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BY THE COMPTROLLER GENERAL

Report To The Chairman

Committee On Appropriations

United States Senate

OF THE UNITED STATES

Further Federal Action Needed To Detect And Control Environmental Contamination Of Food

The Food Safety and Quality Service and the Food and Drug Administration took much longer than necessary to identify the presence and source of chemical contamination in a case involving polychlorinated biphenyls in chickens and other food in the Western States in 1979. These agencies and the Environmental Protection Agency have taken several actions to prevent similar incidents or to deal more effectively with such incidents if they occur in the future.

The agencies have implemented many but not all of GAO's previous recommendations concerning the control of chemicals in the nation's food supply and in the environment. Additional action, which the Office of Technology Assessment has suggested, is needed to clearly define which agency will assume the leadership role in future contamination situations.

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-201213

The Honorable Warren G. Magnuson
Chairman, Committee on Appropriations
United States Senate

Dear Mr. Chairman:

Your letter of September 18, 1979, asked us to investigate the circumstances surrounding the contamination of chickens in several Western States by polychlorinated biphenyls. Because numerous Federal, State, and local investigators were checking into the situation at that time, your office subsequently agreed that we would monitor the Federal agencies' investigations and report to you later on the corrective actions taken or planned to prevent similar incidents. We also agreed to give you a summary of our past recommendations dealing with chemical contamination and our views on whether the agencies' actions on those recommendations have been responsive.

As arranged with your office, we are sending copies of this report to the Director, Office of Management and Budget; the Secretaries of Agriculture and Health and Human Services; the Administrator, Environmental Protection Agency; the Director, Office of Technology Assessment; and other interested parties. We will make copies available to others upon request.

Sincerely yours,

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CHAIRMAN, COMMITTEE ON APPROPRIATIONS UNITED STATES SENATE

FURTHER FEDERAL ACTION NEEDED TO DETECT AND CONTROL ENVIRONMENTAL CONTAMINATION OF FOOD

D I G E S T

Environmental contamination of food occurs when some of the toxic and nontoxic chemicals that are produced, transported, consumed, and disposed of each year escape into the environment.

Federal responsibility for ensuring that all toxic contaminants in food are kept at safe levels is divided among the Food Safety and Quality Service, Department of Agriculture; the Food and Drug Administration (FDA), Department of Health and Human Services (HHS); and the Environmental Protection Agency (EPA).

Both the Food Safety and Quality Service and FDA sample food products and test them for various pesticides and other chemicals. When they find excessive levels of chemical contaminants, the agencies must retrace the product through the food distribution system to isolate and remove the contamination source and to identify other affected food and feed products. (See pp. 1 to 3.)

1979 CONTAMINATION INCIDENT

In June 1979 damage to a spare electrical transformer stored at a hog slaughter and processing plant in Billings, Montana, caused toxic industrial chemicals called polychlorinated biphenyls, or PCBs, to leak unnoticed into the plant's drainage system. There the chemicals were mixed with other wastes and processed into grease and animal feed. These products were widely distributed before the presence and source of contamination were identified. (See pp. 6 to 8 and app. II.)

The Food Safety and Quality Service and FDA took 72 days--up to 45 more than necessary in GAO's opinion--to identify and control the incident. The Food Safety and Quality Service

also concluded that delays occurred in submitting samples, obtaining laboratory analyses, and identifying contamination sources. FDA, however, concluded that the incident posed no threat to consumer health because of the low level of PCBs found in marketed food and the successful efforts to destroy the contaminated products or halt their distribution. (See pp. 6 to 12, 15, and 17.)

The unnecessary delay was due primarily to the agencies' handling the incident as a routine matter. When the risk of contamination in the food system became evident, the incident should have been treated as an emergency, calling for an all-out effort to resolve the situation as soon as possible. If the contamination had been identified and controlled earlier, much of the cost--at least $3.5 million--as well as the risk to human health could have been avoided. (See pp. 9 to 14.)

FEDERAL AGENCIES' STUDIES OF THE INCIDENT

The Food Safety and Quality Service and FDA, with help from EPA, studied the incident to identify needed improvements. All three agencies have taken actions to try to prevent similar incidents or to help them deal more effectively with any future occurrences. For example, the Food Safety and Quality Service created a contamination response system and FDA created an emergency response team of experts to more quickly respond to such incidents. The three agencies also developed and published proposed regulations in May 1980 that would require removing all equipment containing PCBs from food production and feed facilities nationwide. Public comments on these regulations are due in March 1981.

When fully developed and properly implemented, the agencies' actions should provide a quicker response to, and better protection of consumers from, future chemical contaminations of food. (See pp. 15 to 19.)

The Office of Technology Assessment also reviewed the 1979 incident as part of its broader study of environmental contaminants in food. Its December 1979 report identified several ways to improve the Federal response to this problem. Among its suggestions was that a lead agency be designated or a Federal assistance center be established to handle responses to contamination problems. (See pp. 19 to 21.)

FEDERAL AGENCIES' RESPONSES TO PREVIOUS GAO RECOMMENDATIONS

Since December 1972 GAO has issued several reports that recommended changes to improve Government programs to control chemicals in the Nation's food supply and in the environment. The Department of Agriculture, HHS, and EPA have taken a number of actions in response to GAO's recommendations. These actions have resulted in

--improvements in the marketing of raw meat and poultry,

--better regulation of pesticide exports and pesticide residues in imported food,

--better coordination of pesticide residue testing and of contamination investigations, and

--better control of hazardous wastes.

For various reasons, however, actions have not yet been taken or completed on some of GAO's previous recommendations to strengthen chemical residue detection and control programs. For example, significant technological advances are needed before more sophisticated residue detection methods can be developed to more quickly and more completely identify chemical contaminants in food. (See pp. 22 to 46.)

RECOMMENDATION

Because GAO's previous recommendations on which actions have not yet been taken or completed are already on record, they are not

repeated here. However, an action suggested by the Office of Technology Assessment can be taken to strengthen the agencies' residue detection and control programs.

GAO recommends that the Secretaries of Agriculture and HHS and the Administrator, EPA, clearly define which agency will assume the leadership role in various contamination situations in the future. (See p. 48.)

AGENCY COMMENTS

Agriculture, HHS, and EPA generally agreed that the leadership role should be more clearly defined. They pointed out, however, that (1) the Interagency Regulatory Liaison Group and the Federal Emergency Management Agency have responsibilities that should be considered in developing criteria for leadership, (2) each agency should retain direct control over its operations, and (3) the criteria developed should be as flexible as possible. GAO agrees with these observations. (See p. 48.)

Contents

ABBREVIATIONS

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSQS	Food Safety and Quality Service
GAO	General Accounting Office
HHS	Department of Health and Human Services
OTA	Office of Technology Assessment
PBBs	polybrominated biphenyls
PCBs	polychlorinated biphenyls
USDA	U.S. Department of Agriculture

CHAPTER 1

INTRODUCTION

Following a chemical contamination incident involving chickens and other food items in several Western States in mid-1979, Senator Warren G. Magnuson, chairman of the Senate Committee on Appropriations, asked us to investigate the circumstances surrounding the incident. Because numerous Federal, State, and local investigators were checking into the situation at that time, the chairman's office agreed that we would monitor the Federal agencies' investigations and report on corrective actions taken or planned to prevent similar incidents. We also agreed to summarize our past recommendations dealing with chemical contamination and provide our views on whether the agencies' actions on those recommendations have been responsive.

ENVIRONMENTAL CONTAMINATION OF FOOD

The environmental contamination of food is a nationwide problem that affects all food categories. In its December 1979 report entitled "Environmental Contaminants in Food," the Office of Technology Assessment (OTA) said that 18 States and 2 Federal agencies had reported taking regulatory action on 243 contamination incidents during the period 1968-78. According to OTA, these reports did not include all food contamination incidents because many incidents never come to the attention of State or Federal authorities. (Also, only 32 States responded to OTA's request for this information.)

One of the 2 Federal agencies and 6 of the 18 States provided estimates of the cost of food condemned. (See app. I.) Because cost estimates were provided on only about 30 percent of the reported incidents, OTA concluded that the actual cost was at least several times the $282 million reported. OTA added that the total economic impact of environmental contamination would also include health costs and what it termed "distributional" costs--the expenses or losses incurred by affected businesses, individuals, and government agencies. As shown in appendix I, polybrominated biphenyls (PBBs) and polychlorinated biphenyls (PCBs) caused most of the dollar losses reported to OTA.

Each year billions of pounds of chemicals--including some which are toxic--are produced, transported, consumed, and disposed of in manufacturing, farming, mining, and transportation activities in the United States. Environmental contamination of food results when some of these chemicals escape into the environment. Contamination may be (1) long-term, low-level contamination from diffusion of persistent

chemicals throughout the environment or (2) shorter term, higher level contamination from industrial accidents and waste disposal.

Regardless of the source and type of contamination, various Federal and State agencies administer statutes which are designed, in part, to reduce or eliminate public health hazards associated with the presence of toxic contaminants in food. The three Federal agencies responsible for protecting public health against risks associated with chemicals in food, whether added advertently or inadvertently, are:

--The Food Safety and Quality Service (FSQS), U.S. Department of Agriculture (USDA), which devises ways to ensure that harmful chemical residues are not present in meat, poultry, and egg products.

--The Food and Drug Administration (FDA), Department of Health and Human Services (HHS), 1/ which ensures that chemical residues in food (other than meat, poultry, and egg products) and animal feed are within safe levels. It also regulates the use of animal drugs and intentional additives in food and sets tolerances or action levels 2/ for contaminants that are unavoidably present in food or feeds.

--The Environmental Protection Agency (EPA), which (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, (2) sets tolerances for levels of

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1/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 use HHS throughout this report to denote FDA's parent organization.

2/A tolerance specifies the level of a contaminant that will make a food adulterated. Tolerances are adopted through formal Federal rulemaking procedures and if supported by substantial evidence in the rulemaking record, cannot be questioned by any court. 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.

pesticides that might remain in food, feed, and livestock from intentional use, and (3) controls the manufacturing, processing, distribution, use, and disposal of PCBs and other 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 above description is general and does not completely describe the statutory division of Federal responsibility for ensuring that amounts of chemicals in foods do not exceed safe levels. As HHS pointed out in its comments on a draft of this report (see app. V), the division of responsibility is complex because the responsibilities of the departments and agencies involved are not mutually exclusive. According to HHS:

--FDA has broad responsibility to ensure the safety of human and animal food.

--FDA, with respect to meat and poultry products, has authority over food animals before slaughter and after USDA's inspection process is completed.

--FDA shares responsibility for monitoring eggs and egg products with USDA.

Both FSQS and FDA carry out their responsibilities by sampling food products and testing them for various pesticides and other chemicals. When they find excessive levels of chemical contaminants, FSQS and FDA must retrace the contaminated product through the food distribution system to isolate and remove the contamination source and to identify other food and feed products in interstate commerce containing contaminant residues that violate established acceptable levels.

WHAT ARE PCBs?

PCBs are toxic industrial chemicals belonging to a chemical family known as chlorinated hydrocarbons. Because of their desirable chemical and physical properties, PCBs were widely used in electrical transformers and capacitors; as heat-transfer fluids; and as additives in dyes, inks, pesticides, and plasticizers. Early PCB use was extensive and uncontrolled, and PCBs have become a persistent and ubiquitous contaminant of the environment and food, particularly freshwater fish.

PCBs were first identified as food contaminants in the late 1960s. The contamination resulted both from their presence as low-level environmental contaminants and from their accidental leakage from equipment used in food and feed handling facilities. Consequently, in 1973 FDA restricted the use of equipment containing PCBs in food and feed plants and established PCB tolerance levels for certain commodities. PCB tolerance levels in effect at November 7, 1980, included the following.

Commodity	Parts per million
Milk	1.5
Manufactured dairy products	1.5
Poultry	3.0
Eggs	0.3
Fish	5.0
Finished animal feed	0.2
Animal feed components of animal origin	2.0
Infant and junior foods	0.2
Paper food-packaging material	10.0

FDA's 1973 tolerance levels were based on limited toxicity data which indicated that PCBs in food presented a potential hazard to consumers. Although more data is available today, it still is not adequate to indicate the specific levels at which PCBs will create health problems in humans. With respect to carcinogenicity, Government scientists generally agree that any human exposure to a carcinogen poses a risk of cancer to the exposed person. Available data shows that:

--In Japan, rice-bran oil contaminated with PCBs led to the poisoning of 1,291 individuals in 1968. Symptoms reported included chloracne (a severe form of acne), eye discharges, skin discoloration, headaches, liver disturbances, and possibly cancer (malignant neoplasms).

--Mice and rats fed PCBs have developed cancers.

--Monkeys fed PCBs developed reproductive disorders; young monkeys nursing on mothers consuming PCBs developed toxic effects and behavioral abnormalities.

Such data on the hazards of PCB contamination must be seriously considered in light of adverse health effects associated with other chemicals in the chlorinated hydrocarbon family, including DDT, aldrin, dieldrin, and endrin. All of these chemicals have been banned or restricted from use as pesticides because they (1) produce cancers, birth defects, and/or mutations in animals, (2) cause unreasonable adverse effects in species

other than those for which they are intended, and (3) persist in the environment for long periods of time.

OBJECTIVES, SCOPE, AND METHODOLOGY

As requested by the chairman of the Senate Committee on Appropriations, we obtained information on the circumstances surrounding the PCB contamination of chickens in several Western States.

We reviewed reports issued by FDA and FSQS on what went wrong in the PCB-contamination case and what corrective action is needed. We analyzed these reports and discussed related matters with FDA, FSQS, and EPA officials.

We also reviewed OTA's December 1979 report on the broader problem of environmental contamination of food and reviewed the testimony on the PCB incident presented before the Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, on September 28, 1979.

In addition, we obtained information on the agencies' actions on our past recommendations dealing with chemical contamination to evaluate their responsiveness to those recommendations. We made our review at the agencies' headquarters in Washington, D.C.

CHAPTER 2

PCB CONTAMINATION INCIDENT IN THE WESTERN STATES

FSQS and FDA took 72 days--up to 45 more than necessary in our opinion--to identify and control the 1979 incident in the Western States involving PCB contamination of feed, animals, and food products. USDA officials have also concluded that FSQS actions in handling the incident were not as timely as they might have been. In our opinion, the unnecessary delay was due primarily to the agencies' handling the incident as a routine matter.

As a result of their studies of the incident, made with EPA's help, the agencies have taken actions to try to prevent similar incidents or to help them deal more effectively with such incidents if they occur in the future.

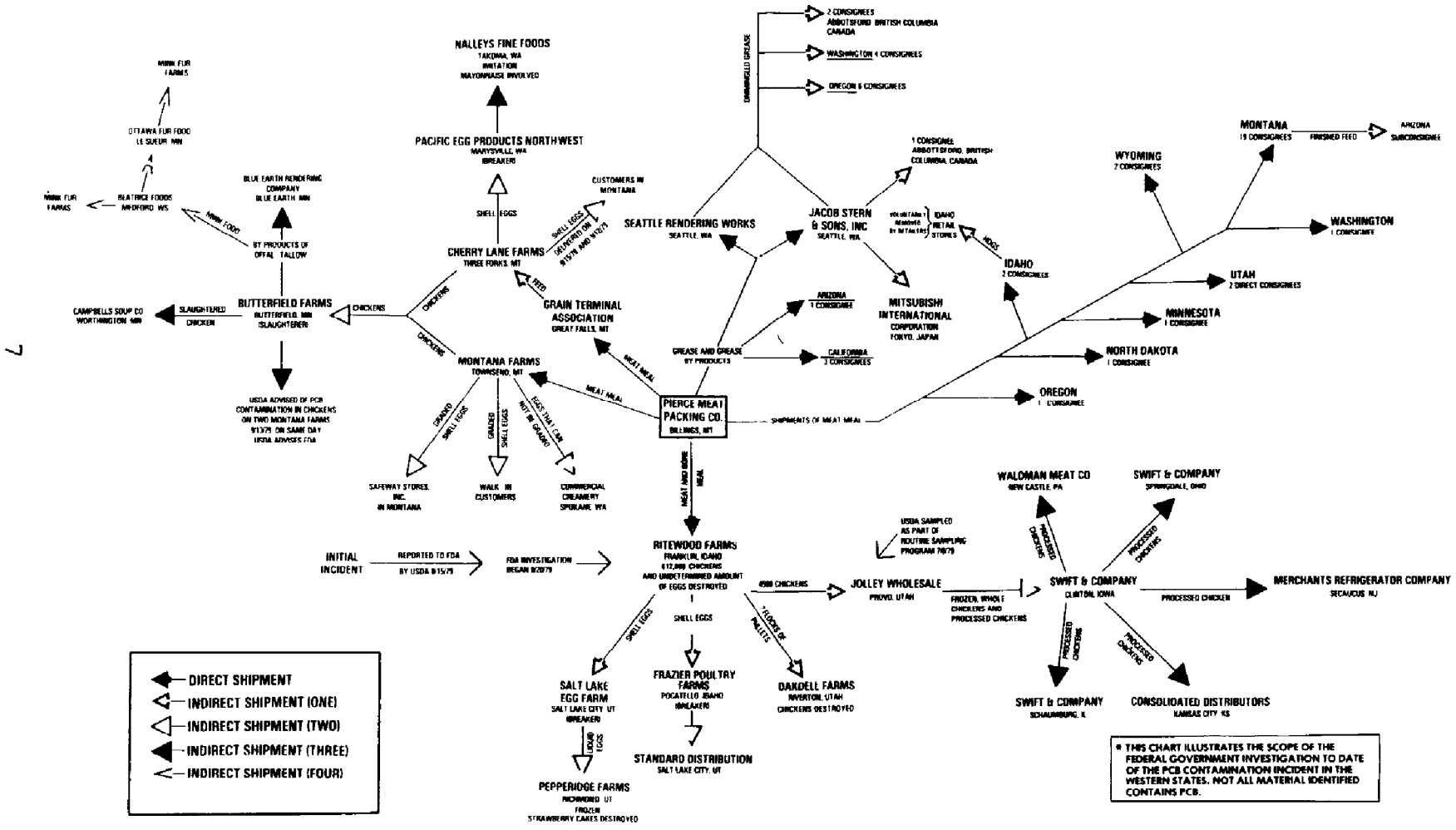
WHAT HAPPENED?

The 1979 PCB incident in the Western States started some time during June 1979 when a spare electrical transformer stored at Pierce Packing Company, a hog slaughter and processing plant in Billings, Montana, was damaged. This damage allowed about 200 gallons of Pyranol, a coolant containing PCBs, to leak into the company's drainage system. Pierce officials have speculated that the accident may have been caused by a tractor, which was inside the facility to pick up animal hair, hitting the transformer.

The PCBs that leaked into the drainage system were mixed with other wastes from the packing plant and processed into animal feed and grease. These products were marketed in the usual fashion to Pierce's customers who then further processed them or fed them to animals. These products, animals, and animal products were ultimately distributed to 19 States, Canada, and Japan. The extent of the PCB-contaminated products' distribution is shown in the chart on the following page. As the chart shows, at least three well-known U.S. food processors received contaminated food that ultimately had to be destroyed. If the contamination had not been discovered, PCB-contaminated food could have reached all 50 States and many other countries. On the other hand, if the contamination had been discovered earlier, much of the distribution of contaminated food could have been avoided.

Pierce's chairman told the House Subcommittee on Oversight and Investigations during hearings on September 28, 1979, that Pierce officials, although taking immediate action once Pierce was identified as the contamination

DISTRIBUTION OF PCB CONTAMINATION



SOURCE: FDA

source, were unaware not only of the accident, but of the health hazards associated with PCB contamination and even of the presence of PCBs on Pierce's premises. The chairman testified that initially Pierce was confident that it was not the contamination source because, as a USDA-inspected meat plant, it is closely monitored by USDA and all materials, supplies, machinery and equipment, raw materials, soaps and cleaning compounds, oils and greases, inks, and pesticides used or stored on the premises must have prior USDA approval.

FEDERAL ACTIONS TO DETECT PCB-CONTAMINATED FOODS WERE TOO SLOW

Although FSQS and FDA successfully identified the PCB contamination and traced its route through the food chain back to its source, they used 72 days to do so. This time period was up to 45 days longer than would have been necessary under ideal conditions. While we realize that ideal conditions seldom exist, we believe that FSQS/FDA actions could be improved significantly, particularly in light of the potential health issues involved and the complexity of, and rapidity with which food moves through, the distribution system.

How Federal agencies actually responded

On July 6, 1979, while the regular FSQS supervisor was on vacation, an FSQS inspector took a routine tissue sample from a barrel of chicken fat at Jolly Wholesale Poultry, a poultry slaughter and processing plant in Provo, Utah. The sample, which must be frozen at least overnight before being shipped, was placed in the plant's freezer. It remained there until July 16 when the regular supervisor, who had returned from vacation, noticed it and sent it to an FSQS laboratory in San Francisco for analysis.

The laboratory, which receives from 30 to 50 residue samples a day, received the sample on July 20. Because it was a routine monitoring sample, it did not receive priority processing; this procedure was consistent with FSQS policy. The sample was kept in the laboratory's freezer until July 24 when it was prepared for analysis. Routine testing of the sample began on July 25.

The sample was subjected to a series of tests. Initial indications of PCB contamination were noted on Friday, July 27, and confirmatory testing began on Monday, July 30. On Friday, August 3, conclusive evidence was found that the sample contained 15.65 parts per million of PCBs (compared with the established tolerance level of 3 parts per million).

The laboratory notified FSQS' western regional office for meat and poultry inspection of the test results late on the same day. On Monday, August 6, the western regional office notified the FSQS supervisor at Jolly Wholesale Poultry and asked him to identify the owner of the chicken from which the sample was taken as quickly as possible so that the regional office could take further steps to deal with the problem.

The source of the contaminated chicken was identified on August 10 as Ritewood Farms, an egg company in Franklin, Idaho. An inspector in FDA's Seattle office was notified on August 15 and FDA began its investigation on August 20. Additional chicken samples were obtained from the egg company on August 21 for pretesting, which began on August 24 and was completed on August 27. During the same week, August 27 to 31, egg samples were obtained from some of the egg company's other customers for testing.

To determine how the chicken became contaminated, FDA tested samples of various possible sources of contamination, including feed, water, and air. On September 12 FDA notified the egg company that a sample of animal feed received from the Pierce Packing Company on June 26 was highly contaminated with PCBs. FDA notified the FSQS veterinarian at Pierce and his circuit supervisor on September 13 that Pierce was possibly the source of the PCB contamination.

At a meeting at Pierce's plant on September 16, FDA said that it had concluded, based on information from a Pierce engineer, that the transformer accident was the source of the PCB contamination. Pierce started cleanup measures the same day. (See app. II for a detailed chronology of events.)

How Federal agencies could have responded under ideal conditions

After PCBs leaked from the electrical transformer at Pierce and entered the food chain undetected, only FSQS' and FDA's surveillance programs for chemical residues prevented millions of unsuspecting American consumers from consuming thousands of pounds of highly adulterated products. To see whether these surveillance programs need improvements to adequately protect consumers, we prepared the following chronology of significant actions associated with the PCB incident to compare when they actually happened with when they could have occurred under ideal conditions.

Dates of Federal Actions Actually Taken Compared With Dates of Actions Under Ideal Conditions

Action	Date of action	
	Actual	Ideal
FSQS monitoring sample taken	7/6/79	7/6/79
FSQS monitoring sample shipped	7/16/79	7/9/79
FSQS monitoring sample arrived at lab	7/20/79	7/13/79
FSQS monitoring sample prepared for analysis	7/24/79	7/17/79
FSQS monitoring sample testing began	7/25/79	7/18/79
Tests indicated PCB contamination	7/27/79	7/20/79
PCB residue confirmed in sample	8/3/79	7/22/79
FSQS regional office notified of violation	8/3/79	7/22/79
FSQS inspector at Jolly Wholesale Poultry notified of violation and asked to provide name of chicken supplier	8/6/79	7/22/79
FSQS inspector provided name of chicken supplier	8/10/79	7/22/79
FSQS notified FDA of violation	8/15/79	7/22/79
FSQS notified Ritewood Farms of violation	8/16/79	7/22/79
FSQS violation notification received by Ritewood	8/19/79	7/22/79
FDA began inspection of Ritewood	8/20/79	7/23/79
FDA took additional samples	8/31/79	7/23/79
FDA extensively sampled feed	9/6/79	7/23/79
FDA detected PCBs in Pierce feed	9/12/79	7/29/79
PCB contamination source identified by Pierce engineer	9/15/79	8/1/79

Our comparison shows that although FSQS and FDA succeeded in identifying the PCB adulteration and tracing it to its source in 72 days, their actions took up to 45 days longer than would have been necessary under ideal conditions. The significant delays that were experienced are as follows.

--After FSQS took the sample at Jolly Wholesale Poultry in Provo, Utah, it took 15 days to get the sample to the San Francisco laboratory for testing--7 days more than under ideal conditions. This delay occurred primarily because the sample was left unnoticed in the plant's freezer for more than a week.

--The laboratory's analysis of the sample took 10 days--5 days longer than under ideal conditions. Within 2 days, the tests showed that the sample was potentially contaminated. Because of his inexperience in analyzing patterns describing PCB contamination, the FSQS chemist testing the sample was not immediately certain that the test showed potential PCB

contamination. Although he discussed the problem with his supervisors on Friday, July 27, and they recognized that further testing was necessary, the confirmatory analysis did not begin until Monday, July 30. The chemist then waited 3 more days, until Thursday, August 2, to further discuss the matter with his supervisor, who determined that a further test was needed. This test, made on Friday, August 3, yielded conclusive evidence of PCB contamination.

In our opinion, once the test showed potential contamination, the nature of the testing should have been changed from routine to emergency, calling for an all-out effort--including work on holidays and weekends--to identify and control the contamination as soon as possible.

--FSQS took 8 days to identify the owner of the contaminated chicken--8 days longer than under ideal conditions. The FSQS inspector who took the sample at Jolly Wholesale Poultry on July 6 failed to record on the inspection form, as he should have, the name and address of the owner of the chicken from which the sample was taken.

--FSQS did not notify FDA of the problem until 5 days after the owner of the contaminated chicken was identified--5 days longer than under ideal conditions. FDA should have been notified at least as soon as the owner was identified.

--FDA did not begin its inspection at Ritewood Farms until 5 days after being notified of the violation--4 days longer than under ideal conditions. Food contamination by toxic chemicals such as PCBs requires a priority response from FDA.

--Twenty-four days elapsed before FDA identified Pierce feed as the source of chicken contamination at Ritewood--at least 17 days longer than under ideal conditions. Based on the previous history of feed contaminations 1/

1/According to FDA's November 1979 report on the 1979 PCB incident, six of the seven documented incidents in the United States since 1969 involving the direct PCB contamination of food were traced to animal feed. Also, FSQS noted in its January 1980 report on the incident that contaminated animal feed had repeatedly been traced as the source of a wide number of residue contamination problems in recent years.

and because Ritewood Farms had multiple feed suppliers, FDA should have extensively sampled feed from each supplier on the first day of inspection and the analyses should have been completed within 7 days.

In addition to the delays described above, a serious lapse occurred in another FSQS program--the failure to detect PCB residues in an egg sample. The egg sample, which was taken on July 17, 1979, at Frazier Poultry Farms in Pocatello, Idaho, a firm that had purchased eggs from Ritewood Farms, was shipped to FSQS' laboratory in Gastonia, North Carolina, for testing.

Due to a testing error, the laboratory reported incorrectly on August 1 that the July 17 egg sample taken at Frazier was negative for PCB residues. About a month later, after Ritewood Farms was identified as a source of contamination and other egg samples from Frazier showed PCB residues, the July 17 sample was reevaluated and found to be positive. This error delayed recalls and quarantines of adulterated eggs by about 1 month and might never have been detected had FSQS not taken the contaminated chicken fat sample at Jolly Wholesale Poultry.

The laboratory error not only exposed consumers unnecessarily to contaminated products, but brings into question the adequacy of FSQS' chemical analysis program. This program must provide timely, accurate results because each sample is the surrogate for thousands of pounds of like products that are not sampled. The need for accurate analyses of each sample is evidenced by the following statement by USDA's Assistant Secretary for Food and Consumer Services before the House Subcommittee on Oversight and Investigations in September 1979.

> "I should explain, however, that detection of one particular incident--such as the one that has caused the contamination in the western States--is very much a matter of chance. It is entirely possible that an occurrence such as the recent PCB incident could go undetected by our monitoring system, for a long period of time. It is also possible that a single incidence of this size could go entirely undetected. The monitoring system is designed to establish significant national trends over a period of 12 months. We were lucky in picking up this single incident relatively quickly."

TRACING DISTRIBUTION OF CONTAMINATED PRODUCTS WAS EXTENSIVE AND CLEANUP WAS COSTLY

Although the source of the PCB contamination was identified on September 15, much remained to be done to track and identify others who purchased contaminated feed, chickens, eggs, egg products, and grease in 19 States, Canada, and Japan. Through mid-November 1979, FSQS/FDA investigators visited more than 350 farms, slaughterhouses, food and feed processors and distributors, and retail establishments. During this 2-month period, more than 1,800 FSQS and 650 FDA samples were taken and analyzed at laboratories around the country. In contrast, during all of 1978, the monitoring phase of FSQS' residue program analyzed a total of 2,432 samples for all chlorinated hydrocarbons.

The added burden of analyzing these samples for PCB residues severely taxed the capabilities of FSQS and FDA laboratories. In its report on the incident (see p. 15), FSQS acknowledged that it (1) collected more samples than it could analyze and (2) needed to find ways to reduce the number of samples required when a contamination incident occurs and to assign priorities to the samples awaiting analysis.

FSQS and FDA estimated that, respectively, they spent $881,000 and $650,000 for salaries, travel, and chemical analysis work associated directly with the PCB incident. Costs were also heavy to private enterprises unlucky enough to have purchased contaminated feed, animals, and food products. By the end of October 1979, the FSQS/FDA investigation had resulted in the destruction of about 800,000 chickens, 3,840,000 eggs, 4,000 hogs, 74,000 bakery items, 800,000 pounds of assorted animal feeds and feed ingredients, and 1.2 million pounds of grease. In addition, 11 firms initiated recalls of about 130 batches of feed and feed ingredients. FSQS estimated that the animals, food, and feed products that were destroyed cost private enterprises more than $2 million.

Perhaps of even greater impact to affected companies will be the loss of public confidence and possible law suits stemming from the incident. For example, during congressional testimony, the chairman, Pierce Packing Company, said that:

> "The accident, which was not reported to management, and caused the toxic contamination of our animal meal department, has caused irreparable damage to our Company. The integrity,

credibility and reputation of our Company has been dramatically impaired * * *."

* * * * *

"The effect of PCB contamination in the State of Montana and the Northwest has resulted in panic in the poultry, egg, feed and livestock industries."

* * * * *

"The effect on the consuming public may never be known. The liabilities may go on ad infinitum. Liability claims no doubt will result in astronomical sums of money far in excess of our ability to pay. It is impossible for any company of our size to be financially responsible for potential claims which may result from this accidental disaster."

FSQS estimated the cleanup costs as follows.

FSQS and FDA costs	$1,531,000
Cost of food and feed destroyed	2,018,000
Total	$3,549,000

These estimated costs represent only the minimum cost of the cleanup and are not useful as a precise measure. They do not include costs incurred by (1) other governmental agencies involved in the incident, (2) consumers, whose costs may never be measured or even traced to the incident, and (3) all private businesses that were damaged by the incident.

FEDERAL STUDIES OF THE CONTAMINATION INCIDENT

Both FSQS and FDA, with EPA help, studied the PCB incident to identify needed improvements and have issued reports on their studies. 1/ Also, OTA included information on the incident in its December 1979 report on its study of environmental contaminants in food. (See p. 1.) These reports and related actions taken by the agencies are discussed below.

1/FSQS's report, issued in January 1980, is entitled "Report on the PCB Incident in the Western United States." FDA's report, issued in November 1979, is entitled "PCB Contamination of Food in the Western United States."

The FSQS study

Both the FSQS report and the Assistant Secretary for Food and Consumer Services during the September 1979 hearings concluded that FSQS actions in handling the PCB incident were not as timely as they might have been. According to the Assistant Secretary, weaknesses in the FSQS residue monitoring program included (1) unacceptable delays in sample taking and analyzing, in identifying the owner of the sampled product, and in notifying the owner and FDA about the violative sample, (2) analyzing an egg sample without detecting PCB contamination, and (3) handling the violation in a routine manner that did not recognize the potential for rapid, widespread contamination of U.S. food supplies.

According to FSQS' report, weaknesses in its monitoring program included delays in (1) submitting samples, (2) obtaining laboratory analyses, and (3) identifying contamination sources. The report also noted confusion in the division of authority within FSQS and the need for substantial improvement in clarifying and coordinating the division of responsibility among FSQS and other Federal agencies, particularly FDA.

The report said that because FDA is primarily responsible for the investigation once a problem is identified, USDA's role is secondary, supportive, and unstructured. It added that from the States' viewpoint, the Federal effort in cleaning up the 1979 PCB incident often seemed highly disorganized. It said that the States were confronted with several Federal agencies, each with different authority and different approaches. It concluded that the existing division of responsibility among FSQS, FDA, and EPA practically ensured that uniform and coherent regulatory policy would be difficult to obtain.

The FSQS report described a number of actions that FSQS had taken or would take to provide a better response to food contamination incidents. Among the more important actions cited were:

--Creating the contamination response system to more quickly respond to such incidents. The system (1) sets conditions that will trigger prescribed step-by-step actions and (2) identifies the responsibilities of each FSQS component at each step. This system was implemented in January 1980 and, according to the FSQS Administrator, was used in a contamination incident in Alabama with excellent results.

--Creating educational programs for both FSQS personnel and the general public to emphasize the dramatic costs and dangers to human health from contamination incidents.

--Integrating the work of FSQS' Poultry and Dairy Quality Division into overall FSQS residue monitoring efforts.

--Studying (1) procedures and sampling techniques at the Poultry and Dairy Quality Division's laboratory in Gastonia, North Carolina (which reported the erroneous egg sample analysis), and (2) the feasibility of introducing new equipment to automate the initial identification of chemicals.

--Clarifying FSQS instructions to (1) give field personnel explicit procedures and timetables to follow in taking, forwarding, and reporting violative residues in samples and (2) direct that priority be given to tracing samples containing violative residues and notifying FDA and EPA of the incident.

In its comments on a draft of this report (see app. III), USDA described the contamination response system as a program that is activated whenever FSQS receives information indicating a known or potential contamination problem in the meat, poultry, or egg products supply. It may be triggered by a sample result from FSQS' national residue program or information furnished by FSQS inspectors, industry, State government, another Federal agency, or any other reliable source. According to USDA, the system is fully operational and has been used to effectively handle more than 70 residue violations since it was organized in January 1980.

USDA said that reporting residue findings has been significantly faster under the new procedures. One reason for this improvement is that samples taken after a positive residue finding are identified as such in the laboratory and given priority. USDA believes that by cutting through much of the red tape involved in handling environmental contamination incidents, the contamination response system has corrected many of the weaknesses that were evident in FSQS' handling of the PCB contamination incident in 1979.

Also, USDA said that FSQS administers two residue monitoring programs--an egg products program, through its Poultry and Dairy Quality Division, and a meat and poultry program, through its science organization. Because they were based on different legislative mandates and were created at different times, the programs were operated independently until the

1979 PCB incident showed the need for their coordination. USDA said that the two programs are now fully coordinated. USDA added that vast improvements had been made at the egg products laboratory in Gastonia, North Carolina, and that a major expansion of the laboratory was being pursued.

Concerning clarification of instructions to field personnel, USDA said that a single directive will be distributed to all employees involved in the program to detail, step by step, the procedures to be followed in the case of a positive residue finding. The instructions will also detail the notifications that are to be made in each case both from the field to FSQS headquarters officials and from FSQS to other Federal and State agencies.

We believe that these actions, if properly implemented, should improve FSQS' residue monitoring efforts and reduce its response time in future contamination incidents.

In addition to the actions described above, FSQS published in the February 29, 1980, Federal Register a proposed regulation that would ban using PCBs in new or replacement equipment in federally inspected meat, poultry, and egg product plants. This proposed regulation was finalized in the October 17, 1980, Federal Register. Also, with FDA and EPA, FSQS developed proposed regulations published on May 9, 1980, that would phase out PCBs in all existing equipment at such facilities. On December 2, 1980, the deadline for public comments on this proposal was extended to March 4, 1981.

The FDA study

In the report summarizing its findings, FDA concluded that the PCB incident posed no threat to consumer health because of the low PCB levels that were found in marketed food and the successful efforts to destroy or halt the distribution of contaminated products. It said, however, that Federal and State health officials, industry, and the American public had ample reason to be concerned because each contamination incident brings with it, in addition to severe economic losses, potential threats to consumer health and a loss of confidence in the safety of the Nation's food supply.

FDA's evaluation of the PCB incident did not address (1) the relatively low priority it originally gave the investigation (FDA did not begin its inspection at Ritewood Farms until 5 days after notification) and (2) the time it took (24 days) to identify the source of contamination at

Ritewood. Nevertheless, the report said that FDA was carefully evaluating, in retrospect, its role in the investigation to see what changes should be made to improve its performance and response. (This evaluation was subsequently completed and submitted to the Congress.)

FDA also noted that to try to prevent future incidents of this kind, FDA officials had met on November 14, 1979, with representatives from the agribusiness community and others concerned with the production of animal feed and food derived from animal products to discuss ways of identifying and preventing chemical contamination problems. This meeting was considered an important first step in educating those involved in food production about PCBs and similar problems.

According to FDA's March 1980 summary of the November 1979 meeting, the participants suggested several actions that industry and the Government should take to control PCB contamination. Among the suggestions were that industry

--inventory all equipment that might contain PCBs,

--label all equipment containing PCBs,

--use established newsletters to educate others about PCBs,

--follow accepted production and distribution standards,

--obtain products from approved suppliers, and

--conduct more testing for chemical contaminants closer to the point of manufacture rather than at the point of consumption.

The participants also suggested that the Government

--designate a lead agency from among FDA, FSQS, or EPA to be responsible for dealing with the different types of accidents that may occur;

--establish an emergency organization to handle contamination accidents;

--implement an awareness program that will reach all food and feed manufacturers; and

--devote research resources to developing new and improved technology to detect contamination.

On May 7, 1980, FDA told us that it (1) had established an emergency response team of experts, subject to call at any time, to handle future food contamination problems, (2) was compiling lists of toxic chemicals that have caused problems and commodities susceptible to chemical contamination, (3) was compiling a list of references of test procedures for industry use in quality-assurance programs, and (4) had scheduled a meeting to inform the American Feed Manufacturers of actions taken and being taken by FDA on suggestions received at the November 1979 meeting.

In its comments on a draft of this report, HHS told us that FDA regularly exchanges information concerning Federal food surveillance efforts through the Interagency Regulatory Liaison Group, a voluntary work group composed of staff from FDA, EPA, USDA, the Department of Labor's Occupational Safety and Health Administration, and the Consumer Product Safety Commission.

HHS also said that, since the Montana incident, FDA has written and implemented a new regulatory procedures manual chapter on emergency procedures. HHS said that the agency's organizational structure includes offices in 146 cities staffed with investigators and equipped for emergency operations.

Also, as noted on page 17, FDA, EPA, and FSQS published proposed regulations in the May 9, 1980, Federal Register that would require removing all equipment containing PCBs from food production and feed facilities nationwide.

We believe that these actions, if properly implemented, should help prevent future incidents or enable FDA to better respond to them if they occur.

The OTA study

In the report on its study of environmental food contamination in the United States (see p. 1), which included information on the 1979 PCB incident, OTA said that:

--Federal and State monitoring systems have failed to detect environmental contaminants as they enter the food supply. In some cases, people or animals have become ill before the responsible contaminant was identified.

--FDA relies on action levels rather than tolerances (see p. 2) to regulate environmental contaminants in food. The less formal action levels are used because the procedures required to set a tolerance,

which FDA is authorized to do under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.), are complex, cumbersome, and time consuming.

--No policy exists defining the relative weights to be given to the evidence when setting an action level or tolerance. Although FDA maintains that the public health factor outweighs all others, it also considers such factors as the potential impact on the national food supply, the costs involved, and the extent to which a substance cannot be avoided in food production.

--Although technology now exists to detect unregulated chemicals as they enter the food chain, little effort is made to do so, apparently because the costs of such a detection system are so high.

--Managing food contamination incidents is hindered because the food system is complex, food moves through the system so rapidly, and State and Federal agencies have not coordinated their information-gathering activities.

In commenting on coordination failures, OTA said that delays similar to those in the 1979 PCB incident--such as the 5 days that elapsed from the time FSQS was confident that it had a PCB incident until it notified FDA of its findings and the additional 5 days it took FDA to begin investigating the incident--would be unlikely if only one Federal agency were involved or communications between the agencies were better. OTA also said that the involvement of three different Federal agencies obstructed efficient communication in Idaho between the State agencies and the Federal Government.

OTA said that EPA, which took air and water samples in the area around Ritewood Farms before the PCB-contaminated animal feed was identified, did not report its negative findings to Idaho officials. It also said that at first, neither FSQS nor the Idaho Department of Agriculture to which FSQS had reported its results had informed the Idaho Department of Health and Welfare, which is concerned with protecting the public health, of the PCB incident. It added that the fact that several different Federal and State agencies are involved with different aspects of controlling and regulating a contamination incident further complicates an already complicated problem.

OTA said that the Congress had four basic options to consider regarding the Federal response to the environmental contamination of food. It said that the Congress could:

--Allow the present system to continue.

--Amend the Federal Food, Drug, and Cosmetic Act to specifically address the unique problems of environmental food contamination. Such amendments could include any or all of the following: (1) simplify administrative procedures for setting tolerances, (2) require that a tolerance be established within a specified time after an action level is set, (3) clarify the extent to which economic criteria can be used in setting tolerances, and (4) grant FDA authority to set tolerances for different regions of the country based on expected levels of exposure, regional levels of contamination, and local eating patterns.

--Establish a national system that monitors for suspected or uncharacterized (not regulated or suspected) environmental contaminants. As an interim measure, a pilot program could be implemented while the necessary research and development is being done to see if such a system would be feasible and cost effective.

--Designate a lead agency or establish a Federal assistance center to handle the Federal response to contamination problems.

OTA said that the last three options were not mutually exclusive; that if the Congress wished to put greater emphasis on protecting consumers from contaminated food, one or more could be chosen.

As of November 30, 1980, the Congress had not taken action to change the present system. As noted previously, however, FSQS and FDA, together with EPA, have taken several actions as a result of the 1979 PCB incident to try to prevent future incidents or help them deal more effectively with such incidents if they occur in the future.

CHAPTER 3

FEDERAL AGENCIES' RESPONSES TO OUR PREVIOUS RECOMMENDATIONS

Over the years, we have issued a number of reports that recommended changes to USDA, EPA, and FDA programs to control chemicals in the Nation's food supply and in the environment. For the most part, the agencies have been responsive in taking actions on our recommendations. However, for various reasons, such as limited resources and inadequate technology, the agencies have not taken or completed actions on some of our recommendations. Recommendations that relate either directly or indirectly to the PCB contamination incident and the agencies' responses to the recommendations are discussed below.

REGULATING CHEMICALS IN FOOD

Environmental contaminants, pesticides, and animal drugs in food and feed products are interrelated because they are all chemicals that are regulated under the same monitoring programs and are often detected by the same multiresidue testing method. Consequently, recommendations regarding pesticides generally apply to detecting and removing food and feed containing environmental contaminants from commerce. The following recommendations have such applicability.

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

In this report we concluded that FDA, USDA, and EPA actions to protect consumers from illegal and potentially harmful residues of animal drugs, pesticides, and environmental contaminants in raw meat and poultry had not been effective. We recommended that the Congress amend 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.) to authorize USDA to (1) quarantine animals from a violative grower (one whose animals are found to contain illegal residues) and (2) require growers to place an identification tag on animals before they are sent to an auction house or slaughterhouse;

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

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

As of November 1980 the Congress had not amended the legislation.

We also recommended several specific actions that USDA, FDA, and EPA could take to improve their programs to prevent the marketing of raw meat and poultry containing illegal residues. We recommended that the Secretary of Agriculture

--revise the methods being used to compute residue violation rates to more accurately reflect the extent to which consumers are exposed to illegal residues in raw meat and poultry;

--expand USDA's monitoring efforts to include, at least periodically, all the animal drugs, pesticides, and environmental contaminants for which detection methods exist;

--develop the capability to conduct residue analyses at slaughterhouses and encourage the expansion of private residue monitoring efforts;

--develop a sampling program designed to enable FDA to develop case histories on violative producers; and

--develop a more effective pretest system to prevent producers from shipping additional violative animals.

We recommended that the Secretary, HHS, direct the FDA Commissioner to

--reevaluate available data on the possible carcinogenicity of arsenical drugs 1/ and take appropriate steps to withdraw approval of the drugs if they are found to cause cancer;

--require animal drug manufacturers to develop residue detection methods that can be completed at slaughterhouses within 24 hours after slaughter;

1/Arsenic is also a pesticide and a ubiquitous environmental contaminant.

--make more effective use of available enforcement methods;

--speed up the development of detection methods suitable for regulatory action; and

--establish guidelines to ensure effective followup on residue violations.

We recommended that the EPA Administrator

--review available data on the safety of cadmium and hexachlorobenzene (both of which are environmental contaminants suspected of causing cancer, mutations, and birth defects) and take appropriate steps to restrict their manufacture, use, and distribution if they are found to cause cancer; and

--require pesticide manufacturers to develop residue detection methods that can be completed at slaughterhouses within 24 hours after slaughter.

The agencies agreed that improvements were needed in their programs. USDA agreed that (1) its residue program should be diversified and substantially expanded through a much larger volume of samples, (2) USDA or other concerned agencies must conduct or foster research to speed the advancement of residue analysis technology, (3) private monitoring efforts should be expanded, and (4) it would work with FDA to strengthen its regulatory programs dealing with violative producers.

In response to our recommendation that it develop a more effective pretest system to prevent producers from shipping additional violative animals, USDA said that it lacked authority to enforce such a system. But it said that it would ask the Congress to enact legislation authorizing USDA to (1) quarantine animals from violative producers and (2) require producers to place permanent identification on animals before they are marketed. In late December 1979 USDA submitted its legislative proposal to the Office of Management and Budget, but as of September 2, 1980, the proposal had not been approved by the administration. According to FSQS' January 1980 report on the 1979 PCB incident, USDA's Assistant Secretary for Food and Consumer Services has testified twice before the Congress on the need for quarantine authority.

EPA started implementing our recommendation on cadmium and hexachlorobenzene. However, in November 1979 EPA informed the chairman, House Committee on Government Operations, that it had to defer this action to give attention to other chemicals that it said posed a greater health hazard.

HHS agreed to reevaluate data on the carcinogenicity of arsenical drugs and to use available enforcement alternatives more effectively. However, neither HHS nor EPA agreed with our recommendation that they require animal drug manufacturers to develop residue detection methods that can be completed at slaughterhouses within 24 hours after slaughter.

According to HHS, significant advances in instrumentation and methodology needed to be developed before regulatory agencies could translate research methods into effective, reliable, and simple test methods for widespread use. HHS said that the state of the art in methodology was not advanced enough to permit development of assay methods for use at slaughterhouses.

According to HHS, FDA was investing resources to develop assay methods and was requiring the regulated industry to submit methods that were accurate and could be used for regulatory purposes. HHS said that it was fully committed to continuing FDA's efforts but believed the capability could not be quickly or easily developed.

HHS said that if it were to require animal drug manufacturers to develop residue detection methods that could be completed at slaughterhouses within 24 hours after slaughter, existing technology would be unable to produce analytical methods that were precise and reliable enough to use under slaughterhouse conditions. According to HHS, research laboratories had methods that some slaughterhouses were experimenting with that could detect and confirm specific drug residues at the extremely low levels permitted to remain in meat and poultry, but they were not generally practical for widespread in-plant use because sophisticated equipment and special expertise are required.

HHS also said that although some screening methods were being developed that could be performed in 24 hours, these methods would not be adequate for regulatory purposes and would require substantial investment of new laboratory capability in or very near all federally inspected slaughterhouses.

EPA said that residue detection methods were available for all pesticides for which tolerances in raw meat and poultry had been established. It also said that many of these methods could be completed within 24 hours even though a 24-hour methodology had never been a requirement for establishing a pesticide tolerance.

EPA said that the real problem was that the residue detection methods required for tolerances apply only to individual pesticides, while USDA and FDA had found it necessary

to use multiresidue detection methods to perform their routine responsibilities. According to EPA, it would be more practical to develop rapid, multiresidue detection methods than to impose a 24-hour completion criterion on methods for individual pesticides. EPA pointed out, however, that it had no clear legal authority under the Federal Food, Drug, and Cosmetic Act to require tolerance petitioners to develop 24-hour, multiresidue detection methods suitable for the particular pesticides for which they wish to establish a tolerance.

EPA said that it lacked the resources to develop multiresidue detection methods itself, but that it would be willing to work with FDA and USDA to develop rapid, multiresidue detection methods where feasible, if such methods would substantially contribute to public health protection. EPA believed that residue testing at slaughterhouses on a 24-hour turnaround would be quite costly. It said that a determination must be made as to whether a substantial additional expense would be justified by whatever additional protection of the public health such testing might provide. According to EPA, the high expense would have to be borne by either the meatpacking industry (and ultimately the consumers through higher prices) or the Government.

EPA said that determining whether the additional expense would be justified would require a careful survey to determine (1) the rate of tolerance violations, (2) the amount by which the violative residues exceed the tolerances, (3) the health problems that may result from eating meat and poultry with these residue levels, and (4) the technical feasibility of developing such residue testing techniques for enforcement purposes. According to EPA, the benefits of onsite residue analysis could then be compared meaningfully with the additional costs.

We said that we recognized that developing residue detection methods that could be completed at slaughterhouses within 24 hours could not be accomplished in the short term and was limited by the existing state of analytical technology. However, we said that we believed that consistent with the Federal Food, Drug, and Cosmetic Act, the responsibility should be placed clearly on animal drug and pesticide manufacturers to develop faster methods. We said that FDA and EPA should consider establishing target dates for developing new methods, which could spur developments in analytical technology.

We pointed out that by placing greater emphasis on industry for developing faster detection methods for individual drugs and pesticides, FDA and EPA could concentrate their limited resources on helping USDA develop rapid, multiresidue screening methods. We said that using rapid screening tests (such as the swab test that USDA cited for detecting antibiotic residues in cattle kidney tissue) may reduce, rather than increase, the costs of residue analysis as EPA suggested. Currently, USDA must complete quantitative and qualitative residue analyses for each sample collected because it has no way of knowing which residues may be present. We said that by using a screening method to identify the presence of a drug or pesticide in an animal, USDA could limit the use of the more complex and expensive quantitative methods to those animals actually known to contain residues. We said that this may enable USDA to expand its monitoring efforts without increasing the cost.

HHS said that it did not believe that speeding up efforts to develop detection methods was practical because HHS' new analytical methods could not always be expedited simply by redoubling resolve or increasing developmental resources, particularly when the technological state of the art is the limiting factor.

According to HHS, FDA was, and had been for the past several years, working to develop rapid screening methods that could be used at slaughterhouses to indicate where more specific and accurate assay methods should be used. HHS said that the screening tests would not be appropriate for regulatory purposes because this relatively unsophisticated methodology was not specific enough and had not yet been developed to the point where it could be used. HHS said that the much more highly sophisticated methodology required to support regulatory action was even more difficult to develop and, in many instances, could not be adequately developed without significant breakthroughs in technology. However, according to HHS, FDA was working toward this goal. HHS said that one function of FDA's Residue Task Force was to review available methodology and recommend changes and priorities when appropriate.

Regarding guidelines to ensure effective followup on residue violations, HHS pointed out that guidelines currently existed in the form of (1) agreements between USDA, EPA, and FDA and (2) publications--the Compliance Program and Program Circulars--that had been issued to FDA field offices. HHS said that as part of FDA's study and reevaluation of its residue programs and in particular the development of alternative enforcement strategies in this area, it expected that the current guidelines would need some modification.

According to HHS, the alternative enforcement strategies coupled with a means to positively identify animal carcasses would help to assure more effective followup.

We pointed out that detection methods that could support legal action against a violative grower had been available for only 3 of the 25 animal drugs included in USDA's monitoring program between 1974 and 1976. We added that

--the Federal Food, Drug, and Cosmetic Act requires animal drug manufacturers to develop practicable detection methods adequate to support regulatory action as a condition of FDA's approval to market the drug;

--FDA regulations state that a method is practicable only if it is adequate for regulatory purposes; and

--although the technological state of the art may prevent some animal drug manufacturers from developing such methods, the Federal Food, Drug, and Cosmetic Act does not exempt those manufacturers from the act's requirements.

Accordingly, we said that FDA should (1) promptly require animal drug manufacturers to develop detection methods suitable for regulatory action and (2) withdraw approval to market those drugs for which adequate methods cannot be developed within an established period.

"Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food Is Essential" (Report to the Congress, CED-79-43, June 22, 1979)

This report concluded that under Federal policies and procedures for monitoring pesticide residues, adulterated food imports often entered U.S. commerce because (1) some foods were rarely sampled, (2) delays occurred in residue analyses, and (3) many potential residues were not detected by the analyses used.

The report said that half of the imported food that FDA found to be adulterated during a 15-month period was marketed without penalty to importers and consumed by an unsuspecting American public. This occurred because FDA's policy permitted perishable products to enter commercial channels before residue analyses were completed.

To ensure that imported food was adequately monitored for pesticide residues, we recommended that the Secretary of HHS require the FDA Commissioner to

--obtain data about foreign pesticide use as a basis for determining what pesticide residue analyses to perform (recommendation 1);

--determine the source and identity of all unknown residues detected in imported food (recommendation 2);

--commit resources necessary to develop analytic methods that detect most pesticide residues likely to be present in imported food (recommendation 3);

--revise the residue sampling program to ensure that all significant imported food commodities are sampled each year for pesticide residues (recommendation 4);

--provide for the timely completion and reporting of laboratory analyses so that actions can be taken to prevent the marketing of adulterated food (recommendation 5);

--take appropriate actions to deny entry of suspected adulterated shipments into U.S. commerce until check (confirmatory) analyses are completed (recommendation 6); and

--consider including provisions for penalties, such as automatic forfeiture of security bonds, in importer agreements to penalize importers of adulterated food that has already been marketed (recommendation 7).

Additionally, we recommended that the Administrator, EPA, together with the Secretary of HHS, through the Commissioner of FDA,

--determine whether existing and proposed action levels are safe and appropriate (recommendation 8);

--establish action levels for residues of suspended and canceled pesticides that may be unavoidably present in food, but only after determining that such residues are safe (recommendation 9); and

--investigate pesticide-use conditions in foreign countries when significant residues of a pesticide are detected in an import to ensure that action levels are, in fact, lower than residue levels that may result from the direct, purposeful application of pesticides to food (recommendation 10).

Recommendation 1

HHS agreed that FDA should have data on pesticides that are approved for use in the production of food in foreign countries. According to HHS, FDA was seeking this information on a voluntary basis, had received official listings of pesticides used in several countries, and had instructed its field offices to use the data received from Mexico in analyzing imported Mexican produce. HHS said, however, that there were limitations to anticipating what pesticide residues might be present in imported foods because of pesticide misuse, inadvertent environmental contamination, and lack of statutory authority to require foreign data.

In October 1980 FDA told us that the special monitoring program for pesticide residues in imported Mexican produce, which was implemented in fiscal year 1979, had served as a pilot test for the feasibility of effectively using information on pesticides recommended for use in foreign countries. It said that for fiscal year 1980, it was continuing to follow the revised program for imported Mexican produce and had restructured its pesticide monitoring program for foods imported from other countries. It said that FDA field offices had been instructed to include analyses of samples of imported food for those pesticides for which recommended Codex 1/ tolerances are pending approval. According to FDA, this list of pesticides will be expanded to include information obtained on pesticide/commodity combinations permitted by other countries.

Recommendation 2

HHS did not agree with our recommendation to determine the source and identity of all unknown residues. But it said that it recognized the need for caution in dismissing unidentified residues as posing no risk to the consumer. It said that FDA's Residue Task Force was developing criteria to help FDA analysts determine when to follow up on unidentified residues, thereby providing a significant degree of

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1/Codex refers to the Codex Committee on Pesticide Residues, an international committee whose membership is comprised of more than 100 national Governments, including the United States. Sponsored by the World Health Organization and the Food and Agriculture Organization of the United Nations, it establishes internationally acceptable tolerances for pesticide residues. It also provides information regarding what pesticides might be used in foreign countries.

consumer protection within existing and projected resource limits.

Recommendation 3

HHS concurred in our recommendation to commit resources necessary to develop methods that detect pesticide residues likely to be present in imported food. HHS said in April 1979 that it had reevaluated this program over the past several years and had assigned additional personnel to develop multiresidue testing methods that can be used to simultaneously detect residues of many different pesticides. HHS cautioned, however, that the complexity and scientific limitations involved in developing additional multiresidue testing methods should be recognized and that before most remaining pesticides can be included in such methods, further major advances in analytical technology must occur.

In October 1980 FDA said that in view of general Federal fiscal limitations, it had been unable to acquire the additional resources needed for this and other programs. It said, however, that in recognition of the priority of pesticide methods development and related research in residue analysis, it had reprogramed 13 existing positions from other food safety activities to the pesticide program in fiscal year 1980. FDA said that it did not anticipate further reprograming to the pesticide program because of the negative impact it would have on equally important programs. FDA added, however, that it was more effectively using the resources assigned to pesticide methods development by using the Surveillance Index 1/ for determining development needs and the relative priorities for meeting current and future pesticide surveillance program objectives.

1/The Surveillance Index provides a means for selecting pesticides for FDA surveillance based on health risk and potential for occurrence in food. The index categorizes chemicals by the relative health risks associated with human exposure to their residues in food. If suitable analytical methodology is not available for high priority index chemicals, the index will provide a mechanism for determining analytical method development priorities. It will also be used in determining which findings of unusual residue occurrences should receive further agency attention.

Recommendation 4

On our recommendation that FDA revise its residue sampling program to ensure that all significant imported food commodities are sampled each year for pesticide residues, HHS said that after the investigative phase of our study, FDA had taken specific steps--the restructuring of the program for Mexican produce (see p. 30)--to improve sampling procedures. It said that this program provided more specific instructions and information about such factors as (1) the volume of import commodities, (2) previous pesticide problems, and (3) the likelihood of residues.

In October 1980 FDA told us that implementation of this recommendation had focused on three activities: (1) establishing criteria for determining what constitutes "significant imported food commodities," (2) identifying current information sources that can be used for identifying imported food commodities that meet the criteria established, and (3) preparing suitable program instructions for guiding FDA field offices in selecting imported food commodities for sampling.

According to FDA, the following general criteria for selecting imported food commodities for pesticide residue analysis were developed and included in the fiscal year 1980 program.

--The commodity has the potential for containing pesticide residues.

--The commodity is of maximum dietary importance.

--Consumption of the commodity, if it contains unsafe pesticides at time of entry, can result in risk to consumers. (This criterion is intended to minimize sampling of certain commodities that will normally be used as a minor ingredient in a finished food product and those commodities that normally undergo further processing that would reduce or remove residue that might be present.)

FDA said that the information sources to be used for identifying imported food commodities that meet the above priority sampling criteria included weekly summaries of shipments unloaded, reports from USDA's Crop Reporting Board, foreign agriculture circulars, and reports on U.S. imports from Mexico and on foreign agricultural trade of the United States.

Regarding program instructions, FDA said that the imported Mexican produce monitoring program for fiscal years 1979 and 1980 included detailed information on the volume and peak

shipping periods during which such commodities are exported to the United States. It said that the program instructed FDA field offices to give priority to sampling commodities based on this information. It added that for its fiscal year 1980 monitoring program for imported foods from other countries, USDA's publication "Foreign Agricultural Trade of the United States" was used by FDA field offices in the same manner that the information on Mexican imports was used. This publication includes volume data on fruits and vegetables imported, countries of origin, and major ports where these foods might be offered for entry into the United States.

Recommendation 5

In response to our recommendation that FDA provide for the timely completion and reporting of laboratory analyses so that actions can be taken to prevent marketing adulterated food, HHS said that analyses may be delayed because of unusually heavy demands on FDA's analytical capability. It said, however, that this was not considered a serious problem because suspect food was held until the analysis was completed.

We said that contrary to HHS' statement, we believed that the delays could be a serious problem because many foods, particularly produce, are perishable and could not be held at the border 11 days--the average time FDA took to determine whether shipments were violative during the period we sampled. We pointed out that if analyses could not be completed more quickly, FDA would have to release the shipment for U.S. entry before analysis was completed, let the shipment spoil, or return the shipment to the country of origin. We said that these options were much less desirable than making timely decisions to allow or deny entry based on residue analyses.

In October 1980 FDA told us that it has always tried to assure that the laboratory analysis of food suspected of being adulterated is completed in a timely manner and that food is not released for distribution until the analysis is done. It said that to further assure that appropriate action is taken, it had initiated improvements in fiscal year 1979 in the use of a computerized residue data reporting system for the special monitoring program for pesticide residues in imported Mexican produce. According to FDA, the improvements included more timely and accurate data for immediate assessment of residue findings, trends, and emerging problem areas and provided for feedback/redirection of field surveillance efforts when residue problems were identified. It said that this, in turn, enhanced the timeliness of FDA's coverage and of actions against potentially violative imported commodities from Mexico. FDA said, however, that the total system had

not been extended to its monitoring of food imported from other countries because of resource limitations.

Recommendation 6

HHS said that FDA did take action to deny entry of suspected violative shipments into U.S. commerce before check analyses were completed. HHS said that FDA's policy and longstanding practice had been to deny entry to such shipments and that check analyses had had no bearing on this practice because shipments were not released until check analyses were completed.

Our review of FDA records had disclosed many instances where violative shipments, which underwent check analyses, entered the U.S. market. However, these records did not show whether shipments were released before or after completion of the analyses which indicated the shipments were violative. Accordingly, we concluded that FDA was not holding commodities at the border that had been found repeatedly violative and was making check analyses on produce shipments that had already been released into commerce and consumed.

In October 1980 FDA said that, as HHS had stated, FDA's longstanding policy is to deny entry of suspected adulterated shipments into U.S. commerce until check analyses are completed. It said that if it has any reason to suspect illegal residues, the shipment is held pending results of the analysis. It said that the only exception to this general rule is that perishable foods sampled on a surveillance basis (that is, when there is no suspicion of illegal pesticide residues) may enter commerce pending analysis. It added that if illegal residues are detected in the sample, importers may be requested to recall the remaining product, and all subsequent shipments of the commodity, even perishable goods, are automatically held pending sample analysis.

Recommendation 7

In its April 1979 comments, HHS said that it would further consider our recommendation that FDA include provisions for penalties--such as automatic forfeiture of security bonds--in importer agreements to penalize importers of violative food that has already been marketed. HHS said that under existing procedures, FDA takes action against shippers, against specific commodities, or against a country until identified problems have been resolved. HHS said that it believed this approach more appropriately addressed the party responsible for violative products rather than just

the importer, 1/ who has no control over pesticide use in foreign produce.

We said that we did not disagree with FDA's approach to prevent violative foods from entering this country. Our recommendation was intended to supplement existing procedures in cases where good faith efforts were not made to recall violative shipments allowed entry and which, therefore, warranted sanctions against importers. We pointed out that as it was constituted, the bonding provision benefited no one except the bonding agent. We said that if FDA chooses not to write penalty provisions in its agreements tied to bond forfeiture, we saw no valid rationale for continuing bonding requirements.

In October 1980 FDA said that after further considering our recommendation, it now believed that including provisions for penalties in importer agreements would be inappropriate. It said that for a number of years its policy has been to regulate both domestic and imported products equitably, to the extent possible under the different provisions of the Federal Food, Drug, and Cosmetic Act. It said that it believed the act's import detention and refusal provisions are somewhat analogous to the civil sanctions (for example, seizure and injunction) that are used for controlling violative domestic products. It said that when considering whether to use bond action to penalize importers for bringing adulterated foods into the country, it was influenced by the language found in the act's penalty section (21 U.S.C. 333), which applies to domestic products. It said that this section contains language which exempts from the penalties of the act a person who has received a violative product in the good faith that it is not violative.

Accordingly, FDA said that it still believed penalties for importing food adulterated with pesticide residues should be directed at the individual (that is, the shipper and/or grower) responsible for the adulteration and not the "good faith" importer of the product. It added that refusing entry to food shipments found to contain illegal pesticide residues, or in the case of repeated violative shipments, an automatic detention or a border closing has a deterrent effect. It said that in the latter action, the shipper, grower, or Government of the country of origin must certify to FDA that the suspect food complies with the law.

1/For brevity in the report, we had defined brokers, agents, or shippers as importers. This definition was intended to apply in this case.

FDA said that as a matter of policy and practice, shipments subject to this requirement, but not accompanied by a certificate, will be detained without FDA sampling and analysis. It said that it had further strengthened this control system in fiscal year 1980 by adopting the policy that when district offices encounter only two violative shipments or a pattern of violative shipments of fresh produce from the same shipper/grower, a certification requirement may be invoked.

FDA said that it agreed that instituting a penalty such as bond forfeiture is appropriate when an importer markets adulterated food after FDA requests that the shipment be held at the port of entry pending analysis. It said, however, that it believed that when it samples imported food on a surveillance basis (that is, when there is no suspicion of violative pesticides), it would not be appropriate to penalize an importer through bond forfeiture if the food which it allows to be marketed pending analysis is subsequently shown to contain illegal pesticide residues. It said that in this case, it would ask the importer to recall the shipment.

Recommendation 8

HHS said that FDA and EPA began a joint effort in September 1978 to reevaluate existing action levels to assure that they were safe and appropriate. HHS said that the effort was being conducted in conjunction with EPA's plan to revoke existing tolerances for canceled pesticides. HHS also said that action levels were established after a determination had been made about the safety of a residue and that the validity of action levels would be reassessed periodically.

We pointed out, however, that EPA began reviewing existing tolerances for canceled pesticides and action levels after we had brought this matter to its attention. We said that unfortunately, no reviews on action levels had been completed in the 7-month period since the program began.

We also pointed out that although HHS said that action levels were established only after appropriate determinations had been made, it did not address our concerns regarding

--action levels being excluded from EPA's calculations of total dietary intake of pesticides and

--whether residues result from purposeful use or from unavoidable environmental contamination.

We said that both determinations must be made to ensure that action levels are safe and appropriate. We added that in doing less, FDA was not complying with its mandate under the Federal Food, Drug, and Cosmetic Act.

EPA said that it considered acceptable daily dietary intake in developing action-level recommendations for non-carcinogenic pesticides or pesticides for which threshhold levels of effects can be demonstrated. For other pesticides, including those that are carcinogenic, however, EPA said that it used risk/benefit balancing to determine at what level an action level should be set. For example, a risk estimate would be made of how many cancer cases could be expected to result from a certain level of residues.

In March 1980 FDA said that it had asked EPA to reevaluate the action levels that had been previously established for unavoidable residues of the pesticides DDT, aldrin, and dieldrin. It said that the action levels it was enforcing for other pesticides would be routinely reevaluated in the future as appropriate. In October 1980 FDA said that in 1978 and 1979 it had provided EPA with residue data generated by food monitoring programs for determining the frequency and levels at which residues of the above pesticides and of BHC (benzene hexachloride, including lindane) were still occurring in the food supply. It said also that it had commented on EPA's tentative action levels for these pesticides.

In its comments on a draft of this report (see app. IV), EPA said that it strongly supported developing a consistent set of objectives for all the monitoring systems and an agreed-upon list of environmental contaminants that should be monitored. It said that its Pesticide Programs staff was helping HHS put together a surveillance index for selecting pesticides that should be monitored based on their potential health risk and occurrence in the food supply. It said also that it was supplying HHS with toxicology profiles, residue chemistry and environmental fate information, and production data for approximately 80 pesticides.

Recommendation 9

HHS said that it did not disagree with our recommendation that in the future FDA establish action levels for unavoidable residues of suspended and canceled pesticides only after determining that such residues are safe, but that some clarification was needed. HHS said that FDA had established action levels for pesticides based on safety, unavoidability, and information available at the time the action levels were established. HHS said that the action levels shown in FDA documents for the pesticides leptophos,

monitor, and azodrin were unwarranted and that FDA had not established action levels for them. HHS also said that FDA's policy was that (1) residues of these pesticides found in imported food are the result of purposeful use, (2) because there is no tolerance for them, such residues are violative, and (3) any detectable, measurable, and confirmable amount would be considered actionable.

We pointed out that although FDA considered any detectable amount of these pesticides actionable, they were not generally treated as such because FDA used a residue detection method that was not sensitive enough for enforcement purposes. For example, monitor was detected in 307 shipments from October 1, 1978, through February 28, 1979; however, only 6 shipments (2 percent) were deemed violative. We said that this data was very disconcerting in light of (1) FDA's policy that these residues result from purposeful use and, therefore, are violative, (2) a history of repeated violations, and (3) the existence of other single-residue testing methods with greater sensitivity.

Further, we said that HHS' comments did not address our concern that EPA's safety evaluations did not consider the potential human exposure allowed by action levels as is done when tolerances are established. We said that we believed it was necessary to make such judgments on the safety of action levels.

We also said that we believed the foregoing clearly demonstrated that improvements were needed to ensure not only that residues at action levels can be safely consumed but that such residues are unavoidable.

EPA said that the human health factor is always one of the primary considerations in recommending an action level.

Recommendation 10

HHS did not concur in our recommendation that FDA investigate pesticide-use conditions in foreign countries when significant residues of a pesticide are detected in an import. HHS said that FDA did not have the authority to investigate pesticide-use conditions in foreign countries and that resources should not be committed unless there was evidence that residues lower than action levels were occurring as a result of the direct, purposeful application of pesticides.

We pointed out that HHS' response regarding FDA's lack of investigative authority was inconsistent with actions already taken by FDA in its pilot program for Mexican imports. We said that we believed this investigative activity was within FDA's authority and should be encouraged.

We also said that HHS and FDA were aware that a wide range of residues--from negligible to several parts per million--will result in food from purposeful pesticide use depending on

--persistence of the pesticide,

--concentration of mixture applied,

--method and rate of application,

--soil and climatic conditions, and

--length of time between application and harvest.

We said that FDA's own data contained an excellent example of this fact. FDA's policy was that residues of monitor on imported Mexican produce were the result of purposeful use, yet only 6 of 307 samples in which the pesticide was detected from October 1, 1978, through February 28, 1979, contained residues large enough to be within levels that FDA could accurately quantify and on which it could take regulatory action.

EPA said that in most cases, if not all, residue levels from deliberate application of a pesticide would exceed unavoidable environmental residue levels. Consequently, according to EPA, foreign commodities deliberately treated with a canceled pesticide would contain residues exceeding the action level and could not legally be marketed in the United States.

In October 1980 FDA said that it still did not concur in this recommendation for the reasons it set forth previously. It said that although residues of cancelled pesticides had been detected in the samples of imported Mexican produce, the residue levels were consistently extremely low, indicating that the pesticides persist in the environment rather than being directly applied to crops in Mexico.

"Federal Pesticide Registration Program: Is It Protecting the Public and the Environment Adequately from Pesticide Hazards?" (Report to the Congress, RED-76-42, Dec. 4, 1975)

This report concluded that the American consumer had not been adequately protected from the potential hazards of pesticide use because of inadequate efforts to implement provisions of the Federal laws regulating pesticides. We recommended among other things that EPA and the Secretary of HHS, through the Commissioner, FDA, develop a plan to expand

FDA's surveillance program so that over a period of years all pesticides with tolerances are tested. This recommendation is especially pertinent because pesticides often become environmental contaminants when they persist in the environment after being used on crops or animals and when they inadvertently enter the food supply. The PCB spill at the Pierce Packing Company is one example of an environmental contaminant entering the food supply inadvertently.

Another example of how seemingly innocuous and undetectable such chemical residues are, is illustrated by a contamination incident that occurred in Michigan in 1973-74. In this case, a plant inadvertently labeled its PBB fire retardant chemical as a dairy feed supplement. The mislabeled chemical was then mixed with cattle feed and widely distributed. This contamination was not detected for 230 days and then only after a farmer sought State and Federal help to determine the reason for the poor health of his dairy herd. Ultimately, about $215 million worth of Michigan livestock and related dairy products had to be destroyed, and according to OTA, practically all Michigan residents were exposed to contaminated food products.

HHS agreed to coordinate future pesticide residue testing with EPA, but it did not agree that FDA should expand its pesticide surveillance program. It said that there were means other than residue testing to ensure safe pesticide use. HHS said that it did not believe pesticide residues in food were serious because

--residues for more than 90 of the more persistent and toxic pesticides (organochlorines and organophosphates) or their metabolites had been found in less than 3 percent of the 7,000 to 8,000 shipments of food and feed tested each year,

--the results of FDA's total diet studies for the past 10 years indicated that the consumer's average daily dietary intake for these same persistent and toxic pesticides (or their metabolites) was well within established acceptable daily intake limits, and

--a fiscal year 1974 examination of 500 food samples for 32 pesticides not detectable under the routine surveillance program had detected only 4 samples with residues above tolerance.

HHS concluded therefore that little reason existed to expect that residues of less persistent pesticides were occurring in the Nation's food supply to a major degree.

We said that although pesticide control encompassed more than testing food for residues, we believed this testing was a very important part of control. We pointed out that FDA's detection of violative residues in the small number of shipments sampled indicated that other aspects of pesticide control in food were not fully effective. In fact, we said that the 3-percent violation rate seemed high when considering that FDA was testing for less than one-fourth of the pesticides with tolerances.

Further, we said that we did not agree with FDA's inference that organochlorine and organophosphate residues were reliable predictors of the residues that will result from other pesticide uses. We added that this testing also should not preclude periodically testing other pesticides.

In October 1980 FDA told us that its position on our recommendation had not changed. It said that there were nearly 300 pesticide chemicals that have tolerances for one or more raw agricultural commodities and that even with unlimited resources, it would be impossible to provide ongoing surveillance over the full expanse of potential pesticide/commodity combinations. Moreover, it said that it believed such an effort was not needed to protect the public health from the potential hazards of pesticides. FDA said that some pesticides with tolerances have low toxicity, rapid dissipation rates, or very limited use (and thus are unlikely to leave residues) and therefore need not be routinely covered under FDA food surveillance activities. It added that most violative pesticide residues it encounters are violative because no tolerance has been established for the particular pesticide/food combination. It said that it considers these situations to be of greater importance than pesticides with established tolerances.

FDA said that rather than testing for all pesticides with tolerances, it believed its surveillance program must

--selectively cover pesticides that pose potentially significant health risks and have a likelihood to occur in the food supply,

--routinely cover food and feed commodities that are of major dietary importance with potential for containing chemical residues of concern, and

--selectively cover potential pesticide residue/commodity combinations where actual use is confirmed or highly suspected.

FDA said that to achieve these objectives, it had adopted a series of refinements to the surveillance program it used in the mid-1970s. It said that the program consists of three operational elements or separate and distinct approaches for covering the food supply for pesticide residues. These are:

--Core element: This element provides for Bureau of Foods-directed field surveillance sampling and analysis of domestic and imported commodities susceptible to chemical contamination from environmental sources and those likely to store and biomagnify fat-soluble chemicals--fish, milk, dairy products, eggs, feed, and feed ingredients. The chemicals to be included are those shown by the Surveillance Index (see p. 31) to pose a high risk and a propensity for persisting in the environment and accumulating in the edible parts of animals.

--District option element: This element provides for the FDA districts' discretion in surveying domestic commodities for residues of chemicals known to be used in their locales. Headquarters provides the districts with information on foods of major dietary importance and the Surveillance Index. District investigators obtain information on actual local pesticide use. The key to this element is gathering intelligence about chemical use within the individual districts before sampling and applying this intelligence to sampling commodities produced in the local area.

--Selective survey element: This element provides for allocating resources for special surveys of selected residue/commodity combinations of either domestic or foreign origin that are not otherwise expected to be included in either the core or district option surveillance activities. This element is to be used to fill data gaps on pesticides with approved agricultural uses and on other chemicals that may contaminate the food supply.

According to FDA, during the first half of calendar year 1980, Surveillance Index documents had been finalized on 40 pesticides and distributed to various interested parties, including FDA's Bureau of Foods, FDA districts, USDA, and State agencies. FDA said that the completed reviews had resulted in initiating selective surveys for residues of several pesticides, including benomyl, maleic hydrazide, and pronamide, for which little or no monitoring had previously been done. It said that Index documents for

all pesticides will eventually be developed and kept current for use by FDA and others as a guide for residue monitoring programs.

FDA also said that in the fiscal year 1980 Pesticides-Domestic Foods Surveillance Program, the entire approach to sample selection and collection was changed from a statistical approach with headquarters-defined commodity quotas to a more flexible system allowing samples to be collected almost exclusively at district option. According to FDA, this change in approach, along with allocating 12 staff years of investigating time for intelligence gathering under the program, had allowed districts to make local determinations of actual pesticide uses through onsite visits to growers, extension agents, applicators, and EPA personnel. FDA added that the program also required investigators to submit reports detailing pertinent pesticide/commodity-use combinations and other information to guide the district laboratories in analyzing the commodities sampled.

"An Incident of Contamination of Livestock Feed and Certain Consumer Products" (Report to the Senate Committee on Agriculture and Forestry, B-164031(2), Dec. 1, 1972)

This report, requested by the chairman, Senate Committee on Agriculture and Forestry, discussed how a 1971 incident involving PCB-contaminated livestock feed (fishmeal) was handled. We concluded that USDA and FDA programs to test for PCBs in consumer products associated with this incident were comprehensive and appropriate. However, we noted that USDA and FDA investigations were not coordinated, and therefore duplicate visits were made to 26 of the 65 customers that had received the suspect fishmeal. We recommended that USDA and HHS establish procedures to coordinate future investigations and to exchange information needed by each agency.

Although HHS did not completely agree with the recommendation, both USDA and HHS agreed to explore the feasibility of establishing the procedures we recommended. We did not find instances of duplication in the 1979 PCB incident; however, as noted on pages 15 and 20, both FSQS and OTA reported that opportunities still exist to improve coordination in dealing with contamination incidents.

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

In this report we said that because of improvements in processing plant sanitary conditions, plant equipment and facilities, and processing methods, USDA could change its practice of inspecting most meat and poultry processing plants daily. One purpose of these inspections is to assure that meat and poultry products distributed to consumers are not adulterated. 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 to the inspection needs of individual plants;

--require meat and poultry processing plants to develop and implement quality-control systems; and

--withdraw inspection from or impose strong penalties on plants failing to take appropriate action when the quality-control system identifies a deficiency or when plants fail to comply with inspection requirements.

We also recommended that if the Congress amended the acts, the Secretary of Agriculture develop criteria for deciding how often individual processing plants should be inspected and for assessing penalties, within the provisions of the acts, when plants do not comply with inspection requirements. We also recommended that the Secretary, in cooperation with industry, develop criteria for determining the quality-control systems needed at various types and sizes of processing plants.

Although the Congress has not amended the legislation as we recommended, USDA has taken some actions that support our recommendations. On September 13, 1979, FSQS published a proposal in the Federal Register that would permit meat and poultry processing plants to develop, on a voluntary basis, quality-control systems that can be used by FSQS inspectors in carrying out their responsibilities. This proposal was finalized and became effective on September 15, 1980. According to the Administrator of FSQS, this action will give FSQS the information and experience necessary to decide whether to ask the Congress to change the law to provide for mandatory quality controls.

DISPOSING OF HAZARDOUS WASTES

The improper disposal of hazardous wastes can also contaminate the U.S. food supply. For example, improper disposal of PCB wastes in the Hudson River and Kepone in the James River and the Chesapeake Bay caused widespread contamination of food fish. Ultimately, this contamination resulted in closing segments of the Hudson River and large segments of the James River and Chesapeake Bay causing financial hardships for area fishermen. Also, consumers probably ate much of the contaminated fish before the waterways were closed to fishermen. Similar problems have occurred with contamination of animal feed. For example, in 1969 cow-grazing areas in West Virginia became contaminated through an herbicide spraying program that used spent PCB fluid as a vehicle for the herbicide. Also, in 1979 Kansas cattle became sick and died because of exposure to PCB-contaminated salvage oil used in an automatic backrubber.

Our recommendations in two reports to the Congress on how EPA administers the hazardous waste program are related to environmental contamination incidents. In the reports, "How To Dispose Of Hazardous Waste--A Serious Question That Needs To Be Resolved" (CED-79-13, Dec. 19, 1978) and "Hazardous Waste Management Programs Will Not Be Effective: Greater Efforts Are Needed" (CED-79-14, Jan. 23, 1979), we said that how hazardous waste programs were to be funded and where disposal facilities were to be located were the two most pressing problems which must be resolved if the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901) was to be effective in protecting the public health and environment.

In the December 1978 report, we recommended that the Administrator of EPA:

--Monitor and evaluate closely the development of State solid waste management plans to (1) identify the magnitude of the problems in locating suitable disposal sites early in the process and (2) propose alternative solutions including--if necessary to protect national interests--a stronger Federal role.

--Propose legislation to create a self-sustaining national trust fund supported by fees assessed on the disposal of hazardous wastes. The fund would cover all postclosure liability and any necessary remedial actions to prevent continued contamination at sites permitted under the act. The fees should reflect the degree and duration of risk posed by specific wastes.

In the January 1979 report, we recommended that the Administrator:

--Encourage State governments and agencies to develop self-supporting funding methods, such as fee systems, to operate and carry out hazardous waste management programs within their jurisdictions.

--Develop model legislation for the States' use in obtaining the necessary authorizations from their legislatures to establish fee systems.

--Request that the Congress authorize and appropriate the funding States need to develop and implement hazardous waste programs beyond fiscal year 1979.

--Request that the Resource Conservation and Recovery Act of 1976 be amended to allow EPA to include a fee system to cover hazardous waste program costs when (1) a State cannot or will not assume responsibility for its program and (2) EPA is required by the act to assume responsibility for the State program.

EPA generally agreed with our recommendations. In May 1980 it issued regulations that require industrial waste producers to systematically control those wastes. The regulations focus on the 10 percent of waste producers who generate 99 percent of the waste. In addition, in December 1980 the Congress approved legislation to create authority for a self-sustaining national trust fund.

CHAPTER 4

CONCLUSIONS AND RECOMMENDATION

CONCLUSIONS

The actions taken or planned by USDA, FDA, and EPA as a result of the 1979 PCB incident should, when fully developed and properly implemented, provide a quicker response to, and better protection of consumers from, future incidents of PCB and other chemical contamination of food. Also, the agencies have taken actions on many of our prior recommendations related to their programs to control chemicals in the Nation's food supply and in the environment.

However, for various reasons, actions have not yet been taken or completed on some of our prior recommendations. For example:

--USDA has submitted, but the administration has not approved, a legislative proposal to authorize USDA to quarantine animals from violative producers and require producers to place permanent identification on animals before they are marketed.

--EPA started but has deferred action on evaluating the safety of cadmium and hexochlorobenzene to give attention to other chemicals considered to be greater health hazards.

--FDA has improved the timeliness of its system for assessing and taking action on potentially violative commodities imported from Mexico, but because of resource limitations, it has not expanded the improved system to cover food from other countries.

--More sophisticated residue detection methods are needed to more quickly and more completely identify chemical contaminants in food, but significant technological advances are needed before these methods can be developed.

Because our recommendations on these and other needed actions are already on the record, they are not repeated here. However, other action, which has been suggested by OTA, would help strengthen the agencies' residue detection and control programs.

Because coordination is a key element in any successful program involving a multitude of organizations and people affected by a common problem--in this case EPA, FDA, and

FSQS--it is essential, as OTA suggested, that a leadership role be clearly defined. This suggestion was also made by participants in FDA's November 14, 1979, meeting to discuss ways of identifying and preventing chemical contamination problems. (See p. 18.) A lead agency could be designated by mutual agreement among the three agencies in a memorandum of understanding or, if the Congress chooses, by congressional mandate.

OTA also suggested establishing a national system that monitors for suspected or uncharacterized environmental contaminants. It said that as an interim measure, a pilot program could be implemented while the necessary research and development is being done to see if such a system would be feasible and cost effective. In a draft of this report, we suggested that because identifying all possible food contaminants would be extremely costly, it would probably be wise to adopt OTA's suggestion for a pilot program. USDA, EPA, and HHS comments on our draft report (see app. III, IV, and V) indicate that ample authority already exists for such a monitoring system, such a system is now being used, and improvements and expansion of the system are planned. We therefore believe that no further action is necessary at this time.

RECOMMENDATION TO THE SECRETARIES OF AGRICULTURE AND HHS AND THE ADMINISTRATOR OF EPA

We recommend that the Secretaries of Agriculture and HHS and the Administrator of EPA, as part of their cooperative program to identify and control harmful substances such as PCBs, clearly define which agency will assume the leadership role under the various circumstances and conditions which are anticipated.

AGENCY COMMENTS AND OUR EVALUATION

In their comments on a draft of this report, USDA, EPA, and HHS generally agreed that the leadership role of the agencies involved in identifying and resolving the problems involving food contamination incidents should be more clearly defined, and they described actions they had taken to improve coordination. USDA said that while it is important that each agency retain direct policy control over its operations, USDA will continue to lead efforts to institute a coordinated team-effort approach whenever possible. EPA pointed out that EPA, USDA, and FDA are all members of the Interagency Regulatory Liaison Group and suggested that the agencies could use that group to help resolve coordination problems. HHS pointed out that, in addition, the Federal Emergency Management Agency

has responsibility for interagency coordination in chemical emergencies and that its role should therefore be considered in developing criteria for designating a lead agency for food contamination incidents. HHS said also that in the past, the leadership role has been assumed by one of the agencies and any criteria for a leadership role will need to be flexible enough to deal with any unforeseen combination of circumstances.

We agree that in developing criteria for the designation of a lead agency for food contamination incidents, the resources and expertise of organizations such as the Interagency Regulatory Liaison Group and the Federal Emergency Management Agency should be considered and used to the extent feasible. We agree also that in coordination efforts, each agency should retain direct policy control over its operations and that the criteria developed should be as flexible as possible.

ECONOMIC IMPACT OF FOOD CONTAMINATION (note a)

Reported incidents		Total estimated cost
State:		
Idaho	Dieldrin	$ 100,000
	PCP	3,000
Colorado	Dieldrin	100
	Mercury	3,700
Maryland	Mercury	23,000
Texas	Mercury	85,000
Indiana	Dieldrin	25,027
	Dieldrin	250,000
Michigan	Mercury	10,000,000
	PCB	30,000,000
	PCNB	100,000
	PBB	215,000,000
	Picloram	12,000
	Chlordane	2,500
	DDT	2,000
	Toxaphene	2,000
	Parathion	328
	Diazinon	13,700
	Pentachlorophenol	28,468
	PCB	150,000
	Dieldrin	12,500
Subtotal		$255,813,323
Federal:		
FSQS	Pesticides	18,900,000
	Mercury	63,000
	PCB	7,450,000
	Phenol	350
Subtotal		$ 26,413,350
Total		$282,226,673

a/These represent only the costs reported to OTA. According to OTA, some States reported the amount of food destroyed without estimating the cost and many States were unable to provide estimates on either the cost or the amount of food condemned.

Source: "Environmental Contaminants in Food," OTA, Dec. 1979.

CHRONOLOGY OF EVENTS IN THE PCB INCIDENT IN THE WESTERN UNITED STATES

The following chronology was adapted from information in FSQS' January 1980 report entitled "Report on the PCB Incident in the Western United States."

June 1979

Pierce Packing Company, Billings, Montana, slaughters and processes meat under a grant of Federal inspection. It also produces animal feed containing inedible animal products. Before September 1979 a spare, unused electrical transformer was stored in a corner of the Pierce facility where inedible products were held before they were processed into animal feed. Hair from slaughtered animals was also collected and kept in this area.

Some time in June 1979, one of the transformer's fins, which was larger but similar in design to the fins on a home air-conditioning unit, was accidently broken. Pierce officials have speculated that the transformer might have been hit by a back-loading tractor that was inside the facility to pick up animal hair. At any rate, the accident caused a rupture of the transformer's cooling system and cooling fluids containing PCBs leaked onto the floor. These fluids ran into a drain pipe where they becamed mixed with various inedible substances that were processed into animal feed.

Pierce officials, who have said that they were unaware of the accident, the presence of PCBs within the transformer, and the health hazards associated with exposure to PCBs, marketed the animal feed in the normal fashion to customers throughout the Western United States. One of the shipments--50,450 pounds of bulk meat and bonemeal--went to Ritewood Feed Mill, Franklin, Idaho, on June 25.

The FSQS monthly sampling plan for July required that a fat sample be taken from a mature chicken at Jolly Wholesale Poultry, Provo, Utah, and sent to FSQS' western regional laboratory in San Francisco, California, to test for chlorinated hydrocarbon residues (including PCBs). The sampling form--MP Form 23-1, #213833--which included this information was sent to FSQS' inspection office at Jolly Wholesale Poultry in mid-June.

July 1 to 13

Jolly Wholesale Poultry is a federally inspected plant that slaughters and processes poultry. Inspections at the plant are ordinarily supervised by Dr. William Boyer, a veterinarian. Dr. Boyer, who is also responsible for two other federally inspected plants in the area, spends approximately half his working hours at Jolly. A full-time Federal line inspector is also assigned to the Jolly plant.

Dr. Boyer received requests for samples at one of the three plants every 4 to 6 weeks. He indicated that his normal procedure was to place these requests in a particular desk drawer in his office and to assume personal responsibility for taking, preparing, and shipping the samples.

Dr. Boyer began a 2-week vacation on July 1, 1979, and a relief veterinarian, Dr. Ronald Baker, assumed Dr. Boyer's responsibilities at Jolly. Dr. Baker indicated that he usually takes an inventory of the inspection office where he is assigned to check for special instructions and assignments such as taking residue monitoring samples. He did so when he arrived at Jolly on July 1, 1979, and discovered the sampling form #213833.

He recalls discussing the sample with Mr. Dan Brickerhoff, the full-time line inspector, on Friday, July 6. He said that after lunch he left Jolly to carry out his responsibilities at other plants after agreeing that Mr. Brickerhoff would take the sample. Mr. Brickerhoff does not specifically recall these conversations but remembers seeing form #213833 in the office that afternoon and deciding that he should take care of it. Mr. Brickerhoff also said that he had little experience in taking such samples, which were normally taken by his supervisory veterinarian.

Since slaughtering for that day was completed, Mr. Brickerhoff took the sample from one of the barrels of fatty tissue set aside in the plant with other inedible products. He prepared the sample in what he felt was the usual procedure by filling out form #213833. He did not, however, specify the original owner of the poultry, as called for by FSQS instructions. He placed the sample and the form in the appropriate shipping container. Because the sample must be frozen at least overnight before being shipped to the laboratory, Mr. Brickerhoff stored the container in the plant's freezer compartment.

Dr. Baker and Mr. Brickerhoff resumed inspection in the Jolly plant during the week beginning July 9. However, they forgot about the sample, never discussed it, and did not notice it in the freezer. Mr. Brickerhoff said that even on those rare occasions when he had taken samples, he had assumed no responsibility for shipping them. Again, shipping was ordinarily done by Dr. Boyer. Dr. Baker agreed that shipping this particular sample was his responsibility. Because the sample was overlooked, it remained in the freezer during the entire week of July 9 to 13.

July 16 to August 3

Dr. Boyer returned to Jolly on July 16. Dr. Baker and Mr. Brickerhoff were both routinely reassigned to other inspected plants beginning the same day. Dr. Boyer discovered the sample in the freezer late on the morning of July 16. While discussing other matters with representatives of FSQS' Boulder, Colorado, area office, which supervises FSQS activities in Utah, he mentioned to his supervisor, Dr. Walter Huber, the area veterinarian-in-charge, that he had found the sample. Dr. Huber directed Dr. Boyer to mail the sample as quickly as possible. The sample was mailed that day to the FSQS western laboratory in San Francisco, California.

The FSQS western laboratory does most of the residue testing in FSQS' western region--which includes Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming. The laboratory is directed by Dr. Paul H. Smith who supervises a staff of 39. Residue testing is a significant part of the laboratory's workload; the laboratory receives from 30 to 50 residue samples a day.

Upon arrival at the laboratory, samples are logged in, assigned a number, and placed in a freezer. Monitoring and surveillance samples are separated. The surveillance samples, which are those taken after a particular residue problem has been identified, are given priority, and every attempt is made to complete the necessary analyses within 3 working days of their receipt. Monitoring samples, on the other hand, are considered routine; laboratory personnel have no indication that this type of sample may be violative until it is tested. How quickly the monitoring samples are processed depends on the laboratory's workload in the surveillance area. The laboratory tries to test the routine monitoring samples within 14 calendar days of their receipt, which is consistent with FSQS policy.

The fat sample mailed by Dr. Boyer from Jolly on July 16 was a monitoring sample. It arrived at the laboratory on July 20 and was processed in the usual manner. It was kept in a laboratory freezer until it was prepared for analysis on July 24. On July 25, Michael Wong, staff chemist, began routine testing.

Sample #213833 was initially tested with nine other samples. They were subjected to what is referred to as the Alumina screening procedure. Fatty substances are separated from the product, which is then processed through a solvent designed to separate residues from other substances. This solvent extract is then concentrated. At this point, a portion of the remaining solution is injected into a machine known as a gas chromatograph. Samples from all substances being tested were injected into such a machine by Mr. Wong on July 27.

The machine reacts to each substance being tested by printing a pattern on a graph. Different types of residues generate different types of patterns. Interpreting these patterns requires a certain amount of scientific expertise, because different residues within the same chemical family may have similar patterns.

Because his experience in analyzing patterns showing PCB violations was limited and because the patterns are similar to those generated by other chemicals, Mr. Wong was not immediately certain that this printout indicated a PCB violation. However, he was aware that the finding was potentially violative and concluded that there should be further, confirmatory testing. He discussed the problem on July 27 with his supervisors, Ronald Eichner, supervisory chemist, and Mitsuo Okamoto, chemist-in-charge, who agreed that further testing was necessary. The following Monday, July 30, the sample was subjected to confirmatory analysis for PCB residues by the officially approved procedure, known as the Mills method. According to Mr. Wong, this test indicated that unknown interferences and many chlorinated hydrocarbon pesticides were believed to be present in this sample, which might conceivably have led to inaccurate results.

On August 2 he reviewed the matter further with Dr. Eichner, his immediate supervisor. They subjected the sample to a perchlorination process, which on August 3 yielded conclusive evidence of PCB contamination in sample #213833 at levels of 15.65 parts per million. On that same

day, a Friday, Dr. Eichner called Dr. Norman Pang of FSQS' western regional office for meat and poultry inspection in Alameda, California, and reported this violation.

The Alameda office is responsible for meat and poultry inspection activities in the 14-State western region. The office is directed by L. J. Rafoth; his assistant is M. C. McNay. They supervise a staff of six professionals, including two veterinarians who specialize in slaughtering--Dr. Pang in the meat area and Dr. Michael Nusias in the poultry area.

Ordinarily, the call received by Dr. Pang on August 3 would have been received by Dr. Nusias, since it involved a poultry sample. However, the two veterinarians assist and supplement each other's work. They both have stated that they do not remember specifically but believe the call was received after Dr. Nusias had left for the day. Since the call was received relatively late in the day, Dr. Pang did not try to contact any FSQS employees in the field, who are in the Rocky Mountain, as opposed to the Pacific, time zone and are therefore 1 hour ahead in time. Instead, he left a note for Dr. Nusias, expecting him to follow up on the violation on the following Monday, August 6.

During this same July 16 to August 3 period, the following events took place in the FSQS Egg Products Inspection Program. On July 17, pursuant to the random quarterly inspection program, an egg product sample of whole egg was taken from Frazier Poultry Farms, Pocatello, Idaho, for chlorinated hydrocarbons residue testing at the FSQS laboratory in Gastonia, North Carolina, which is directed by Dr. David Frahm. Testing was completed on August 1. Due to a laboratory error, the test result on this sample was incorrectly interpreted as indicating no violation.

August 6 to 10

Dr. Nusias read Dr. Pang's note on the Jolly sample on Monday, August 6. On the same day he contacted Dr. Boyer at Jolly to inform him of the violation. Since the completed MP Form 23-1 for sample #213833 did not list the name and address of the owner of the chickens, Dr. Nusias asked Dr. Boyer to identify this owner as quickly as possible.

Dr. Nusias called the Boulder area office on this violation on August 9. This was the first time that Dr. Huber was aware that the sample he had first discussed with Dr. Boyer on July 16 was violative. Dr. Huber then contacted Dr. Boyer about the matter on the same day.

Before speaking to Dr. Huber on August 9, Dr. Boyer was apparently not certain that he was dealing with a PCB problem. He indicated that Dr. Nusias, who speaks with somewhat of an accent, was difficult to understand. While he knew from the August 6 telephone call that sample #213833 was violative, he at first believed that he might be tracing another chemical residue problem rather than one involving PCBs. Dr. Boyer has said that he had had little experience with PCB problems before this incident.

Dr. Boyer indicated that he encountered some difficulty between August 6 and August 9 getting Andrew Jolly, proprietor of Jolly, to tell him the original owner of the chicken from which sample #213833 was taken. Dr. Boyer said, "Everyday he (Jolly) had a different excuse." Dr. Boyer said that he was told that a particular secretary would have the information, but she was not in the office on Thursday, August 9. After a few telephone calls between the two veterinarians and conversations with Andrew Jolly, the source of the contaminated chicken was identified on August 10 as the Ritewood Egg Company, Frank[illegible] Idaho. This information was immediately relayed to Dr. Nusias in Alameda, who then began to draft the routine letter that is sent to owners of products containing violative residues. He completed his initial draft of this letter on the same day and gave it to a clerical assistant for typing.

August 13 to 17

Dr. Nusias spent the following week, August 13 to 17, in Denton, Texas, attending meetings. After Dr. Nusias' initial draft of the letter to Ritewood was typed, Dr. Pang, who remained in the Alameda office, reviewed the letter. Dr. Pang made a few revisions, including a specification of the term polychlorinated biphenyls, and the letter was retyped and resubmitted to Dr. Pang on August 16. Because Dr. Rafoth and Dr. McNay were not available, Dr. Pang signed the letter for Dr. Rafoth the same day and sent it to Ritewood.

Copies of the letter were sent to a number of other State and Federal officials, including FSQS area meat and poultry inspection officials and residue evaluation personnel, representatives of EPA and FDA, and Idaho State officials.

Before signing the August 16 letter, Dr. Pang made several telephone calls regarding the violation. On August 14 or 15 he called Dr. Joseph A. Jones, the assistant area supervisor in Boulder, who was acting for Dr. Huber. (During the week of August 13 to 17, Dr. Huber was in the Alameda office for general supervisory meetings.) Dr. Pang also called Dr. William Leese, national residue coordinator in Washington, D.C., to alert him to the problem.

These individuals immediately took steps to coordinate an effort to trace products shipped from Jolly to its customers at the time the violative residues were detected. Products shipped to Swift and Company, Clinton, Iowa, in late July were identified and detained for testing. This action involved communication with FSQS compliance and meat inspection personnel in the FSQS north-central region where Swift is located.

On August 17 the north-central region sent Dr. Leese information on Swift products derived from chickens purchased from Jolly. The memorandum said that 30 chicken samples had been collected and would be submitted for laboratory analysis on August 20.

On August 15 Dr. Pang had also called an FDA representative, James Davis, the chief investigator in FDA's Seattle office, about the violation. Usually, FDA is notified by a copy of the violation letter. However, Dr. Pang decided to accelerate this process because the violator (Ritewood) also produced eggs and any contaminated shelled eggs would be under FDA's jurisdiction. Mr. Davis did not specify to Dr. Pang exactly what action FDA might take based on this information.

Also on August 15 Dr. Pang called Sam Traylor, assistant regional director of the Stockton, California, area office (now located in Modesto, California) of FSQS' Poultry and Dairy Quality Division, and discussed the violation. Dr. Pang believed that a violation involving an egg company might come within that division's regulatory responsibilities. Mr. Traylor informed Dr. Pang that this would become the division's responsibility only if it involved egg products' processing, since the Egg Products Inspection Act is specific about USDA's responsibility and authority concerning egg products.

August 20 to 24

The August 16 letter was received by Ritewood on August 19. FDA and FSQS' Boulder area office received their copies early in the week of August 20. FDA's investigation at Ritewood began on August 20. Dr. Huber returned to the Boulder office on the same day and followed up on Dr. Jones' work in tracing products shipped from Jolly to Swift. This action involved followup calls and matching records obtained from Swift and Jolly. Testing on the Swift samples submitted for laboratory analysis on August 20 was completed on August 24. The tests revealed consistently violative levels of PCBs in the poultry that had been shipped from Ritewood, slaughtered by Jolly, and processed by Swift.

FDA started its investigation at Ritewood in Franklin, Idaho, on August 20. Dr. Huber was in frequent contact during the entire week with Mr. Marlow Woodward, Ritewood's owner, and with representatives of the Alameda office. His primary function was to coordinate the followup testing of additional chickens from Ritewood.

On August 21 in Provo, Dr. Boyer took 30 samples of 59 chickens shipped by Ritewood to Jolly on August 20 for pretesting. These were packed and shipped to the San Francisco laboratory the same day. The laboratory received them on August 23 and began testing on the 24th.

During this week Mr. Woodward expressed a number of concerns to Dr. Huber by telephone. In particular, he could not understand why he was not advised, through FSQS' August 16 letter or through any other source, of the possible problem of egg contamination.

August 27 to 31

The San Francisco laboratory completed pretesting of the Ritewood chicken samples on August 27. Dr. Eichner called Dr. Boyer directly on August 27 to inform him of the high PCB levels (36 to 67 parts per million) found by the pretest. A letter confirming these results was prepared in the Alameda office and signed by Dr. Rafoth on August 31.

During this week V. L. Hutchings, compliance officer-in-charge for FSQS' western region, became aware of the problem for the first time through Dr. Pang. While no specific requests for action on his part were made, he did assign a compliance officer, Charles Anderson, to attend meetings

with State officials and to keep him advised of any developments. He also relayed the information to John Gould, deputy director of FSQS' compliance program's evaluation and enforcement division, in Washington, D.C. Mr. Gould told Mr. Hutchings to continue to keep him informed if problems arose.

On August 29 Sam Traylor of FSQS' Poultry and Dairy Quality Division office in Stockton was contacted by an Idaho State Department of Agriculture representative who informed him that egg products might be involved in the PCB contamination incident. He also told Mr. Traylor that ungraded eggs had been shipped from Ritewood to egg product breaking plants in Salt Lake City, Utah (Salt Lake Egg Farm), and Pocatello, Idaho (Frazier Poultry Farms). These plants are under the jurisdiction of FSQS' Poultry and Dairy Quality Division. This information was relayed to Howard Magwire, national supervisor of the division's egg products staff, in Washington, on August 30.

After this report was discussed with Idaho officials, John Osborn, a supervisor in the Stockton office, was sent to the field to investigate this problem the next day (August 31). Mr. Osborn took about 14 "library" samples at Frazier covering the previous 60 days and forwarded them on August 31 to the Poultry and Dairy Quality Division laboratory in Gastonia, North Carolina, for analysis.

During his investigation, Mr. Osborn found that Frazier had 67 customers who could have received contaminated egg products. He also found that eggs were being broken at Spokane (Commercial Creamery) and Marysville, Washington (Pacific Egg Products Northwest), and that pullets were going from Ritewood to Oakdell Farms, Riverton, Utah. Mr. Osborn coordinated his followup activities with FDA and representatives from the affected States.

On August 31 extensive efforts were being made at Ritewood to try to identify the contamination source. Eggs were systematically resampled along with replacement and laying birds not sampled by USDA. Feed, water, and even air were considered possible contamination sources.

September 3 to 7

On September 3 Mr. Woodward (Ritewood) advised Dr. Huber that he had obtained EPA's permission for deep burial of the contaminated flock. On September 4 Ritewood voluntarily

stopped marketing its eggs as of the September 3 production. On the same day Ritewood received Dr. Rafoth's August 31 letter, which gave the results of the August 21 pretesting of Ritewood's chickens indicating PCB levels of from 36 to 67 parts per million.

On September 6 FDA collected samples at Ritewood of meatmeal and bonemeal delivered from various suppliers between May 16 and August 14. It also sampled other feed ingredients and products not previously sampled, including dust and feed residue. Air sampling also continued.

Between September 3 and 7, the Poultry and Dairy Quality Division's laboratory in Gastonia began receiving the test results on the Frazier "library" samples. In addition, the Frazier egg product sample taken on July 17 and previously reported as negative for PCBs was reevaluated and found to be positive. When the testing was finished, it was shown that PCB contamination had been present in the Frazier samples since about July 17.

September 10 to 16

Howard Magwire received a memorandum dated September 10 from the Idaho State Department of Agriculture regarding the details of an egg product recall. The memorandum noted that the cooperation by Frazier and its distributors on this matter had been very good and that final laboratory results on all samples were obtained that morning. USDA and Idaho cooperated in monitoring this recall.

During this period FDA continued its investigation to determine the contamination source, and representatives of all interested agencies continued their efforts to find and recover contaminated products. On September 12 FSQS' north-central region notified Dr. Harold Trabosh, senior staff officer of the FSQS science program's epidemiology staff, that Campbell Soup Company had received chicken meat contaminated with PCB residues from Cherry Lane Farms, Three Forks, Montana, and Montana Farms, Townsend, Montana. Dr. Trabosh relayed this information to FDA representatives in Rockville, Maryland, pointing out that the investigation should focus on a common source of feed between these two suppliers and Ritewood.

On September 12 Marlow Woodward (Ritewood) received a notice from FDA that a sample of meatmeal delivered on June 26, 1979, from Pierce was highly contaminated with

PCBs. On September 13 Dr. Huber was advised of Pierce's possible involvement and was informed that feed from Pierce was also being fed to turkeys in Utah. On the next day, September 14, Dr. Huber spoke to a representative of the Utah Department of Agriculture who expressed disappointment at not being notified of the initial PCB violation in Franklin, Idaho (just over the Utah State line). The Idaho State Department of Agriculture was also in contact with Dr. Huber on this date.

On September 13 Dr. Michael J. Conley, relief veterinarian, who was responsible at that time for operations at Pierce, and Dr. Carl Nash, circuit supervisor in the area, were contacted by Charles Breen, an FDA field investigator. This was the first time either had been told that Pierce was the possible source of the PCB residue problem. Dr. Nash contacted his immediate supervisor, Dr. Vernon Spears, the acting area supervisor, about this matter on the same day. Dr. Spears in turn called Dr. Nusias and suggested that he be allowed to institute an immediate emergency sampling plan in the area. Dr. Nusias advised him to await further instructions.

On Saturday, September 15, a representative of Pierce told Dr. Nash that FDA had requested a meeting the following morning at Pierce. Dr. Nash attended. Those present were advised that FDA had concluded that a transformer accident in June caused the PCB contamination--a Pierce engineer had alerted FDA that the transformer might be the contamination source. Pierce started cleanup measures the same day.

APPENDIX III

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

30 OCT 1980

Mr. Henry Eschwege
Director, Community and
Economic Development Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Eschwege:

We appreciate the opportunity to comment on your draft report entitled "Further Federal Actions Needed to Detect and Control Environmental Contamination of Food." The 1979 PCB incident in the western U.S. was one of the largest food contamination problems encountered by the U.S. Department of Agriculture since the beginning of its National Residue Program in 1967.

Our evaluation of the incident showed a number of instances where the Food Safety and Quality Service's (FSQS) response was delayed, its technology, legislative authority and resources inadequate, and its personnel not sufficiently aware of the seriousness of the situation. These gaps in performance were unacceptable, and substantial changes have since been made to improve our handling of environmental contamination problems.

These changes were based on actions proposed in the FSQS "Report on the PCB Incident in the Western United States." Implementation of those actions has enabled us to improve overall residue control efforts for meat, poultry and egg products, and to reduce response time in subsequent contamination incidents. You have noted these actions in your draft report, and we would like to update you on our progress in implementing them:

CONTAMINATION RESPONSE SYSTEM (CRS)

FSQS' Contamination Response System is a program which is activated whenever the agency receives information indicating a known or potential contamination problem in the meat, poultry or egg products supply. It may be triggered by a sample result from the National Residue Program, or information furnished by our inspectors, industry, State government, another Federal agency or any other reliable source. CRS prescribes step-by-step actions and identifies responsibilities of each FSQS component during a contamination incident. It also provides for liaison with other involved State and Federal agencies.

CRS is fully operational and has been used to effectively handle over 70 residue violations since it was organized in January, 1980. A contamination response team, with members from each FSQS component and other involved USDA agencies, meets weekly to review pending cases and discuss action required by new residue findings. Emergency meetings of this team are held whenever information indicates a potential food contamination problem.

Reporting of residue findings has been significantly faster in CRS cases under the new procedures. Samples taken subsequent to a positive residue finding are identified as such in the laboratory and given priority. This results in quicker response to potential contamination incidents.

Personnel have been assigned to work exclusively on CRS cases, thus elevating the handling of contamination problems above routine job responsibilities.

By cutting through much of the red tape involved in handling environmental contamination incidents, CRS has corrected many of the weaknesses which were evident in our handling of the PCB contamination. The team approach we have implemented through CRS brings together all parties who need to be involved at an early point, thereby enhancing our ability to bring these incidents under control earlier and more effectively. In sum, CRS is a management system which enables us to rapidly and effectively mobilize capable personnel and expertise to confront the difficult problems encountered in an emergency situation.

INVOLVEMENT OF POULTRY AND DAIRY QUALITY DIVISION IN RESIDUE PROGRAMS

The PCB incident highlighted the need for better coordination between the two residue monitoring programs administered by FSQS--egg products (liquid, frozen and dried eggs), administered by the Poultry and Dairy Quality Division, and meat and poultry, administered by the Science program.

Because they are based on different legislative mandates, and were created at different times, the two programs have operated fairly independently in the past. That system of organization has worked well for us because of significant differences in the flow of production and marketing between egg products, and meat and poultry. In the PCB incident, however, some duplicative sampling occurred, and agency resources in general would have been better utilized by better coordination.

To solve this problem, Poultry and Dairy Quality is now an active participant in CRS, and the division is now fully integrated with the emergency operations of the meat and poultry residue program.

STUDY OF THE GASTONIA EGG PRODUCTS LABORATORY

The FSQS laboratory in Gastonia, North Carolina performs analyses of samples for the agency's residue monitoring program for egg products. The lab incorrectly reported a sample as being negative for PCB residues during the western states incident. This error may have slowed our ability to trace the source of the contamination.

Since that time, vast improvements have been made at the egg products laboratory in Gastonia, North Carolina. Additional analytical equipment purchased for the laboratory gives the facility the capability to meet crisis demands for testing services, and expertly trained personnel have been added to assure accurate and precise laboratory procedures. In addition, a major expansion of the laboratory is currently being pursued.

CLARIFICATION OF INSTRUCTIONS TO FIELD PERSONNEL

Many procedures, directives and policies regarding residue monitoring and response to contamination incidents have been developed over the years, and the piece-meal nature of these instructions contributed to delays in controlling the PCB incident.

A single directive will be distributed to all employees involved in the program to detail, step-by-step, the procedures to be followed in the case of a positive residue finding. The instructions will also detail the notifications which are to be made in each case, both from the field to headquarters FSQS officials, and from FSQS to other agencies including the Food and Drug Administration, Environmental Protection Agency and departments of agriculture in affected States.

The directive will bring together, for the first time, all of the various existing directives, together with new instructions designed to improve our response to environmental contamination of the food supply.

Below are our comments on your proposed recommendations for USDA:

1. Clearly define which agency will assume the leadership role under various circumstances and conditions which are anticipated.

The handling of the PCB incident, with each involved agency handling its own functions and responsibilities, was at times somewhat time-consuming and cumbersome. In large-scale contamination incidents, we agree that one of the involved agencies should coordinate the Federal agencies' liaison efforts with the public, State governments and media. When the food chain becomes contaminated, it is imperative that concise, straight-forward and up-to-date information is disseminated in a timely manner. It is particularly urgent in crisis situations involving the public health that a single source of contact be provided to those who can aid the Federal effort to bring the problem under control.

In a PCB contamination incident in the southeast earlier this year, the Food Safety and Quality Service, in cooperation with the Food and Drug Administration, Environmental Protection Agency and the Tennessee Valley Authority, established a command center to serve as a coordination point for the Federal effort. Although the incident fortunately did not develop into a large-scale problem, the command center served an extremely useful function as a central control point and clearinghouse for information.

We agree that this team effort approach is the most effective and expeditious manner with which the Federal government can deal with environmental contamination incidents, and will continue to lead efforts to institute such an approach whenever possible. While it is important that each agency retain direct policy control over its operations in a contamination emergency, it is just as crucial that the efforts of the agencies not be hampered by a lack of coordination. By implementing this team approach, all agencies can best utilize their technical, analytical and administrative resources, while

retaining their unique regulatory responsibilities. In this way, we can serve our common goal of fast and effective control of environmental contamination problems.

2. Develop a legislative proposal for the implementation of a pilot program to test the feasibility and cost effectiveness of various approaches to the establishment of a national investigatory monitoring system that monitors for suspected environmental contaminants.

The existing FSQS National Residue Program was founded 13 years ago in response to the first wave of public alarm over dangerous chemicals in our environment. In the monitoring aspect of the program, over 25,000 samples are analyzed yearly to identify residue problems, gather information, and help assure that animals slaughtered for food will not contain residues above legally permitted levels.

Investigatory monitoring is already a major component of our ongoing program; therefore, additional legislative authority for this purpose would be unnecessary. Further, it is unclear how implementation of your recommendation would augment our present efforts.

We do, however, recognize the need to provide increased investigatory monitoring to prepare us for the changing nature of food contamination problems. To help us better allocate our resources, we will soon study the feasibility of using more sophisticated mathematical models to assist decisionmaking in this area. Through this study we seek to insure that FSQS uses its existing sampling and analytical laboratory capabilities in the most expeditious manner to meet the goal of safe and wholesome food products.

The sophisticated analytical capabilities, extensive data storage and retrieval facilities, and resources needed for an expanded investigatory monitoring system make this first step essential so that we may evaluate the monitoring which can be accomplished under current conditions. We intend to devote increased resources in the coming years to research and development in order to build on that existing base.

Additional comments concerning technical data in your report are attached.

I hope our comments will be helpful to you in preparing the final report and look forward to its publication.

Sincerely,

Carol Foreman

CAROL TUCKER FOREMAN
Assistant Secretary for
Food and Consumer Servic

Mr. Henry Eschwege

ADDITIONAL COMMENTS 1/

1. Third page of the Table of Contents, under the heading "Abbreviations," "FQS" should be "FSQS."

[GAO note: Abbreviation corrected.]

2. Page 44, last paragraph--the FSQS proposal to permit the meat and poultry processing plants to develop voluntary quality control systems has been finalized, and became effective September 15, 1980.

[GAO note: Information added.]

1/This portion of the Department's letter was retyped to facilitate showing our comments. The page number was changed to reflect that in the final report.

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

OCT 27 1980

OFFICE OF
PLANNING AND MANAGEMENT

Mr. Henry Eschwege
Director, Community & Economic Development Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Eschwege:

The Environmental Protection Agency (EPA) has reviewed the General Accounting Office (GAO) draft report entitled "Further Federal Action Needed To Detect and Control Environmental Contamination of Food."

The report describes an incident in 1979 involving the Food Safety and Quality Service (FSQS) and the Food and Drug Administration (FDA) in detection and control of polychlorinated biphenyl (PCB's) as a contaminant in food. The GAO concluded that the agencies involved had not acted in a timely fashion and made recommendations to improve future activities of this type.

In its recommendations, GAO stressed the need for coordination among all agencies involved in identifying and preventing chemical contamination problems. Further, it recommended that the agencies (1) clearly define which agency will take the lead under various conditions and (2) develop a legislative proposal for a pilot program to test the feasibility of establishing a national monitoring system for suspected environmental contaminants. GAO has recognized a valid need to develop mechanisms to ensure prompt action by those agencies responsible for controlling toxic contaminants in food.

The three agencies specifically discussed in the GAO report are all members of the Interagency Regulatory Liaison Group (IRLG). GAO, therefore, could strengthen its recommendation by suggesting that the agencies use the existing IRLG forum to define responsibilities and develop proposals. For example, a work group on food contaminants might be established to discuss and resolve the issues raised by GAO. This work group might also obtain IRLG funding to develop testing methods or to perform sampling for case studies. A specific reference to use of the IRLG, therefore, may elicit a more prompt and favorable response by the agencies involved.

APPENDIX IV

It should be noted that monitoring programs to develop data on the nationwide occurrence of pesticide and industrial chemical residues in food do exist. The United States Department of Agriculture (USDA) monitors meat and poultry, and The Department of Health & Human Services (HHS) monitors all other commercial foods and feeds. These are surveillance programs, rather than strictly compliance activities done as a follow-up on previous violations of food tolerances. The sampling is aimed mostly at high-production food commodities.

However, these existing programs can be improved. HHS is revamping its monitoring program now, in part as a response to an earlier GAO report and Congressional hearings. USDA is also developing public rules and regulations to document their procedures better. One major improvement which we support strongly is the development of a consistent set of objectives for all the monitoring systems and an agreed upon list of environmental contaminants which should be monitored. EPA's Pesticide Programs is helping HHS to put together a surveillance index for selection of pesticides which should be monitored based on their potential health risk and occurrence in the food supply. We are supplying HHS with toxicology profiles, residue chemistry and environmental fate information, and production data for approximately 80 pesticides.

We appreciate the opportunity to comment on the draft report prior to its issuance to Congress.

Sincerely yours,

William Drayton, Jr.
Assistant Administrator for
Planning and Management

APPENDIX V

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

7 NOV 1980

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Further Federal Actions Needed to Detect and Control Environmental Contamination of Food." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard B. Lowe III
Inspector General (Designate)

Enclosure

Comments of the Department of Health and Human Services on the General Accounting Office's Draft Report Entitled: "Further Federal Actions Needed to Detect and Control Environmental Contamination of Food"

General Comments

We believe that the GAO report does not describe completely or accurately the statutory division of Federal responsibility for ensuring that amounts of chemicals in foods do not exceed safe levels. The situation is complex because the responsibilities of the departments/agencies involved are not mutually exclusive.

The FDA, pursuant to the Federal Food, Drug and Cosmetic Act ("the Act"), has broad responsibility to ensure the safety of food, both human and animal. With respect to meat and poultry products, the Act gives FDA authority over food animals before slaughter and after completion of the USDA inspection process. For eggs and egg products, FDA shares responsibility for monitoring these products with USDA. Thus FDA and USDA act in concert to ensure broad public health protection from the time the food production process begins until such food ultimately reaches the consumer.

Further, as part of Federal food surveillance efforts, FDA and other concerned agencies, regularly exchange information through the Interagency Regulatory Liaison Group, a voluntary work group composed of staff from FDA, EPA, USDA, Labor's OSHA, and the Consumer Product Safety Commission. Here the involved agencies share information on possible toxic contaminants obtained from their independent monitoring systems. Interagency contact is at both headquarters and regional office levels.

In addition, FDA pursuant to its own statutory authority, has proposed regulations limiting the use of PCB-containing equipment in food production or storage facilities. USDA and EPA have also proposed regulations dealing with this issue.

Since the Montana incident FDA has written and implemented a new regulatory procedures manual chapter on emergency procedures. This document is essentially a compilation and expansion of existing procedures that were in various agency manuals. In describing responsibilities, this document recognizes that dealing with potential emergencies are nearly an everyday occurrence in FDA. Further it states that the agency's permanent organizational structure is designed, in part, to respond to both large and small crises. The organization includes offices in 146 cities staffed with investigators and equipped for emergency operations. In a crisis situation, it is important that individual assignments and responsibilities be generally consistent with normal functions and duties. This provides for a very quick response to unexpected situations and rapid communication of information without the delay from establishing special systems.

GAO Recommendation

We recommend that the Secretaries of Agriculture and HHS and the Administrator of EPA, as part of their cooperative program to identify and control such deleterious substances as PCBs,

(1) clearly define which agency will assume the leadership role under the various circumstances and conditions which are anticipated.

HHS Comment

We concur that whenever incidents of food contamination occur, the agencies involved in identifying and resolving the problem should cooperate to the maximum extent possible.

However, we want to point out that on June 19, 1978 in his Reorganization Plan No. 3, President Carter proposed a comprehensive reorganization of the Federal Government's emergency-preparedness and disaster response programs. As stated in a Federal Emergency Management Agency (FEMA) White Paper,

> "The plan merges into one agency closely allied Federal programs involved with preparedness, mitigation and response to national emergencies ranging from natural and man-made disasters to nuclear attack."
>
> "On September 14, 1978, the reorganization plan was approved by the Congress."

Among the responsibilities assigned to FEMA is interagency coordination in chemical emergencies, including massive contamination of food. In developing criteria for the designation of a lead agency for occurrences of chemical contamination of food we and other involved agencies will need to take FEMA's role into consideration.

Generally, the agency with the greatest ability to collect information, communicate findings, coordinate the activities of state and local agencies, and take protective actions under a particular set of circumstances has assumed the leadership role. While no lead agency was formally designated in past contamination incidents, the leadership role was frequently assumed by FDA. For example, in the Michigan PCB incident (Reference: 1977 GAO Report entitled "Federal Efforts to Protect Consumers from Polybrominated Biphenyl Contaminated Food Products") and, in the Montana PCB incident, a variety of consumer products, i.e., foods, drugs and cosmetics, were contaminated and FDA in cooperation with other agencies assured their removal from distribution channels. Other agencies have assumed the leadership role in other incidents. In the Kepone incident, the central problem involved environmental contamination, particularly rivers and streams; therefore, EPA assumed primary responsibility. Earlier this year the ingestion of PCB-contaminated barn siding by swine resulted in the contamination of meat. Other food products were not significantly involved; therefore, USDA had the lead responsibility for protective action. FDA supported both the EPA and USDA efforts in these instances.

In summary, while we agree in principle with this GAO recommendation, we believe that any criteria for a leadership role will need to be flexible enough to deal with any unforeseen combination of circumstances.

GAO Recommendation 1/

> (2) develop a legislative proposal for the implementation of a pilot program to test the feasibility and cost effectiveness of various approaches to the establishment of a national investigatory monitoring system that monitors for suspected environmental contaminants.

HHS Comment

We support the concept of testing the feasibility and cost of various approaches to monitoring the environment for food contamination. In fact, FDA has been evolving a more cost effective method of surveillance over the recent few years. FDA and other agencies have built on the data system mandated in the Toxic Substances Control Act for the purpose of improving their collective impact.

We also recognize that some of the statutes enforced by the regulatory agencies could be strengthened. Consequently, several agencies have proposed legislation; for example, FDA has requested that food detention authority be added to the F,D & C Act.

As a result of the evolving allied effort and because of the several independently sponsored pieces of legislation, a legislative proposal for a pilot program is not necessary at this time.

Technical Comments

1. Page 2, paragraph 2: The responsibilities listed for USDA and FDA are inaccurate. FDA shares responsibility for monitoring eggs and egg products with USDA. See General Comments.

[GAO note: Information added on p. 3.]

1/This portion of the Department's letter was retyped (with minor editorial changes) to facilitate showing our comments. The page numbers were changed to reflect those in the final report.

2. Page 4, list of tolerances: This list is incomplete. Also the tolerance for fish should read 5.0 ppm. The 2.0 ppm quoted by GAO was published by FDA as a Final Order, but it has subsequently been the subject of a request for a hearing that resulted in a stay of the Final Regulation. The tolerance then reverted to the previously established level of 5.0 ppm. Also, we are not aware of any tolerance for PCB's in grease. The complete list of FDA's tolerances for PCBs is available in 21 CFR 109.30.

   [GAO note: List revised.]

3. Pages 8-10: The section entitled, How Timely Were Federal Efforts In Detecting PCB-Contaminated Foods? is inconsistent with the "Best Situation Scenario" on page 10. We believe that events described in the narrative should be listed under the "Best Situation Scenario" to avoid confusion.

   [GAO note: Additional events described in the narrative were listed in the table.]

4. Page 11, last line of text: The sentence beginning "Based on the previous history..." is unclear as to whether GAO is referring only to the history of the establishments involved in this incident or to the history of food establishments in general.

   [GAO note: Footnote added.]

5. Page 13, line 4: Should read "...in 19 States..."

   [GAO note: Corrected.]

6. Page 13, line 30: Should read "...and 1.2 million pounds of grease."

   [GAO note: Corrected.]

7. Page 18, lines 1-4: The retrospective evaluation mentioned in this sentence has been completed and submitted to the Congress. New FDA procedures and the USDA/FDA Emergency Response System discussed in that evaluation are intended to reduce time lapses such as the ones experienced in this PCB contamination incident. Additionally, the Interagency Regulatory Liaison Group consisting of USDA, FDA, EPA, and CPSC held a Seminar on Toxic Substances versus Public Health in Helena, Montana, earlier

this year. The seminar reached consensus in four areas that we believe will continue to strengthen ties between the four agencies and help not only in investigating contamination incidents but also in preventing their occurrence. These areas are:

The need to continue and strengthen communication and coordination between the agencies.

The need to continue to pursue the goal and recognize the importance of preventing chemical contamination of the environment.

The need to establish an emergency response team that encompasses all levels of government, including State, regional, and national organizations.

The need for each State to address the problem of hazardous waste collection and disposal.

[GAO note: Information added.]

8. Page 18, lines 25 and 26: To our knowledge, FSQS has not approved a voluntary residue control program. This line should be revised to state that industry should adopt a Voluntary Quality Control Program as is suggested in the Bureau of Veterinary Medicine Educational Guide for Contamination of Animal Feedstuffs.

[GAO note: Reference to FSQS program deleted.]

9. Page 19: Paragraph beginning, "On May 7, 1980...item (3) should read: "...was compiling a list of references of test procedures for industry use in quality assurance programs..."

[GAO note: Revised as suggested.]

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