Notice of Adverse Findings letter remains generally problematic because so many violations have to be documented in building a criminal case. According to the Associate Director for Surveillance and Compliance, BVM, only one court case had been brought under FFDCA for residue violations prior to fiscal year 1983. In fiscal year 1983, because of a severe problem with veal producers using a banned growth hormone, FDA successfully obtained injunctions against six violative producers.

The Acting Deputy Director, BVM, stated that he believed the current FDA enforcement authority for residues to be too cumbersome, among other animal residue regulation difficulties, and that intermediate authority such as civil penalties is needed. BVM is considering the use of certificates by animal producers or auction barns which would certify that the animal was produced in compliance with regulations. Also, USDA has changed its regulatory philosophy to emphasize preventing residues through cooperative producer education and residue programs in the industry itself, rather than emphasizing sampling as a basis for FDA regulatory action.

Residues have dropped. We found that violative residues in animals sampled by USDA have dropped. We calculated the current percent by dressed weight of USDA-sampled raw meat and poultry containing violative residues. For the period 1979-81, the percent was 7.4 percent, almost half the 14.3 percent we reported as

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

[33]FDA issues regulatory letters to warn the alleged violator that, unless he or she takes corrective action, the agency is prepared to take additional regulatory action.

occurring in 1974-76. The chart below shows the changes in violation rates and sample sizes.

Species	1974-76 Number sampled	1974-76 GAO-calculated violation rate (percent)	1979-81 Number sampled	1979-81 GAO-calculated violation rate (percent)
Cattle	16,780	14.96	12,634	7.0
Calves	8,217	8.84	6,427	8.2
Sheep	3,315	2.60	2,948	0.9
Swine	8,613	15.83	24,367	8.1
Chickens	9,157	5.08	7,242	1.7
Turkeys	6,743	8.46	5,462	12.8
(Percent violative by dressed weight)		(14.30)		(7.4)
Total	52,825		59,080	

Source: Internal FSIS documents and GAO report HRD-79-10.

The Director, Residue Evaluation and Planning Division, FSIS, stated that some progress had been made in reducing sulfa drugs in swine, antibiotics in calves and cull dairy cows, and in chlorinated hydrocarbon pesticide residues generally, because some of those substances have been banned. FSIS officials also stated that the reduction can be attributed to FSIS initiatives in developing and using in-plant screening tests, and cooperative producer education.

Enforcement in USDA-inspected plants

In reports[34] issued in 1977 and 1981 about USDA inspection of meat and poultry processing and slaughter plants, we found that USDA rarely imposed inspection withdrawal for plants having substantial records of problems in complying with meat and poultry inspection program requirements. Under USDA's inspection program FSIS can withdraw inspection when a plant has been found to produce adulterated products due to unsanitary plant conditions, or where plant management fails to destroy condemned products. Inspection withdrawal hurts plants economically because it prevents production and shipping of products.

In our 1977 report, we concluded that authority for USDA to require processing plant managements to develop and carry out adequate, reliable quality control systems should be coupled with

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[34]"A Better Way for the Department of Agriculture To Inspect Meat and Poultry Processing Plants" (CED-78-11, Dec. 9, 1977) and "Improving Sanitation and Federal Inspection at Slaughter Plants: How To Get Better Results for the Inspection Dollar" (CED-81-118, July 30, 1981).

authority to apply strong penalties or ctions when plant managements fail to carry out their respon lities. We recommended to the Congress that the Federal Meat I ection Act and the Poultry Products Inspection Act be amended t among other changes, authorize the Secretary of Agriculture to impose civil penalties of up to $100,000 for meat and poultry processing plants failing to take appropriate corrective action.

USDA, in response, advised us that it could not take a position on our recommendations at the time of the report. As discussed on page 20, a bill to effect changes in USDA's processing inspection was introduced in the 97th Congress, but the bill was not passed. However, the bill did not provide for civil penalty authority.

In our 1981 report about FSIS inspection at slaughter plants, we concluded that FSIS needs to have its inspectors and supervisors adopt a stronger enforcement attitude. We recommended, among other actions, that the Secretary of Agriculture direct the FSIS Administrator to provide meat and poultry inspection program supervisors with improved plant rating criteria that (1) could be applied uniformly and (2) specified review findings which would require a plant to be rated unacceptable in each rating area and overall. We also recommended that the Administrator require meat and poultry inspectors and supervisors to enforce FSIS sanitation requirements more strictly. USDA did not comment on those recommendations at the time of the report.

Update

USDA has not responded to our concerns because FSIS officials do not agree with the need for plant review criteria which specify findings that require a plant to be rated unacceptable. The FSIS establishment review and evaluation reporting system provides a new plant review form for use by inspection program supervisors. However, as discussed on page 39, the form and its glossary do not spell out what constitutes a minor or major plant variation from inspection program requirements, or how many variations must be scored to trigger an unacceptable rating. Meat and poultry inspection program officials believe such ratings are appropriately judgmental. We disagree because we continue to believe the ratings will provide little assurance that the raters are as objective as they should be and that uniform rating criteria are used and understood by all raters, as we reported in 1981.

We were not able to document any improvement in enforcement of sanitation requirements. We were told by the Deputy Administrator, Meat and Poultry Inspection Technical Services, that FSIS emphasizes to its in-plant personnel that they are not in plants to penalize firms for mistakes, but to achieve compliance with laws and regulations through corrective action. This includes the use of existing authority to condemn adulterated products, withhold inspection pending correction of problems, or other day-to-day enforcement actions which achieve the objectives of the laws and also have a financial impact.

In discussing the need for a stronger enforcement attitude, evidenced by more frequent plant inspection suspensions or withdrawals, the Director, FSIS Review and Evaluation Staff, commented that she believes inspection withdrawal is not a practical enforcement tool because by the time documentation is compiled to suspend or withdraw inspection, causes will have been corrected and other problems will have appeared. An internal USDA study, "Food Safety and Quality Service: A Strengthened Meat and Poultry Inspection Program" (June 1978) also concluded that inspection withdrawal is not an effective enforcement tool. USDA has not sought additional authority for enforcement tools which might be more practical and timely, such as civil penalties.

REPORTS FOUND SCIENTIFIC CONSIDERATIONS LIMITED AGENCIES' FOOD REGULATION EFFORTS

Much public attention has focused recently on the 1958 Delaney Clause of FFDCA. That clause prohibits use of food additives found to cause cancer in animals or in man. We reported in 1981[35] that experts generally agreed the clause was too inflexible as it is written because technology since its 1958 passage had progressed so that very low levels of substances could be detected, calling into question the human health risk presented.

We have reported that in other food regulation areas, scientific considerations limited agencies' ability to increase their effectiveness in areas such as pre-market additive approvals or in monitoring food supply safety because sometimes the scientific data are unclear or technology is unavailable. Our update showed progress in this area; however, the scientific state of the art will continue to limit Federal food regulation programs.

Procedures for FDA pre-market approvals

Under FFDCA, FDA is responsible for regulating direct food additives such as preservatives and indirect food additives such as packaging materials, including approving these additives' use before marketing. In an August 1980 report,[36] we found that FDA had not published regulations clearly defining the scientific evidence needed to support the safety of a food additive or the criteria it used to evaluate such information in petitions submitted for its approval, which would have made the process more efficient. We stated that legitimate differences of opinion can occur in the evaluation of scientific evidence, and some experts

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[35] "Regulation of Cancer-Causing Food Additives--Time for a Change?" (HRD-82-3, Dec. 11, 1981).

[36] "Need for More Effective Regulation of Direct Additives to Food" (HRD-80-90, Aug. 14, 1980).

might be willing to accept less scientific evidence of safety than FDA considers adequate. We recommended that the Secretary, HHS, direct the FDA Commissioner to publish regulations establishing review criteria for assessing the safety of food additives and issue guidance defining methods and controls to be used in conducting scientific safety tests.

FDA had recognized the need to develop and publish definitive scientific testing guidelines and review criteria for determining the safety of food substances. In response to our recommendation, HHS said that FDA had drafted a series of protocols for biological studies and criteria for evaluating those tests. These were to be published both in scientific literature and in the Federal Register. HHS pointed out, however, that it was not possible to develop standards specific enough to anticipate all situations, nor was it desirable to preclude the exercise of scientific judgment.

Update

FDA has responded to our concerns. FDA published the notice of availability for public comment of the "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used In Food" in the Federal Register on October 15, 1982.

In our January 1980 report[37] on an FDA-sponsored study of nitrite, a substance used to preserve, color, and flavor meat, poultry, and fish, we noted that FDA did not have guidelines for design, data collection and reporting, and statistical evaluation of long-term toxicity studies done to determine the safety of food additives. A Massachusetts Institute of Technology study had indicated that nitrite might cause cancer. Reviews by scientists inside and outside of Government raised questions about the nitrite study's validity. We recommended, among other actions, that the Secretary, HHS, direct the FDA Commissioner to develop guidelines for design and data collection and reporting of long-term toxicity studies and establish standards and methods for statistically evaluating such studies.

Responding to the report, HHS commented that FDA agreed that guidelines could be helpful in designing long-term toxicity studies but pointed out the difficulty in developing a single set that would receive universal approval by the scientific community.

In following up, we found that FDA had published guidelines for toxicity testing of food additives, mentioned above, but that FDA had determined that it would not be appropriate to develop rigid standards for statistical evaluation of studies. Commenting

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[37]"Does Nitrite Cause Cancer? Concerns About Validity of FDA-Sponsored Study Delay Answers" (HRD-80-46, Jan. 31, 1980).

in October 1980, FDA noted that "tremendous biological variability" had been observed among experiments. FDA decided not to develop statistical evaluation procedures for long-term toxicity studies because it believes that the data produced by such studies are so varied that one set of guidelines would not be helpful.

Residue detection methods

Federal agency efforts to detect illegal residues of animal drugs, pesticides, or environmental contaminants in foods and to prevent distribution of residue-contaminated food have been and remain limited by the methods available for residue testing, although progress has been made. For example, in our 1979 report[38] about illegal residues in raw meat and poultry, we stated that during 1974-76, USDA's national residue monitoring program tested for 46 of the 143 drugs and pesticides we identified as likely to leave residues, and for 8 environmental contaminants (total number of contaminants unknown). Fifty-four toxic substances thus were included in USDA's monitoring program. We recommended that USDA expand its monitoring program.

Commenting on our report, USDA agreed that its residue program should be diversified and substantially expanded through a much larger volume of samples but noted that it was important to remember that some toxic substances lacked regulatory analytical methods that were feasible for routine monitoring. USDA said it was attempting to develop better methods and that it or other concerned agencies must conduct or foster research to speed the advancement of residue analysis technology.

Update

USDA has responded to our concerns. It has added new analysis methods and used existing methods for new compounds, although it still cannot detect residues of all possible contaminants. Using data supplied to us by FSIS Science Program officials, we determined that from 1979 to 1981, the national residue monitoring program included tests for 24 additional substances, including 6 additional environmental contaminants, compared to the period from 1974 to 1976. Four substances tested for from 1974 to 1976 were not tested for from 1979 to 1981. From 1979 to 1981, the national residue monitoring program tested for 60 animal drugs and pesticides and 13 environmental contaminants, a total of 73 substances.

Commenting on this study, the Deputy Director, Residue Evaluation and Planning Division, FSIS, stated that the number of compounds FSIS is capable of detecting may vary depending upon how the count is made--for example, whether related compounds such as DDT, DDE, and TDE are counted as one compound.

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

We also stated in our 1979 report that although raw meat and poultry were usually not held at the slaughterhouse longer than 48 hours, USDA took from 6 to 25 days to complete a residue analysis. Contaminated products would usually have been marketed and consumed before USDA could confirm a violation.

In our update, we found that USDA has improved the timeliness of its sample analysis, but products still may have been marketed and consumed before a violation is confirmed. A residue sample could be confirmed as violative within an average of 10.5 days during the period covered by our review. FSIS officials indicated that in their view more improvement using existing technology would not be cost effective.

USDA also has available a rapid screening test for antibiotic residues. The Swab Test on Premises, which screens suspect carcasses for antibiotics within 18 hours, allows the USDA inspector to detain a suspect carcass from being marketed.

REPORTS FOUND THE INDUSTRY SLOW TO IMPROVE QUALITY PRACTICES

Federal efforts to regulate the safety and wholesomeness of the U.S. food supply rely ultimately on the capacity and willingness of the food industry to regulate itself. Federal laws place responsibility for processing food under sanitary conditions and for producing wholesome and safe products on manufacturers. Our reports stated that some manufacturers had been slow in accepting their responsibility, making Government regulatory efforts more difficult.

Plants relied on Government personnel

We found in past reviews that many meat and poultry slaughter and processing plants had good quality-assurance practices but that others continued to rely on USDA personnel to perform quality-assurance functions which should have been the plants' responsibility.

In assessing USDA meat and poultry processing inspection program operations in 1977, we evaluated 24 plants and found that in 18 plants, plant management had fully accepted its responsibility for producing wholesome, unadulterated products, while in 6 plants, plant managements had not.[39] Those six plants (1) relied on the USDA inspector for quality control, (2) would do only what the inspector required in maintaining proper sanitary conditions, and (3) did not maintain a good history of plant compliance with inspection requirements.

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[39]"A Better Way for the Department of Agriculture To Inspect Meat and Poultry Processing Plants" (CED-78-11, Dec. 9, 1977).

We recommended legislative changes, including mandatory in-plant quality control at processor plants and civil penalties to address the issues of rising USDA inspection program costs and continued industry laxity. USDA did not comment on our recommendations because it was performing its own study.

Update

No action has been taken on our recommendations concerning mandatory quality control programs or civil penalties, and USDA did not agree with the need for them. As discussed on page 20, USDA introduced legislation during the 97th Congress which would have authorized less-than-continuous inspection at meat and poultry processing plants but which did not provide for mandatory quality control programs or civil penalties.

In 1981, we found that meat and poultry slaughter plants also sometimes did not fulfill their responsibilities for proper quality control.[40] Our report discussed instances of excessive plant reliance on USDA inspectors to police sanitation. We concluded that plant managers were not sufficiently committed to maintaining a high level of sanitation because problems such as flaking paint and rust, dirty overhead structures, and grease buildup indicated long-term neglect. We recommended that USDA develop a system of financial disincentives for slaughter plant managers who evidenced poor attitudes about good sanitation, including financial penalties, although this would require additional legal authority. USDA commented that it did not believe a system of financial penalties could be equitably or effectively administered.

In our update we found USDA continues to disagree with the recommendation to seek additional authority for financial penalties. USDA believes that current legal authorities are sufficient to correct sanitation problems. USDA does not plan to act on this recommendation.

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[40]"Improving Sanitation and Federal Inspection at Slaughter Plants: How To Get Better Results for the Inspection Dollar" (CED-81-118, July 30, 1981).

CHAPTER 4

ISSUES REMAIN TO BE ADDRESSED ALTHOUGH PROGRESS HAS BEEN MADE

ORGANIZATIONAL AND STATUTORY ISSUES REMAIN TO BE ADDRESSED

Past studies documented problems in Federal food regulation and made recommendations for organizational or statutory changes that have not been acted on by the Congress. Agencies have made progress in areas pointed out by our past reports and studies by other groups, but some issues remain to be addressed.

Past studies pointed out that the lack of an overall food safety policy had contributed to the regulatory system's complexity and regulatory overlaps and gaps in agency food safety programs. Overlap of USDA and FDA in-plant monitoring currently is not a matter of agency concern. The agencies negotiated an interagency agreement covering joint inspectional jurisdiction in 1979. One identified regulatory gap, toxic contamination of the food supply on the farm, will be addressed by a new USDA educational initiative, but enforcement problems for raw meat and poultry residues appear to be made more difficult by shared agency jurisdiction.

Agencies continue to monitor the food supply and enforce statutes using significantly different approaches. Although recommendations have been made to more closely align the agencies' authorities and allow greater flexibility, no changes have resulted.

Agency coordination through formal interagency agreements or working-level groups is ad hoc, although agency officials stated that coordination is good. USDA and FDA continue to coordinate monitoring and enforcement efforts case by case, negotiating interagency agreements in areas such as joint inspectional jurisdiction and toxic residues.

If the responsibility for food safety regulation continues to be divided, the issue of whether agencies should be guided by a common policy framework may need to be addressed. Food safety legislation has been enacted and amended over a period of almost 80 years, resulting in a patchwork regulatory process. Recent discussions in the Congress and the administration about modifying existing statutes offer an opportunity to assess the need for a consistent Federal food safety policy.

Another issue to be considered is whether existing approaches to monitoring and enforcement will be adequate in the future. Government cooperation with the food industry is increasing partly in response to Federal resource realities rather than because of a deliberate change in policy. As Federal dollars devoted to regulating food safety become more constrained and the U.S. food

supply becomes more complex, agencies will rely to a greater extent on the ability of the food industry to regulate itself.

PROGRAM ADMINISTRATION ISSUES REMAIN TO BE ADDRESSED

Although FDA and USDA have made some changes in food safety program administration which we recommended in past reports, the following broad issues raised by our recent look at agency progress in implementing past recommendations remain:

--How adequate are food regulatory agencies' management data systems? Recommendations calling for improved data have been met by agency resistance in some cases when the data have been costly to obtain and are viewed by management as being of little importance to certain programs.

--How well are food regulatory agencies managing their staff resources? Our followup suggests continuing problems with staff shortages and inefficient procedures.

--How well are agencies following up on repeat violators? Agencies have paid attention to the need for better recordkeeping, but tracking the source of problems remains difficult, in some cases partly because no one agency is totally responsible.

--How effective are existing enforcement options in obtaining corrective action or deterring violations? Agencies still pursue the mildest enforcement options and evidence exists of growing reliance on food industry volunteerism because of budget constraints and changing regulatory philosophies.

BUDGETS OF MAJOR FOOD SAFETY-RELATED PROGRAMS IN FISCAL YEAR 1982

U.S. Department of Agriculture[a]

Program	Act(s) and section(s)	Program description	Salaries and expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Egg and egg products inspection	Egg Products Inspection Act	To assure that eggs and egg products are wholesome, unadulterated, and properly labeled.	186 Federal 17 State	$ 8,222 appropriation 554 fees	Agricultural Marketing Service
Meat and poultry inspection	Federal Meat Inspection Act; Wholesome Meat Act; Poultry Products Inspection Act	To prevent the sale and distribution of adulterated or misbranded meat and poultry products.	9,324 Federal	308,228 appropriation	Food Safety and Inspection Service
Total			9,510 Federal 17 State	$316,450 appropriation 554 fees	
				$317,004	

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U.S. Department of Health and Human Services[b]

Program	Act(s) and section(s)	Program description	Salaries and expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Food sanitation and quality control	Food, Drug, and Cosmetic Act, 402, 702, 702(a), 704 Public Health Service Act, 301, 311, 361	To prevent food from being sold at consumer markets that is hazardous to human health because of microbiological contamination, filth, decomposition, or foreign objects. This objective is pursued through inspections and other enforcement activities, development of manufacturing guidelines, industry consultation, and research to identify new hazards and improve their detection and control.	960	$37,840 appropriation	Food and Drug Administration
Food and color additives	Food, Drug, and Cosmetic Act, 402, 409, 706	To ensure the safety of ingredients added to foods, whether they are added directly or indirectly, FDA reviews food additive petitions and Generally Recognized As Safe affirmation petitions, and conducts research to evaluate the safety of additives already marketed.	320	14,689 appropriation[c]	Food and Drug Administration

APPENDIX I

U.S. Department of Health and Human Services (cont.)

Program	Act(s) and section(s)	Program description	Salaries and expenses		Administering Organization
			Positions	Amount	
				(000 omitted)	
Chemical contaminants	Food, Drug, and Cosmetic Act, 402, 406, 408	To identify and prevent health hazards of chemical contaminants in food such as industrial chemicals, pesticides, heavy metals, and natural toxicants such as aflatoxin. FDA conducts research, surveys food to detect and prevent contaminants and establishes regulatory levels (except pesticide tolerances which are established by EPA).	533	$19,610 appropriation	Food and Drug Administration
Nutrition	Food, Drug, and Cosmetic Act, 403, 411, 412	To assure the nutritional quality of foods through development of guidelines on nutrient composition, regulations on nutrition labeling and dietary claims, and research on nutrient requirements, safety, and bioavailability. Specific statutory requirements apply to the composition and monitoring of infant formulas.	162	7,189 appropriation	Food and Drug Administration

APPENDIX I

U.S. Department of Health and Human Services (cont.)

Program	Act(s) and section(s)	Program description	Salaries and expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Interstate travel	Food, Drug, and Cosmetic Act, 402 Public Health Service Act, 311, 361, 368	To assure the safety of food and water used or transported on interstate conveyances, and to prevent the spread of communicable disease, by conducting inspections of interstate aircraft, buses, trains, vessels, and trucks.	61	$2,266 appropriation	Food and Drug Administration
Food service, shellfish, and milk safety	Food, Drug, and Cosmetic Act, 401, 402 Public Health Service Act, 301, 311, 361	To provide for FDA coordination of State activities in the areas of food service inspection, shellfish safety, and milk safety, through research, technical assistance, promotion of uniform sanitation standards, and cooperative programs such as the National Shellfish Sanitation Program and the Interstate Milk Shippers Certification Program.	165	5,794 appropriation	Food and Drug Administration

APPENDIX I

U.S. Department of Health and Human Services (cont.)

Program	Act(s) and section(s)	Program description	Salaries and expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Food economics	Food, Drug, and Cosmetic Act, 401, 402, 403 Tea Importation Act Fair Packaging and Labeling Act, 4, 5	To prevent economic deception of the consumer brought on by partially filled containers, foods that do not meet standards, and inadequate food labeling. FDA develops and revises food standards for specific foods, develops and enforces labeling regulations, and conducts limited surveillance to prevent economic adulteration and misbranding. FDA also sets standards for and samples all imported tea.	62	$2,243 appropriation[d]	Food and Drug Administration
Safety of animal derived human foods	Food, Drug, and Cosmetic Act, 512	To ensure that drug and chemical residues which are a risk to human health are not found in edible animal tissue, FDA participates in various programs to detect drug residues, pesticides, and industrial chemicals in meat for human consumption; and conducts research on the toxicity of veterinary drugs in food animals.	117	4,538 appropriation	Food and Drug Administration

APPENDIX I

U.S. Department of Health and Human Services (cont.)

Program	Act(s) and section(s)	Program description	Salaries and expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Animal feed safety	Food, Drug, and Cosmetic Act, 402, 403, 409, 501, 502, 512, 702, 704	To ensure that animal foods are not adulterated or misbranded and are safe and effective, and that harmful residues do not enter the human food supply. This is accomplished through medicated feed mill inspections and other enforcement activities and through research on the transfer of drug resistance from animal to man.	158	$8,100 appropriation	Food and Drug Administration
New animal drug evaluation	Food, Drug, and Cosmetic Act, 409, 501, 510, 512	To ensure that animal drugs and feed additives are safe and effective, FDA reviews New Animal Drug Applications (NADAs), Investigational NADAs, Feed Additive Petitions, and conducts research to evaluate the effects of drugs in animals.	103	4,262 appropriation	Food and Drug Administration

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U.S. Department of Health and Human Services (cont.)

Program	Act(s) and section(s)	Program description	Salaries and expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Animal Drugs: bioresearch monitoring	Food, Drug, and Cosmetic Act, 406, 408, 409, 512, 701(a), 702, 704, 706	To ensure that clinical and nonclinical investigations are conducted in a scientific manner that will demonstrate safety and effectiveness of animal drugs to the target species and safety to the consumer, FDA inspects clinical investigators and animal drug sponsors and evaluates all bioresearch data submitted to determine validity and accuracy.	29	$1,022 appropriation	Food and Drug Administration
Total			2670	$107,553	

APPENDIX I

Environmental Protection Agency[e]

Program	Act(s) and section(s)	Program description	Salaries and Expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Registration standards[f]	Federal Insecticide, Fungicide, and Rodenticide Act, 3	To develop registration standards for active and inert ingredient chemicals to facilitate registration of currently registered pesticides and registration of new pesticides.	66	$2,700 appropriation	Office of Pesticide Programs
Rebuttable presumption against registration[g]	Federal Insecticide, Fungicide, and Rodenticide Act, 3	To evaluate pesticides which have an identified potential for producing significant adverse health or environmental effects.	72	3,600 appropriation	Office of Pesticide Programs
Special Registration[h]	Federal Insecticide, Fungicide, and Rodenticide Act, 5, 18, 24(c) Food, Drug, and Cosmetic Act, 408	Activities include State and Federal experimental use permits; preparation and review of regulations for State registrations; emergency exemptions; special local needs registration; and temporary tolerances.	26	1,000 appropriation	Office of Pesticide Programs

APPENDIX I

Environmental Protection Agency (cont.)

Program name	Act(s) and section(s)	Program description	Salaries and expenses		Administering organization
			Positions	Amount	
				(000 omitted)	
Tolerances	Food, Drug, and Cosmetic Act, 402, 408, 409	To establish tolerances (maximal pesticide residue limits permissible) or exemptions from tolerance requirements for pesticides used on food and feed crops.	55	$2,000 appropriation	Office of Pesticide Programs
Pesticide use management[i]	Federal Insecticide, Fungicide, and Rodenticide Act; No specific sections except sections 22 and 23 concerning cooperation with States	Program includes consultation and the exchange of information and technical advice between the Agency and Federal, State, and local officials with interests in pesticide regulations, as well as assistance to pesticide users, pesticide producers, and the general public to promote compliance with pesticide regulations and safe use practices.	3	120 appropriation	Office of Pesticide Programs
Registration[j]	Federal Insecticide, Fungicide, and Rodenticide Act, 3	To register new pesticide products and amendments to add uses and/or new formulations for currently registered pesticides.	84	3,000 appropriation	Office of Pesticide Programs
Total			306	$12,420	

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GRAND TOTAL	12,486 Federal 17 State	$436,423 appropriation $ 554 fees

[a]Information provided by the Agricultural Marketing Service and Food Safety and Inspection Service, USDA.

[b]Information provided by the Food and Drug Administration, HHS.

[c]Certification of colors is supported by industry fees.

[d]Fees paid by tea importers are forwarded directly to the Department of the Treasury.

[e]Information provided by the Office of Pesticide Programs, EPA.

[f]The Office of Pesticide Programs estimates 75 percent of this program activity involves food use pesticides.

[g]The Office of Pesticide Programs estimates 80 percent of this program activity involves food use pesticides.

[h]The Office of Pesticide Programs estimates 50 percent of this program activity involves food use pesticides.

[i]The Office of Pesticide Programs estimates 70 percent of this program activity involves food use pesticides.

[j]The Office of Pesticide Programs estimates 40 percent of this program activity involves food use pesticides.

APPENDIX I

APPENDIX II

COMPARISON OF FISCAL YEAR 1977 FOOD SAFETY PROGRAM RESOURCE LEVELS WITH FISCAL YEAR 1982 RESOURCE LEVELS

Administering agency	Program	FY 77 resources[a]	FY 77 Resources expressed in 1982 dollars[b]	FY 82 resources[c]	Percent change
		(000 omitted)			
FDA	Food sanitation control	$ 34,311	$ 51,782	$ 37,840	-26.9
FDA	Food additives	13,264	20,018	14,689	-26.6
FDA	Chemical contaminants[d]	14,272	21,539	19,610	- 9.0
FDA	Nutrition	3,891	5,872	7,189[e]	22.4
FDA	Interstate travel	2,751	4,152	2,266	-45.4
FDA	Food service, shellfish and milk safety	5,707[f]	8,613	5,794	-32.7
FDA	Food economics	2,890	4,362	2,243	-48.6
USDA	Egg and egg products inspection	6,513	9,829	8,222	-16.3
USDA	Meat and poultry inspection	240,640	363,175	308,228	-15.1[g]

[a]Source of these figures is "Food Testing and Inspection Programs of the U.S. Department of Agriculture and the Food and Drug Administration," Congressional Research Service, June 1977.

[b]To arrive at these figures, we developed an inflator for 1977 dollars by using the ratio of 1977 and 1982 Gross National Products, obtained from the Economic Report of the President, February 1983. The resulting ratio is 0.6626.

[c]These figures were provided by FDA and USDA.

[d]Chemical contaminants and mycotoxins and other natural poisons were separate programs in FY 77; we have combined them for comparison.

[e]FY 82 program includes new responsibilities under the Infant Formula Act of 1980.

[f]Shellfish safety and food service safety were included in FY 77 as separate programs. Milk safety was not included as a separate program in FY 77 because it was part of food sanitation control.

[g]In commenting on this study, the Administrator, FSIS, stated that part of the decrease is due to actual savings achieved by introducing more efficient slaughter and processing inspection techniques and better personnel management and that the decrease should not be interpreted as a 15 percent decline in regulatory effectiveness.

GAO REPORTS ON FOOD REGULATION AND RELATED ISSUES

REPORTS DISCUSSING ISSUES INVOLVING SHARED AGENCY RESPONSIBILITY

"Stronger Enforcement Needed Against Misuse of Pesticides," CED-82-5, Oct. 15, 1981.

"Grain Fumigation: A Multifaceted Issue Needing Coordinated Attention," CED-81-152, Sept. 10, 1981.

"Gains and Shortcomings in Resolving Regulatory Conflicts and Overlaps," PAD-81-76, June 23, 1981.

"Further Federal Action Needed To Detect and Control Environmental Contamination of Food," CED-81-19, Dec. 31, 1980.

"Comments on Proposed Food Labeling Regulations," CED-80-89, Apr. 21, 1980.

"Maze of Food Regulations--Need for a Regulation Indexing System," CED-80-14, Feb. 4, 1980.

"Government Programs and Organizations Affecting Exports," ID-79-41, Aug. 17, 1979.

"Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential," CED-79-43, June 22, 1979.

"Problems in Preventing the Marketing of Raw Meat and Poultry Containing Potentially Harmful Residues," HRD-79-10, Apr. 17, 1979.

"Food Salvage Industry Should Be Prevented From Selling Unfit and Misbranded Food to the Public," HRD-79-32, Feb. 14, 1979.

"Beef Marketing: Issues and Concerns," CED-78-153, Sept. 26, 1978.

"Federal Regulatory Policies," PAD-78-68, Mar. 29, 1978.

"Federal Efforts To Protect Consumers From Polybrominated Biphenyl Contaminated Food Products," HRD-77-96, June 8, 1977.

"Government Regulatory Activity: Justifications, Processes, Impacts, and Alternatives," PAD-77-34, June 3, 1977.

"National Nutrition Issues," CED-78-7, Dec. 8, 1977.

"Need To Reassess Food Inspection Roles of Federal Organizations," B-168966, June 30, 1970.

FOOD AND DRUG ADMINISTRATION

"Regulation of Cancer-Causing Food Additives--Time for a Change?" HRD-82-3, Dec. 11, 1981.

"Does Nitrite Cause Cancer? Concerns About Validity of FDA-Sponsored Study Delay Answer," HRD-80-46, Jan. 31, 1980.

"Followup of Sanitary Conditions in the Food Industry," April 11, 1978.

Federal Responsibilities for Insuring Safe and Pure Fish Products, Nov. 3, 1977.

"Food Additive, Acrylonitrile, Banned in Beverage Containers," HRD-78-9, Nov. 2, 1977.

"Food and Drug Administration's Program for Regulating Imported Products Needs Improving," HRD-77-72, July 5, 1977.

"Need To Establish Safety and Effectiveness of Antibiotics Used in Animal Feeds," HRD-77-81, June 27, 1977.

"Dimensions of Insanitary Conditions in the Food Manufacturing Industry," B-164031 (2), Apr. 18, 1972.

FOOD SAFETY AND INSPECTION SERVICE, USDA

"Improving Sanitation and Federal Inspection at Slaughter Plants. How To Get Better Results for the Inspection Dollar," CED-81-118, July 30, 1981.

"Proposed Changes in Meat and Poultry Net Weight Labeling Regulations Based on Insufficient Data," CED-79-28, Dec. 20, 1978.

"A Better Way for the Department of Agriculture To Inspect Meat and Poultry Processing Plants," CED-78-11, Dec. 9, 1977.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE, USDA

Procedures for Testing Garbage To Be Fed to Swine Need Strengthening, Sept. 3, 1980.

"Improvements Needed in Department of Agriculture's Certification That Export Shipments of Grain Conform to Phytosanitary Regulations of Foreign Countries," CED-80-42, Dec. 28, 1979.

ENVIRONMENTAL PROTECTION AGENCY

"Need for Comprehensive Pesticide Use Data," CED-80-145, Sept. 30, 1980.

"Delays and Unresolved Issues Plague New Pesticide Protection Programs," CED-80-32, Feb. 15, 1980.

"Serious Problems With EPA's Pesticide Reference Standards Program," CED-78-109, Apr. 26, 1978.

"Need To Notify Foreign Nations of U.S. Pesticide Suspension and Cancellation Actions," CED-78-103, Apr. 20, 1978.

"Special Pesticide Registration by the Environmental Protection Agency Should Be Improved," CED-78-9, Jan. 9, 1978.

NATIONAL MARINE FISHERIES SERVICE, DEPARTMENT OF COMMERCE

"Follow-up on the National Marine Fisheries Service's Efforts To Assess the Quality of U.S.-Produced Seafood," CED-81-125, June 22, 1981.

"Need To Assess Quality of U.S. Produced Seafood for Domestic and Foreign Consumption," CED-81-20, Oct. 15, 1980.

APPENDIX IV

STUDIES OF FEDERAL FOOD REGULATION

"Federal Regulatory [sic] and Regulatory Reform," Report by the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Oct. 1976.

"Food Testing and Inspection Programs of the U.S. Department of Agriculture and the Food and Drug Administration," Congressional Research Service, June 1977.

"A Study of the Federal Meat and Poultry Inspection System," Booz, Allen and Hamilton, Inc., June 1977.

"Regulatory Organization," Vol. V, Study on Federal Regulation, Committee on Governmental Affairs, U.S. Senate, Dec. 1977.

"Food Safety and Quality Service--A Strengthened Meat and Poultry Inspection Program," USDA, June 1978.

"Cancer-Causing Chemicals in Food," Report by the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Dec. 1978.

"Food and Nutrition Study Final Report," President's Reorganization Project, Dec. 1978.

"Food Safety Policy: Scientific and Societal Considerations. Part 2," Committee for a Study on Saccharin and Food Safety Policy, National Academy of Sciences, Mar. 1, 1979.

"Food Safety: Where Are We?" Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, July 1979.

"Environmental Contaminants in Food," Office of Technology Assessment, Dec. 1979.

"Food Safety Policy Issues," Congressional Research Service, June 1981.

RECOMMENDATIONS FOR LEGISLATIVE CHANGE IN GAO FOOD SAFETY REPORTS AND STATUS AS OF FEBRUARY 1983

REGULATION OF CANCER-CAUSING FOOD ADDITIVES-TIME FOR A CHANGE? (HRD-82-3, Dec. 11, 1981)

The report discussed current views on the need for changes to the Delaney Clause of the Federal Food, Drug, and Cosmetic Act. The clause requires the Food and Drug Administration to ban food additives which are found to cause cancer when ingested by humans or animals or are found, after tests which evaluate the safety of food additives, to induce cancer in humans or animals.

We determined that experts generally agree that the Delaney Clause is too inflexible as it currently is written because technology since its 1958 passage has progressed so that very low levels of substances now can be detected, while no good means exists or can exist to determine human risk from such low exposure, especially in the long term. Carcinogens other than those added to food are regulated by a risk/benefit approach as contrasted to the zero-risk approach employed for food additives. Consumer groups disagree with the need for change.

Matters for consideration by the Congress

Because of (1) the advances in the ability of analytical detection methods to identify substances at very low levels, (2) the uncertainties about the risk to humans of low levels of carcinogens, and (3) the inflexibility that exists under FDA's present regulatory policy, we believe that the Congress should consider whether the present food safety policy for cancer-causing food additives is still appropriate.

Three options for amending the Delaney Clause are: (1) leave it unchanged, (2) delete it and regulate carcinogens under the general safety clause, and (3) amend it. Three alternatives for amendment appear to have the most support: risk-based (set an acceptable level of risk), risk-benefit (compare the risks from using a carcinogen with the benefits derived from its use), risk-risk (compare the health risk from using a carcinogen with the health risk from not using it).

Current status

Several bills to amend the Delaney Clause were introduced during the 97th Congress; none were voted on. As of February 1983, they had not been reintroduced in the 98th Congress.

IMPROVING SANITATION AND FEDERAL INSPECTION AT SLAUGHTER PLANTS: HOW TO GET BETTER RESULTS FOR THE INSPECTION DOLLAR (CED-81-118, July 30, 1981)

The report discussed effectiveness of FSIS inspection of federally approved meat and poultry slaughter plants, problems found, and opportunities to improve inspection program activities.

We made surprise visits to 62 randomly selected plants in 6 States, accompanied by FSIS supervisors, and found 27 percent of the meat plants and 24 percent of the poultry plants unacceptable in one or more of six basic inspection program requirements.

Recommendation

To better assure that meat and poultry plants produce only wholesome and unadulterated products, we recommended that among other actions, the Secretary of Agriculture direct the Administrator, FSIS, to develop a system of financial disincentives for slaughter plant managers who allow less than sanitary conditions to exist in their plants. Such a system could include financial penalties for which additional legal authority would be required.

Current status

USDA disagreed with this recommendation. No action has been taken.

NEED FOR MORE EFFECTIVE REGULATION OF DIRECT ADDITIVES TO FOOD (HRD-80-90, Aug. 14, 1980)

The report discussed the inconsistency of food additives regulation by FDA. More than half the current food additives in use are used without FDA review and approval of their safety. The Federal Food, Drug, and Cosmetic Act exempts from review and approval substances generally recognized as safe by experts, or approved for use before 1958, and allows the safety determination for some of these substances to be based on experience drawn from common use in food.

Recommendation

To achieve consistency in regulating all substances added directly to food, thus ensuring the consistency of criteria employed to determine the safety of such additives, we recommended to the Congress that it amend the Federal Food, Drug, and Cosmetic Act to eliminate exemptions for generally recognized as safe (GRAS) and prior-sanction substances. Changes to the law should provide enough flexibility to encourage the use of information already available and to recognize that different types of scientific evidence may be appropriate to support the safety of food additives. The amendment should also provide a date on which the

safety of all GRAS and prior-sanction substances must be subject to Federal review and approval.

Current status

No action has been taken.

PROBLEMS IN PREVENTING THE MARKETING OF RAW MEAT AND POULTRY CONTAINING POTENTIALLY HARMFUL RESIDUES (HRD-79-10, Apr. 17, 1979)

The report discussed the problems experienced by USDA in preventing the marketing of raw meat and poultry found to contain illegal residues of animal drugs, pesticides, and environmental contaminants.

We reviewed efforts by the USDA, FDA, and EPA for making sure that only safe levels of drugs, pesticides, and environmental contaminants will be present in raw meat and poultry and estimated that 14 percent by dressed weight of the meat and poultry sampled by USDA between 1974 and 1976 contained illegal residues. With few exceptions, neither USDA nor FDA can locate and remove from the market raw meat and poultry found to contain illegal residues.

Recommendations

To enable the responsible agencies to more effectively prevent the marketing of raw meat and poultry containing illegal residues, we recommended that the Congress amend the

--Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize USDA to (1) quarantine animals from a violative grower and (2) require growers to place an identification tag on animals before they are marketed;

--Federal Food, Drug, and Cosmetic Act to make misuse of an animal drug illegal and to authorize the use of civil penalties for residue violations; and

--Federal Insecticide, Fungicide, and Rodenticide Act to better enable EPA to identify the possible misuse of pesticides.

Current status

A bill to quarantine animals from violative growers was introduced in 1980 but it was not enacted.

APPENDIX V

A BETTER WAY FOR THE DEPARTMENT OF AGRICULTURE TO INSPECT MEAT AND POULTRY PROCESSING PLANTS (CED-78-11, Dec. 9, 1977)

The report discussed ways in which USDA could use its inspection resources at meat and poultry processing plants more efficiently and effectively by tailoring inspection frequency to the needs of individual plants.

Working with consultants with expertise in quality control and Federal meat and poultry inspection requirements, we reviewed Federal meat and poultry processing inspection activities by, among other things, visiting 70 randomly selected processing plants in California, Ohio, and Michigan and further reviewing records and observing inspection activities at 18 of those plants and 6 others.

Recommendations

Because an opportunity existed to change USDA's practice of inspecting most meat and poultry processing plants daily, allowing USDA to inspect more plants or inspect plants needing upgrading more frequently, we recommended that the Congress amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize the Secretary of Agriculture to:

--Make periodic, unannounced inspections of meat and poultry processing plants, tailoring the inspection frequency of the inspection needs of individual plants based on (1) the reliability of the plant's quality-control system, (2) the plant management's attitude toward complying with inspection requirements, (3) the plant's history of compliance with inspection requirements, and (4) such other factors as the Secretary deems necessary.

--Require meat and poultry processing plants to develop and implement quality-control systems that can be relied on to ensure that wholesome, unadulterated, and properly branded products are produced. The necessary criteria for determining the quality-control systems needed at various types and sizes of plants should be developed by the Secretary in cooperation with industry. Such systems should provide for maintaining appropriate records of quality-control tests, tests results, and corrective actions. These records should be available to Agriculture's inspection personnel for monitoring the quality-control systems.

--Withdraw inspection or impose civil penalties of up to $100,000 for processing plants failing to take appropriate action when the quality-control system identified a deficiency or when plants fail to comply with inspection requirements.

Current status

A bill providing the Secretary of Agriculture with authority to determine which plants required full-time inspectors was introduced during the 97th Congress. This bill was not enacted and had not been reintroduced in the 98th Congress as of February 1983.

USDA has issued regulations which allow plants to develop, on a voluntary basis, quality-control systems which can be used by the Department's inspectors for inspection planning.

A bill providing authority for USDA civil penalties was introduced in 1980 but was not discussed or enacted.

DIMENSIONS OF INSANITARY CONDITIONS IN THE FOOD MANUFACTURING INDUSTRY (B-164031 (2), Apr. 18, 1972)

The report discussed the inadequacy of FDA regulation of food products which are adulterated (contain filth or are packed under insanitary conditions) and suggested ways to improve FDA's management of the program which is intended to ensure industry compliance with sanitation standards required by the Federal Food, Drug, and Cosmetic Act.

To assess sanitary conditions in the food manufacturing industry, we requested FDA to inspect 97 food manufacturing and processing plants randomly selected from about 4,550 plants in six FDA districts in 21 States. We accompanied FDA inspectors on 95 plant inspections. We estimated 40 percent of the 4,550 plants were operating under insanitary conditions; 24 percent were operating under serious insanitary conditions.

Recommendation

In order to allow FDA additional flexibility in enforcing the Federal Food, Drug, and Cosmetic Act and to address insanitary conditions in the food manufacturing industry, we recommended that the Congress consider amending the law to provide for civil penalties when food sanitation standards are violated.

Current status

No action has been taken on this recommendation.

APPENDIX VI

A CHRONOLOGY OF

FOOD SAFETY AND RELATED LEGISLATION

Year	Statute	Provisions
1897	Tea Importation Act, 29 Stat. 604 (Mar. 2, 1897)	Requiring imported tea to be examined for purity, quality, and fitness for consumption.
1906	Food and Drugs Act of 1906, 34 Stat. 768 (June 30, 1906)	An act to regulate manufacture, sale, or transportation of adulterated or misbranded food, drugs, and drinks in interstate commerce.
1906	Meat Inspection Act of 1906, 34 Stat. 669 (June 30, 1906)	Mandating post-mortem inspection of carcasses for transportation or sale in interstate commerce of cattle, sheep, swine, and goats for human consumption.
1907	Meat Inspection Act of 1907, 34 Stat. 1256 (Mar. 4, 1907)	Same statute as above.
1910	Insecticide Act of 1910, 36 Stat. 331 (Apr. 26, 1910)	An act to regulate the manufacture, sale, or transportation of misbranded or adulterated insecticides or fungicides.
1912	Act of August 23, 1912, 37 Stat. 416 (Sherley Amendment)	Amendments to Food and Drugs Act of 1906 to cover mislabeling of the curative and therapeutic effects of food or drugs.
1913	Act of March 3, 1913, 37 Stat. 732 (Net Weight Amendment)	Amendments to Food and Drugs Act of 1906 to require labeling as to quantity.

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Year	Statute	Provisions
1927	Import Milk Act, 44 Stat. 1101 (Feb. 15, 1927)	Requiring imported milk and cream to be sanitary and meet certain specified conditions.
1930	McNary-Mapes Amendment (Pure Foods), 46 Stat. 1019 (July 8, 1930)	Amending Food and Drugs Act of 1906 to cover standards of quality and fill for canned goods.
1938	Wheeler-Lea Act, 52 Stat. 111, 114 (Mar. 21, 1938)	Amending Federal Trade Commission Act to control false advertising of food, drugs, cosmetics, and therapeutic devices.
1938	Federal Food, Drug, and Cosmetic Act of 1938, Public Law 75-717, 52 Stat. 1040	An act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for related purposes.
1938	Act of June 29, 1938, Public Law 75-776, 52 Stat. 1235	Amending Meat Inspection Act of 1907 to clarify definitions, marking requirements, and penalties.
1942	Act of June 10, 1942, Public Law 77-602, 56 Stat. 351	Amending Meat Inspection Act of 1907 to facilitate Federal meat inspection of meat-packing establishments engaged in intrastate commerce during duration of World War II.
1944	Department of Agriculture Organic Act of 1944, Public Law 78-425, 58 Stat. 734 (Sept. 21, 1944)	Among other things, provides for control and eradication of certain animal and plant pests.

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Year	Statute	Provisions
1957	Poultry Products Inspection Act of 1957, Public Law 85-172, 71 Stat. 441 (Aug. 28, 1957)	To prevent the movement in interstate or foreign commerce of unwholesome or adulterated poultry or poultry products through mandatory ante- and post-mortem inspection of poultry.
1958	Food Additives Amendment of 1958, Public Law 85-929, 72 Stat. 1784 (Sept. 6, 1958) (Delaney Amendment)	Amending Federal Food, Drug, and Cosmetic Act to regulate and define food additives and to prohibit use of additives unsafe to the health of man or animal.
1959	Nematocide, Plant Regulator, Defoliant and Dessicant Amendment of 1959, Public Law 86-139, 73 Stat. 286 (Aug. 7, 1959)	To expand scope of Federal Insecticide, Fungicide, and Rodenticide Act and scope of 1954 amendments to Federal Food, Drug, and Cosmetic Act to include newly developed chemical pesticides.
1960	Color Additive Amendments of 1960, Public Law 86-618, 74 Stat. 397 (July 12, 1960)	Amending Federal Food, Drug, and Cosmetic Act to regulate and define color additives and to prohibit use of additives unsafe to the health of man or animal.
1962	Drug Amendments of 1962, Public Law 87-781, 76 Stat. 780 (Oct. 10, 1962)	Amending Federal Food, Drug, and Cosmetic Act to require FDA to affirmatively approve marketing of new drug.

APPENDIX VI

Year	Statute	Provisions
1962	Talmadge-Aiken Act of 1962, Public Law 87-718, 76 Stat. 663 (September 28, 1962)	Authorizing USDA to establish cooperative arrangements with States in administering and enforcing Federal laws relating to marketing agricultural products and eradicating plant and animal diseases.
1964	Act of May 12, 1964, Public Law 88-305, 78 Stat. 190	Amending Federal Insecticide, Fungicide, and Rodenticide Act to, among other things, eliminate practice of protest registration permitting manufacturers to market economic poisons nothwithstanding USDA's refusal to register.
1966	Fair Packaging and Labeling Act, Public Law 89-755, 80 Stat. 1296 (Nov. 3, 1966)	Preventing the use of unfair or deceptive methods of packaging or labeling certain consumer commodities, including food and drugs distributed in interstate or foreign commerce.
1967	Wholesome Meat Act of 1967, Public Law 90-201, 81 Stat. 584 (Dec. 15, 1967)	Revised Federal Meat Inspection Act to authorize cooperation with State meat inspection programs, including financial assistance up to 50 percent of State program costs; to authorize regulation of meat storage and handling to prevent adulteration and misbranding; and for other purposes.

APPENDIX VI

Year	Statute	Provisions
1968	Animal Drug Amendments of 1968, Public Law 90-399, 82 Stat. 342 (July 13, 1968)	Amending Federal Food, Drug, and Cosmetic Act to consolidate and clarify requirements applicable to animal drugs.
1968	Wholesome Poultry Products Act of 1968, Public Law 90-492, 82 Stat. 791 (Aug. 18, 1968)	Revised Poultry Products Inspection Act to authorize cooperation with State poultry inspection programs and for other purposes.
1970	Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623, 84 Stat. 2086 (Dec. 2, 1970)	Among other things, transferring to EPA FDA's pesticide tolerance-setting authority, USDA's pesticide registration authority, and Interior's pesticide research authority.
1970	Egg Products Inspection Act of 1970, Public Law 91-597 84 Stat. 1620 (Dec. 29, 1970)	Providing for restrictions on disposition of certain egg products, uniformity of standards for eggs in interstate and foreign commerce, inspection of certain egg products, and for other purposes.
1972	Federal Environmental Pesticide Control Act of 1972, Public Law 92-516, 86 Stat. 973 (Oct. 21, 1972)	Revising Federal Insecticide, Fungicide and Rodenticide Act to, among other things, require registration of pesticides, including ones sold intrastate, and to provide for national monitoring program for pesticide residues.

APPENDIX VI

Year	Statute	Provisions
1976	Act of March 15, 1976, Public Law 94-231, 90 Stat. 215	Amending Department of Agriculture Organic Act of 1944 to clarify authority of Secretary of Agriculture to control and eradicate plant pests, and for other purposes.
1976	Toxic Substances Control Act of 1976, Public Law 94-582, 90 Stat. 2867 (Oct. 21, 1976)	Authorizing regulation of commercial chemicals not adequately addressed by other regulatory controls and programs.
1976	United States Grain Standards Act of 1976, Public Law 94-582, 90 Stat. 2867 (Oct. 21, 1976)	Amending U.S. Grain Standards Act of 1916 to establish the Federal Grain Inspection Service in USDA to administer inspection and weighing requirements, to prescribe and collect inspection fees, and for other purposes.
1977	Food and Agriculture Act of 1977, Public Law 95-113, Sec. 1602, 91 Stat. 1025 (Sept. 29, 1977)	Amending fee-setting authority to exclude administrative and supervisory costs of grain weighing and inspection service.
1978	Federal Pesticide Act of 1978, Public Law 95-396, 92 Stat. 819 (Sept. 30, 1978)	Amending Federal Insecticide, Fungicide, and Rodenticide Act to, among other things, expedite registration and classification of pesticides.
1980	Infant Formula Act of 1980, Public Law 96-359, 94 Stat. 1190 (Sept. 26, 1980)	Amending the Food, Drug, and Cosmetic Act to give FDA regulatory authority over the processing, manufacturing, quality control procedures, and testing of infant formulas.

Source: "Food Safety: Where Are We?" Committee on Agriculture Nutrition, and Forestry, U.S. Senate, July 1979; "Regulatory Organization," Study on Federal Regulation, Vol. V, Committee on Governmental Affairs, U.S. Senate, Dec. 1977; and "Food Bibliography," CED-78-37, May 1978.

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