REPORT TO THE COMMITTEE ON AGRICULTURE AND FORESTRY UNITED STATES SENATE

RELEASED

An Incident Of Contamination Of Livestock Feed And Certain Consumer Products

B-164031(2)

Food and Drug Administration

Department of Health, Education, and Welfare

Department of Agriculture

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

DEC 1,1972

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D C 20548

B-164031(2)

Dear Mr. Chairman:

This is our report on an incident of contamination of livestock feed and certain consumer products with the chemical polychlorinated biphenyl at East Coast Terminals, Inc , in North Carolina. We made our review pursuant to your request of July 30, 1971, and subsequent discussions with your office It concerns the handling of the incident by the Food and Drug Administration, Department of Health, Education, and Welfare and the Department of Agriculture.

As agreed upon with your office, we obtained formal written comments from the Department of Health, Education, and Welfare and the Department of Agriculture

We plan no further distribution of this report unless copies are specifically requested and then only after we have obtained your agreement or you have publicly announced its contents

Sincerely yours,

Elmer B. Staats

Comptroller General
of the United States

The Honorable Herman E. Talmadge
Chairman, Committee on Agriculture
and Forestry
United States Senate

Contents

ABBREVIATIONS

ECT	East Coast Terminals, Inc.
FDA	Food and Drug Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
PCB	polychlorinated biphenyl
USDA	United States Department of Agriculture

COMPTROLLER GENERAL'S REPORT
TO THE COMMITTEE ON
AGRICULTURE AND FORESTRY
UNITED STATES SENATE

AN INCIDENT OF CONTAMINATION OF LIVESTOCK FEED AND CERTAIN CONSUMER PRODUCTS

Food and Drug Administration
Department of Health, Education, and Welfare
Department of Agriculture
B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

By letter dated July 30, 1971, the Chairman of the Senate Committee on Agriculture and Forestry requested the General Accounting Office (GAO) to investigate and report on the handling of an incident of contamination of livestock feed with polychlorinated biphenyl (PCB)--a toxic industrial chemical--by the Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), and by the United States Department of Agriculture (USDA)

Background

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act to insure that livestock feed or feed ingredients are not adulterated USDA is charged--under several other laws--with the responsibility of insuring that meat, meat products, poultry, poultry products, and egg products are wholesome and safe At the time of GAO's fieldwork, FDA was responsible for eggs in shells, but effective July 1, 1972, primary responsibility for eggs in shells was transferred to USDA

PCBs are industrial chemicals which FDA considers to be of moderately acute toxicity Little is known about how long-term, low-level exposure to PCBs might affect human health, but results of some toxicological tests on rats have shown PCBs to affect their livers and reproductive systems (See p 5.)

FINDINGS AND CONCLUSIONS

Contamination incident

On July 16, 1971, the manufacturer of PCBs informed FDA that large amounts of fishmeal--an ingredient used in feed for livestock, such as poultry and swine--processed by East Coast Terminals, Inc , had been contaminated with PCBs as a result of a leak in the processor's equipment

A poultry processor in North Carolina which grows and slaughters its own poultry reported to USDA on July 19, 1971, that PCBs had been found in its flocks and that the cause had been identified as fishmeal processed by East Coast Terminals, Inc.

Processing equipment of East Coast Terminals, Inc , leaked intermittently from about April 30 to June 28, 1971. FDA found that East Coast Terminals, Inc , had distributed about 11,987 tons of potentially contaminated fishmeal to 65 customers in 12 States from April 30 to July 16, 1971 East Coast Terminals, Inc., recovered about 2,335 tons of the fishmeal from its

customers, and FDA approved the use of the fishmeal as fertilizer

FDA cited East Coast Terminals, Inc , to a hearing on April 25, 1972, to show cause why it should not be prosecuted for distributing an adulterated product in interstate commerce from April 30, 1971, through July 16, 1971 South Pacific Proteins, Inc , the importer and shipper of the fishmeal, was cited to a hearing on July 28, 1972 As of August 18, 1972, the record of that hearing was under review to determine further actions, if any, to be taken. (See p 10.)

FDA and USDA investigations

FDA's and USDA's investigations of PCB-contaminated fishmeal were generally comprehensive, however, there was little coordination and, as a result, they duplicated visits to customers that had received the fishmeal

FDA visited all 65 customers that had received the contaminated fishmeal, even though USDA had had full-time inspectors assigned to plants operated by 39 of the customers and USDA had visited 20 of the remaining 26 customers prior to FDA visits USDA obtained information during its visits that was similar to the information later obtained by FDA, however, no procedure existed for the exchange of such information

GAO believes that USDA and FDA should establish procedures which would provide for coordinating future investigations and for exchanging needed information (See p 14)

Product testing

Because of the East Coast Terminals, Inc , incident, USDA and FDA tested consumer products FDA established guidelines for use in removing from the market products which were found to be contaminated with PCBs as a result of the incident at East Coast Terminals, Inc

USDA's investigation showed that the fishmeal had been used principally in poultry feed and had been used to a limited extent in feed for swine USDA initiated an intensified program to test poultry, swine, and egg products for PCB residues FDA's investigation of products other than fishmeal included the testing of shell eggs, fish feed, and commercially grown fish for PCBs

GAO believes that the programs conducted by FDA and USDA to test consumer products for PCBs appeared to be appropriate for their investigation of the East Coast Terminals, Inc , incident (See p 19.)

RECOMMENDATION

GAO recommends that USDA and HEW establish procedures which provide for coordinating future investigations and for exchanging information needed by each agency in its respective area of responsibility. (See p 17)

AGENCY ACTIONS

Although HEW considers its course of action for the incident to have been appropriate, HEW agreed to explore with USDA the feasibility of establishing formal procedures to

prevent or minimize, wherever possible, duplication of effort for this type of investigation

USDA agreed generally with our recommendation USDA believes the problem of exchanging information to be more complicated than generally recognized but has stated that steps are being taken with FDA which are expected to result in improved coordination of joint operations and exchange of information. (See p 5.)

CHAPTER 1

INTRODUCTION

The Food and Drug Administration (FDA), a constituent agency of the Department of Health, Education, and Welfare (HEW), is responsible for administering the Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 301) The act is intended to prevent the manufacture of adulterated or misbranded foods, drugs, devices, and cosmetics and their distribution and sale through interstate commerce. About 600 FDA inspectors monitor about 100,000 establishments involved in the interstate marketing of products covered by the act.

Products, like fishmeal, used as ingredients in feed for livestock--such as poultry and swine--are included in the definition of food under the act. FDA carries out its responsibility for livestock feeds through periodic inspections of the manufacturers, processors, and distributors of livestock feeds or feed ingredients and through analyses of product samples.

The United States Department of Agriculture (USDA) is responsible for administering the Poultry Products Inspection Act, as amended by the Wholesome Poultry Products Act (21 U.S.C. 451); the Federal Meat Inspection Act, as amended by the Wholesome Meat Act (21 U.S.C. 601); and the Egg Products Inspection Act (21 U.S.C. 1031).

The Secretary of Agriculture had delegated the authority for the enforcement of the provisions of the poultry, meat, and egg products inspection acts to the Administrator, Consumer and Marketing Service.[1]

About 7,000 USDA inspectors inspect the products processed by about 4,800 federally inspected plants.

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[1]Effective April 2, 1972, the Consumer and Marketing Service was renamed the "Agricultural Marketing Service" and the meat and poultry inspection functions were transferred to the new Animal and Plant Health Inspection Service. The Agricultural Marketing Service retained responsibility for the inspection of egg products.

The Poultry Products Inspection Act provides for the Federal inspection of poultry and poultry products to prevent the movement in interstate or foreign commerce of poultry products which are unwholesome, adulterated, or otherwise unfit for human consumption. Similarly, the Federal Meat Inspection Act provides for the Federal inspection of meat and meat food products to prevent the movement in interstate commerce of meat products which are unwholesome; adulterated; or improperly marked, labeled, and packaged.

The Egg Products Inspection Act provides for continuous Federal or State inspection of the processing of egg products to prevent intrastate, interstate, or foreign commerce of any misbranded or adulterated egg products which are capable of being used as food for humans. An "egg product" is defined as any dried, frozen, or liquid egg but does not include products which contain eggs in a relatively small proportion, such as eggnog mixes, noodles, and cake mixes, or which historically have not been considered as products of the egg food industry.

At the time of our fieldwork, FDA was responsible, under the Federal Food, Drug, and Cosmetic Act, for eggs in shells, but, effective July 1, 1972, the Egg Products Inspection Act transferred primary responsibility to USDA. FDA will continue to have some responsibility for shell eggs, such as monitoring them for pesticide residues. USDA and FDA have established a cooperative agreement which identifies the responsibility of each.

The principal difference between the inspection practices of FDA and USDA is that USDA-inspected products generally must be processed in establishments under continuous inspection programs, whereas FDA carries out its responsibility by periodic inspections of establishments.

FISHMEAL PROCESSING AT EAST COAST TERMINALS, INC.

East Coast Terminals, Inc. (ECT), is a public warehousing firm in Wilmington, North Carolina, which provides storage facilities for bulk steamship goods. ECT began processing fishmeal after contracting with South Pacific Proteins, Inc., in 1969. South Pacific Proteins, Inc.,

Darien, Connecticut, is the importer, owner, and seller of the fishmeal processed by ECT. When ECT began processing fishmeal, FDA became responsible for inspecting the facilities of the firm and for monitoring the processing of the fishmeal.

ECT's contract with South Pacific Proteins, Inc., provides that ECT will (1) store the fishmeal, (2) process the fishmeal through heat treatment, and (3) ship the processed fishmeal to designated customers. South Pacific Proteins, Inc., owns all heat processing and handling equipment ECT uses for processing the fishmeal.

ECT pasteurized the fishmeal by using a heat-processing system which consisted of an enclosed trough containing two hollow screw conveyors. A heat exchange fluid containing polychlorinated biphenyl (PCB) was heated to temperatures of 300° to 400° F. and was moved through the hollow walls of the screw conveyer, thus increasing the temperature in the enclosed trough and destroying harmful bacteria.

From January 16, 1970, through April 12, 1971, ECT received about 54,000 tons of fishmeal. It processed and distributed an estimated 49,000 tons before operations were temporarily ceased on July 16, 1971, because of a PCB contamination problem.

PCBs

PCBs are extremely stable and fire-resistant industrial chemicals which have a variety of industrial uses. PCBs have the same general chemical and toxicological characteristics of certain pesticides and have a tendency to accumulate in the fatty tissues of animals.

Although on the basis of available information FDA considers PCBs to be of moderately acute toxicity, very little is known about how long-term, low-level exposure to PCBs might affect human health. In summarizing the results of test data on the toxicological effects of PCBs, FDA stated that rats receiving 1,000 parts per million (p.p.m.) of PCBs in their daily diet had shown growth depression and increased liver size. FDA stated also that tests on rats had shown that, at levels of about 100 p.p.m. of PCBs in

the diet, liver and thyroid weights increased and adverse reproductive effects were noted with a decrease in litter sizes and survival rates.

Because PCBs are not intended for human consumption, they are not permitted to be used in food. When industrial accidents result in PCB-contaminated food products, FDA may establish a guideline which allows certain levels of PCBs in affected consumer food products. Following the discovery of PCBs in fishmeal processed by ECT, FDA established guidelines of 5 p.p.m. or less of PCBs in poultry or poultry products and of 0.5 p.p.m. or less of PCBs in shell eggs or liquid or frozen whole eggs. These guidelines applied only to consumer food products affected by the PCB-contaminated fishmeal processed by ECT.

On July 28, 1971, FDA adopted a policy on PCBs in feeds or feed ingredients as follows:

> "The use of feed or feed ingredients containing detectable levels of polychlorinated biphenyls for food producing animals, poultry or fish is not condoned or approved by FDA. Such adulterated feeds may be used as feed for animals not used for food, provided they are not toxic to the animals; or for such non-food purposes as fertilizers, or industrial chemicals."

On September 1, 1971--at a meeting initiated by FDA--an interdepartmental task force was created to conduct a Government-wide investigation into PCB contamination of food and other products. The task force was coordinated by two of the participating member organizations--the Office of Science and Technology and the Council on Environmental Quality of the Executive Office of the President. Other member organizations include the Environmental Protection Agency, FDA; the National Institute of Environmental Health Sciences of HEW's National Institutes of Health; USDA; the Department of Commerce; and the Department of the Interior.

The task force's objectives were to (1) insure maximum effective coordination of Government response to specific and preventable PCB contamination as such problems may arise and (2) develop a long-range strategy for coordinating

scientific resources to better define the PCB problems and the possible implications for human health. The task force was to expedite the search for answers and solutions by bringing together the combined resources and authorities of cooperating Government agencies.

The task force's report, issued in May 1972, primarily points out that PCBs should be restricted to essential or nonreplaceable uses which would minimize the likelihood of human exposure or leakage to the environment.

SCOPE OF REVIEW

We reviewed FDA's and USDA's policies, procedures, and practices as they related to the investigation and followup activities of the contamination of fishmeal and certain consumer products discussed in this report. We also reviewed the appropriate laws and regulations covering the contamination of fishmeal and affected consumer products.

We examined FDA reports on inspections of ECT and other FDA and USDA records concerning the incident and interviewed cognizant officials of FDA and USDA. Our review was conducted at FDA headquarters in Rockville, Maryland, and at USDA headquarters in Washington, D.C.

CHAPTER 2

INCIDENT AT EAST COAST TERMINALS, INC.

Representatives of the manufacturer of PCBs informed FDA on July 16, 1971, that large amounts of fishmeal had been contaminated during a pasteurization process by a heat exchange fluid containing PCBs. The contamination was reported to have been caused by a leak in the processing equipment at ECT.

Fishmeal is an ingredient used in feed for poultry, swine, cattle, sheep, and fish, and FDA is responsible for insuring that livestock feeds are not adulterated. The Atlanta District Office of FDA inspected ECT on July 17 and 18, 1971, and collected and analyzed samples of the fishmeal. The district office informed FDA headquarters on July 19, 1971, that samples of processed fishmeal ready for distribution by ECT were found to contain between 15 and 20 p.p.m. of PCBs. Samples of unprocessed fishmeal from the same shipment did not contain PCBs. Also ECT's heat-processing equipment had been leaking.

On July 19, 1971, a commercial poultry processor in North Carolina, which grows and slaughters its own poultry, informed USDA that PCBs had been found in its poultry flocks. The firm reported that its investigation had implicated fishmeal as the cause of the reduced rate of hatching of eggs from its flocks. Additional investigation by the firm showed that the contaminant was PCB and that ECT had processed the fishmeal. The firm subsequently destroyed about 100,000 chickens because its analysis showed PCB residues in excess of that allowed in the guideline.

FDA's inspection reports showed that ECT's heating unit had leaked intermittently from about April 30 to June 28, 1971. According to discussions between ECT and the FDA inspector, the firm became aware of the leakage problem in its system on April 30, 1971, when an unknown quantity of heat exchange fluid had to be added to the system. Production records showed that the operator of the unit had recorded that oil was leaking in the equipment on April 30, 1971. Operations were shut down about 3-1/2 hours after the leak was discovered and did not resume until May 5, 1971.

ECT's management examined the equipment during the shutdown period and found a hole of about the diameter of a toothpick and about six or eight "sweat spots." These spots were worn and weakened areas where the hot transfer fluid had soaked or sweated through the equipment. ECT officials informed FDA that attempts had been made to correct the situation by re-welding the problem area. ECT officials informed FDA that subsequent attempts to correct sweat spots had been made by recladding. "Recladding" is a process of applying 1/8-inch-thick steel plates to those areas of the heat-processing units which have developed weak spots.

Production records examined by the FDA inspector showed that a minimum of 70 gallons of the heat exchange fluid had been added to the system. According to the inspection report, 60 gallons of fluid had been added on May 7, 1971; about 10 gallons had been added on May 15, 1971; and an unknown quantity had been added on April 30, 1971. The production records showed that the equipment had been shut down because of leaks, or to check for leaks, on 13 days during May, 10 days during June, and 1 day during July 1971.

FDA made eight inspections of ECT's operations from December 1969 to October 1970 because of insanitary conditions and bacteria contamination of fishmeal. ECT improved its operations and, as a result, FDA did not inspect ECT from October 1970 to July 1971 but relied on results of analyses of fishmeal samples for bacteria contamination by a private laboratory. Such analyses would not reveal the presence of PCBs in the fishmeal.

ACTIONS TAKEN AFTER NOTIFICATION OF INCIDENT

Upon notification of the contamination on July 16, 1971, FDA acted to determine the size and significance of the problem. FDA's Atlanta District Office conducted a joint inspection of ECT with the North Carolina Department of Agriculture on July 17 and 18, 1971.

The FDA inspection report stated that ECT had closed to make repairs to the heat-processing units on July 16, 1971. An ECT official informed the FDA inspector that the firm had

ceased operations after discussions about the leakage problem with officials of the manufacturer of PCBs.

The FDA inspector estimated that about 16,000 tons of fishmeal had been processed and had been distributed by ECT after April 30, 1971, and were potentially contaminated with PCBs. FDA's review of ECI's distribution records showed that only 11,987 tons of fishmeal had actually been distributed. The difference was reported as being due primarily to the fact that ECT did not process on a 24-hour basis every day during the period April 30 to July 16, 1971.

During the July 17 and 18 inspection, four samples were taken of processed fishmeal which was ready for shipment, and FDA's analysis of these samples showed levels of PCBs ranging from 13 to 25 p.p.m No detectable levels of PCBs were found in samples of unprocessed fishmeal. An additional seven samples were collected from interstate shipments of fishmeal, and FDA's analysis showed levels of PCBs ranging from 13.7 to 29 p.p.m

On July 21, 1971, FDA inspectors returned to ECT to determine whether the firm would voluntarily hold the PCB-contaminated fishmeal until seizure action could be completed. The inspectors also requested the distribution records of all fishmeal processed on or after April 30, 1971 Although ECT agreed to voluntarily hold the fishmeal, the North Carolina Department of Agriculture placed the fishmeal under embargo on July 21, 1971

ECT officials advised the FDA inspectors that all fishmeal distributed after April 30, 1971, would be voluntarily recalled by South Pacific Proteins, Inc. ECT provided FDA with a list of 65 customers in 12 States which had received the fishmeal. The 12 States were Alabama, Arkansas, Delaware, Florida, Georgia, Indiana, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia. The list was forwarded to the FDA Atlanta District Office for followup actions.

On July 23, 1971, USDA issued a press release announcing that it was investigating the extent to which some poultry produced in the southeastern United States might be

contaminated with PCBs. USDA requested FDA to join in the press release, but it declined to do so FDA did respond to inquiries from the press for information. In an information memorandum dated July 29, 1971, to the Secretary, HEW, the Commissioner of Food and Drugs stated that the draft of the USDA press release was inaccurate in terms of factual information and that FDA did not have sufficient information to join in a press release which would serve a constructive purpose. The inaccuracies were subsequently corrected before the final press release, according to FDA.

FDA's Deputy Executive Director of Regional Operations informed us on November 12, 1971, that 2,335 tons of the 11,987 tons of distributed fishmeal had been recovered. FDA had approved the use of the contaminated fishmeal as fertilizer. About 300 tons had been distributed as fertilizer by March 1972.

Under section 305 of the Federal Food, Drug, and Cosmetic Act, FDA cited ECT to a hearing on April 25, 1972, to provide ECT with an opportunity to present reasons why it should not be prosecuted for distributing an adulterated product in interstate commerce from April 30, 1971, through July 16, 1971. Additionally, South Pacific Proteins, Inc., the importer and shipper of the fishmeal, was cited to a hearing on June 28, 1972. As of August 18, 1972, the record of that hearing was under review to determine further actions, if any, to be taken.

CHAPTER 3

INVESTIGATION OF PCB-CONTAMINATED FISHMEAL

FDA's and USDA's investigations of PCB-contaminated fishmeal were generally comprehensive; however, there was little coordination and, as a result, they duplicated visits to customers that had received the fishmeal.

DUPLICATE VISITS BY FDA AND USDA

Of the 65 customers that had received the fishmeal, 61 were located within the boundaries of the FDA Atlanta District Office and four were located in States covered by FDA's district offices at Baltimore, Maryland; Detroit, Michigan; New Orleans, Louisiana; and Philadelphia, Pennsylvania. FDA visited all 65 customers to determine how much fishmeal was still on hand and how the fishmeal had been used. Followup investigations by FDA, USDA, or State authorities were necessary in instances in which the fishmeal had been fed to food-producing livestock.

Previously FDA had provided a list of the 65 customers to USDA on July 22, 1971, so that USDA could determine if the contaminated fishmeal received by the 65 customers had been used to feed food-producing livestock and if the livestock would be slaughtered at USDA-inspected plants. USDA determined that 39 of the customers were integrated poultry processors. An "integrated poultry processor" is one that raises the poultry and has its own feedmill and slaughter plant. These processors generally have a full-time USDA inspector assigned to the slaughter plant. USDA determined that the poultry of these 39 customers would be processed at USDA-inspected slaughter plants and would be tested under a USDA sampling program for PCBs.

USDA visited the 26 other customers to determine how the fishmeal was being used, if it had been fed to livestock which would be used for food, and where these livestock would be slaughtered. USDA's review of the 26 firms showed that the livestock fed with feed containing fishmeal from ECT were to be slaughtered only at federally inspected slaughter plants. It found that the fishmeal had been used

as a feed ingredient in feed for food-producing livestock in only 10 of the 12 States where the fishmeal had been distributed. USDA initiated a testing and sampling program in these 10 States which provided for the sampling of poultry, swine, and egg products for PCB residues at federally inspected plants.

Although USDA does not have statutory authority to obtain information concerning the use or distribution of fishmeal at the 26 firms which it visited, USDA generally was able to obtain needed information regarding the fishmeal. Also USDA visited 20 of the 26 firms 6 to 15 days before the FDA inspector and both generally obtained similar information.

There was little coordination, USDA officials said, between FDA and USDA in tracing the fishmeal or its users. They said no instructions had been issued to provide FDA with information obtained from USDA's visits, and the information had not been provided to FDA officials. An official in FDA's Bureau of Veterinary Medicine informed us that FDA provided USDA with information on products which were USDA responsibility, such as potentially contaminated eggs being sold to an egg-processing plant.

DISTRIBUTION OF PCB-CONTAMINATED FISHMEAL AFTER JULY 1971

Following the July 1971 incident of PCB contamination of fishmeal, ECT operations were closed down until September 1971. After installing certain new equipment, replacing the heat exchange fluid with a product not containing PCBs, and making other equipment modifications, ECT notified FDA that it intended to begin processing fishmeal on September 28, 1971.

FDA inspected ECT on September 28, 1971, to determine if PCBs were continuing to contaminate the fishmeal being processed. FDA's analysis of the sample showed that the processed fishmeal contained 13.7 p.p.m. of PCBs. Samples of the same test batch taken by management and analyzed by an outside laboratory showed 0.42 and 0.47 p.p.m. of PCBs. ECT held this lot of fishmeal and later received FDA's approval to use it as fertilizer.

FDA records do not show the reasons for the difference in the results of the analysis. An FDA official informed us that there should not be such a large difference in the analysis results. He stated that he would rely on FDA's analysis because of its experience in making such analyses and because of the complexity of the test procedure.

By November 3, 1971, ECT had distributed about 49 tons of fishmeal interstate after it restarted its operations. FDA inspected ECT again on November 4, 1971, to determine its current status and to sample the fishmeal being processed. During the inspection, an ECT official stated that a sample of processed fishmeal which had been collected by ECT on October 5, 1971, and analyzed by an outside laboratory was found to contain 0.16 p.p.m. of PCBs. The official advised the FDA inspectors that ECT intended to fill orders for fishmeal because ECT believed the PCB problem had been solved.

FDA collected samples during this inspection from both the bulk unprocessed fishmeal and from every available point in the processing line. FDA informed us that the unprocessed fishmeal showed 0.9 to 1.2 p.p.m. of PCBs, that the in-process fishmeal showed 1.4 to 1.6 p.p.m, and that the processed fishmeal showed 2.4 to 2.6 p.p.m. According to FDA's inspection report, ECT distributed between 44 and 48 tons of the processed fishmeal intrastate to a feed firm on the day of the FDA inspection.

FDA did not take action on the basis of its sample results. According to FDA's Deputy Associate Commissioner for Compliance, the level of PCBs found in the November 4, 1971, sample was considered an unavoidable environmental level of PCBs, which did not pose an appreciable health hazard for food-producing livestock. He said that, if the source of PCBs had been identified or if the PCB level had exceeded 5 p.p.m., FDA would have taken action.

The Deputy Associate Commissioner for Compliance advised us that FDA initiated a program on November 24, 1971, to survey feeds to determine, on a national basis, the extent and levels of PCB contamination. FDA established guidelines to be used by the district offices during the survey for followup actions. The guidelines state that followup investigations should be made of all samples containing

1 p.p.m. or more of PCBs and that samples found to contain 5 p.p.m. or more of PCBs are to be recommended for regulatory action.

The Commissioner of Food and Drugs proposed regulations on March 18, 1972, which would establish temporary tolerances limiting the levels of unavoidable PCB contamination in milk, dairy products, poultry, fish, eggs, feeds, feed ingredients (including fishmeal), infant and junior foods, and food-packaging material. The proposed regulations would also prohibit, within 30 days of the effective date of the proposal, the use of PCB fluids and PCB-containing material in food, feed, and food-packaging-material processing plants. According to FDA, implementation of this proposal should preclude the type of accidental contamination that occurred at ECT.

CONCLUSION

FDA and USDA each had a responsibility to investigate the PCB contamination incident since it affected products for which both were responsible. Although the investigations by both agencies were generally comprehensive, the investigations were not coordinated and duplicate visits were made to 26 of the 65 customers that had received the ECT fishmeal. FDA visited the 39 other customers, although USDA had full-time employees assigned to the slaughter plants operated by these customers. USDA obtained information during its visits that was similar to the information later obtained by FDA; but this information was not provided to FDA, and no procedure existed for the exchange of such information.

USDA and FDA should establish procedures which would provide for coordinating future investigations and for exchanging information needed by each agency.

RECOMMENDATION

We recommend that USDA and HEW establish procedures which provide for coordinating future investigations and for exchanging information needed by each agency in its respective area of responsibility.

AGENCY COMMENTS

We solicited the views of HEW and USDA, respectively, on a draft of this report. By letter dated August 18, 1972 (see app. II), the Assistant Secretary, Comptroller, submitted HEW's comments on our report. HEW considers its action to have been appropriate for the incident at ECT and believes some duplication of effort is unavoidable because of differences in the type of information needed and differences in the procedures to effect corrective actions. HEW stated, however, that it would explore with USDA the feasibility of establishing formal procedures to prevent or minimize, wherever possible, duplication of effort for this type of investigation.

By letter dated September 20, 1972 (see app. III), the Assistant Inspector General submitted USDA's comments on the report. USDA stated that it agreed generally that USDA and HEW should establish procedures which would provide for coordinating future investigations and for exchanging information needed by each agency in its respective area of authority. USDA believes the problem of exchanging information between all governmental units to be more complicated and pervasive than is generally recognized. USDA has stated, however, that steps are being taken with FDA which are expected to result in improved coordination of joint operations and exchange of information.

CHAPTER 4

TESTING OF CONSUMER PRODUCTS

Because of the ECT incident, USDA and FDA tested consumer products such as poultry, swine, shell eggs, egg products, and commercially grown fish. The programs conducted by USDA and FDA to test consumer products which could have been contaminated with PCBs appeared to have been appropriate for the ECT incident.

GUIDELINES FOR TESTING CONSUMER PRODUCTS

On July 19, 1971, USDA requested FDA to establish a guideline for use in removing poultry contaminated with PCBs from the market. FDA established a guideline of 5 p.p.m. or less for PCBs in poultry for the specific ECT incident. FDA officials informed USDA on July 22, 1971, that:

> "FDA would not object to the distribution of poultry containing 5 ppm or less PCB's. This level is applicable to the edible tissue on a whole tissue basis or to the separate fat removed during slaughter or processing and intended for use as a food ingredient. *** The guideline represents our best judgment based on toxicological information available at this time, and is subject to change as additional toxicological studies are completed."

FDA established an informal guideline for the level of PCBs which would be acceptable in eggs affected by the ECT incident. FDA informed USDA that 0.5 p.p.m. or less of PCBs in shell eggs or liquid or frozen whole eggs would be acceptable for distribution into marketing channels on the basis of current toxicological information on PCBs.

TESTING PROGRAMS FOR CONSUMER PRODUCTS

USDA's investigation of the contaminated fishmeal distributed by ECT showed that the fishmeal had been used principally in feed for poultry and to a limited extent in feed for swine. No other livestock--such as cattle and sheep--apparently received feed containing the fishmeal.

USDA initiated an intensified program to test poultry and swine and to test egg products for PCB residues. FDA's investigation of products other than fishmeal included the testing of shell eggs, fish feed, and commercially grown fish.

PCB testing program in poultry and swine

USDA initiated a two-phase intensive testing program for PCBs in poultry and swine on July 23, 1971. Under the first phase, about 402 samples of slaughtered poultry and swine were collected from federally inspected plants located in the 10 affected States.

USDA officials advised us that the poultry included in these samples were primarily broiler poultry. Broilers, which are young chickens that are 8 to 10 weeks old, are marketed earlier than other types of poultry. Laboratory analyses of the 402 samples showed that none of the samples contained PCBs in excess of the FDA guideline of 5 p.p.m.

On August 16, 1971, USDA initiated the second phase of the program. Under this phase all lots of commercial laying hens, breeder hens, and turkeys originating in the 10 States were to be sampled before slaughter and tested for PCBs. Broilers were not included because tests under USDA's first phase did not show excessive levels of PCBs in the broilers tested. USDA discontinued this second phase on April 14, 1972.

The second phase presented three options to the producers for testing their poultry for PCBs--certification, pretesting, and retention and testing.

Under the first option--certification--the producer and the feed supplier were required to present a certificate with the poultry brought for slaughter certifying that the poultry was not fed any of the contaminated fishmeal. The USDA inspector was required to take a sample from each lot for analysis at a Government laboratory, after which the poultry would be slaughtered and marketed. If the sample revealed excessive PCBs, USDA would not honor further certifications by the producer and could have initiated a recall of the product, if necessary.

Under the second option--pretesting--the producer could have poultry samples tested at his own expense by a private laboratory before slaughter. Samples from the same lot of poultry were also submitted by USDA to a Government laboratory for analysis. The samples--whether tested by a private laboratory or by a Government laboratory--were taken by USDA or under USDA-approved supervision. The private laboratories were required to send the results of their analyses to USDA.

The producer presented the private laboratory's certificate indicating the PCB results to the USDA inspector when the poultry was brought for slaughter. If the results indicated a nonviolative product the poultry could be slaughtered and marketed. A USDA official advised us that only about 10 percent of the pretest samples received by the Government laboratories had actually been analyzed, primarily as a verification of the reliability of the analysis made by the private laboratories.

Under the third option--retention and testing--the producer could choose to have his poultry slaughtered without certification or pretesting, but the carcasses would be retained in cold storage pending the results of Government laboratory analysis. The producer had the option also of submitting samples to a private laboratory at his own expense. The results from the private laboratory were submitted to USDA and USDA would determine the disposition of the retained carcasses.

Under the above three options, at least 6,369 poultry samples were received in six USDA laboratories and six Environmental Protection Agency laboratories as of January 31, 1972. The Environmental Protection Agency analyzed the samples it received on a reimbursable basis for USDA. As of February 8, 1972, the laboratories had completed analyses on 3,305 samples of poultry, 413 of which contained PCBs in excess of FDA's guideline.

Under USDA procedures, the 413 violative samples were then to be analyzed individually to determine how the poultry might still be salvaged for marketing by the producer.

USDA procedures for salvaging the PCB-contaminated poultry provided for cooking the poultry and then removing the skin, bone, and fat--those portions of the poultry where PCBs have a tendency to accumulate. The skin, bone, and fat are buried, incinerated, or used in feed for nonfood animals provided that they are not toxic to the animals. The poultry meat remaining after the cooking process may be used by the producer in food products, such as soups and potpies.

An FDA official informed us that the USDA submitted testing procedures and results to FDA on a case-by-case basis for FDA's review and approval. He stated that FDA approved of the use of salvaged meat in food products for humans when detectable levels of PCB residues were not found in the meat.

PCB testing program for egg products

USDA began sampling egg products on August 2, 1971. USDA took samples from egg-processing plants which (1) sold egg products to the Federal Government, (2) were located in the identified 10-State problem area, and (3) were outside of the 10-State area but which had purchased eggs for processing from firms in the 10 States.

By December 1971 USDA had tested 641 samples of egg products from egg-processing plants in the 10-State area. Also it had tested 99 samples from all U.S. plants selling egg products to the Federal Government. A USDA official informed us that information compiled on samples taken of eggs purchased by egg-processing plants outside of the 10-State area had been combined with information on other samples of eggs from these firms and was not readily separable.

By September 7, 1971, USDA had reported that 123,750 pounds of egg products were being held because sample analyses showed they contained PCBs in excess of the FDA guideline of 0.5 p.p.m. USDA procedures provide for such contaminated egg products to be condemned and destroyed or used in feed for nonfood animals provided that they were not toxic to the animals.

USDA officials informed us that an inspector had reported sampling egg products from one production lot totaling 32,460 pounds but that only 720 pounds had actually been on hand, sampled, and held at the owners' establishments. The remaining 31,740 pounds had been distributed before USDA had issued its instructions to sample and hold all production lots of egg products. USDA officials stated they did not notify FDA about the distribution of the 31,740 pounds of egg products because the discrepancy was not discovered until 7 months after production and the product would not have been available.

A USDA official informed us that, as of May 22, 1972, final action had been taken on 84,330 of the 92,010 pounds of egg products which had been held and actually identified as containing PCBs in excess of the amount allowed by the FDA guideline and that 7,680 pounds were waiting final disposition. Of the 84,330 pounds of egg products on which final action had been taken, 16,050 pounds were released after retesting by USDA had shown the products were fit for use in foods for humans, 67,560 pounds were used for pet foods on the basis that it would not harm them, and 720 pounds were destroyed.

PCB testing program for shell eggs

FDA began investigating shell eggs for PCB contamination on August 3, 1971. By September 14, 1971, FDA had completed its investigation and had collected 232 samples of shell eggs, of which 72 samples from nine firms exceeded FDA's guideline. FDA recommended seizure action on the lots from which 13 of the 72 violative samples had been taken. Lots represented by the remaining 59 violative samples of eggs were destroyed, removed from the market, not used in the production of food for humans or feed for food-producing livestock, or were prevented from reaching marketing outlets by USDA or by the States.

FDA advised us that lots represented by 10 of the 13 samples recommended for seizure action had been seized. One of the remaining three samples was subsequently determined to have been taken from a lot which had been seized. Seizure action was not completed on the lots represented by the remaining two violative samples because the lots were distributed before the seizure action could be effected.

FDA records showed that the PCB-contaminated eggs were considered an undesirable food adulteration and not an identifiable imminent health hazard. For this reason the public was not notified after FDA found the eggs were not available for seizure.

PCB testing program for fish feed and fish

FDA's investigation showed that PCB-contaminated fishmeal was used as an ingredient in feeds for commercially raised fish. FDA seized 24,650 pounds of fish feed manufactured by one company which contained excessive amounts of PCBs. The same company also destroyed 150 pounds of fish feed and recalled approximately 650 tons of it. FDA also tested commercially raised fish from 19 fish farms which may have received contaminated fish feed. The results of the samples showed PCB levels in the fish had been below 5 p.p.m.

CONCLUSION

USDA and FDA conducted programs to test consumer products which could have been contaminated with PCBs as a result of the ECT incident. The test programs appear to have been appropriate for the ECT incident.

United States Senate

COMMITTEE ON
AGRICULTURE AND FORESTRY
WASHINGTON D C 20510

July 30, 1971

The Honorable Elmer B Staats
Comptroller General of the United States
General Accounting Office
Washington, D C 20548

Dear General

As you know, the newspapers have been full of stories about millions of tainted chickens The present crisis concerns contamination of chicken feed by a chemical called "polychlorinated biphenyl" (PCB) Apparently a feed mill which had defective machinery released some PCB in fish meal used for feeding chickens There are charges that the Food and Drug Administration has been negligent in their inspection procedures, both in terms of frequency of inspection and a failure to inspect "equipment" for soundness

As Chairman of the Senate Committee on Agriculture and Forestry, I am extremely interested in finding out the true facts in this situation Therefore, I would like for your agency to investigate the handling of this matter by the Food and Drug Administration and the USDA I understand that the Food and Drug Administration has jurisdiction over the inspection of chicken feed, while the USDA has the inspection responsibility for the slaughter of chicken and meat animals I am requesting that your agency conduct an investigation of

1 the adequacy of the Food and Drug Administration's inspection procedures,

2 the adequacy of the number of their inspectors,

3 the frequency of inspection of feed processing plants,

4 the extent to which the USDA and the FDA cooperate on inspection procedures, and the merits of having an inspection procedure which includes two agencies instead of one,

5 the way in which the two agencies acted in the current case of contaminated chickens with special attention being given to the manner and timing involved with respect to when the

chicken-producer firms and the general public were notified of the potential danger involved

I would like to have this investigation completed as soon as possible and I wish to have my staff coordinate with your staff on this matter as the investigation proceeds Please have your staff work with Mike McLeod of the Senate Agriculture Committee, on this matter

Sincerely,

Herman E Talmadge

HERMAN E TALMADGE
Chairman

DEPARTMENT OF HEALTH EDUCATION AND WELFARE
WASHINGTON D C 20201

OFFICE OF THE SECRETARY

AUG 18 1972

Mr Morton A Myers
Assistant Director
Manpower and Welfare Division
U S General Accounting Office
Washington, D C 20548

Dear Mr. Myers.

The Secretary has asked that I reply to your letter dated June 27 in which you asked for the Department's comments on a draft of your report to the Senate Committee on Agriculture and Forestry, entitled, "An Incident of Contamination of Livestock Feed and Certain Consumer Products".

The enclosed comments set forth this Department's views on your report We appreciate the opportunity to comment on this report in draft form

Sincerely yours,

James B Cardwell
Assistant Secretary, Comptroller

Enclosure

Comments of the Department of Health, Education and Welfare on a draft of a GAO report to the Committee on Agriculture and Forestry, United States Senate, entitled, "An Incident of Contamination of Livestock Feed and Certain Consumer Products" B-164031(2)

GAO Recommendation

That (USDA) and HEW establish procedures which provide for coordinating future investigations and for exchanging information needed by each agency in its respective area of responsibility

Department Comment

As recommended, the Food and Drug Administration (FDA) of this Department will explore with the U . Department of Agriculture (JSDA) the feasibility of establishing formal procedures to prevent or minimize, wherever possible, duplication of effort fo this type of investigation

While we agree that (i) FDA and USDA duplicated visits and (ii) formal procedures for coordinating such visits were lacking, we feel that some duplication of effort is unavoidable because the type of information needed and the procedures to effect corrective action differ FDA must rely on evidence collected during its investigations for enforcing the Food, Drug and Cosmetic Act Their inspectors are experienced in carrying out the precise procedures necessary to collect the evidence needed to sustain any legal action that may have been required. Our immediate concern in this particular instance was to locate the contaminated fishmeal and to determine the steps to take to remove it and other potentially contaminated products from commercial channels As pointed out in the GAO report, USDA's area of immediate concern was somewhat different.

We consider our course of action to have been appropriate for the incident in question

[See GAO note]

GAO note The remaining comments have been deleted, as they pertained to material presented in the draft report which has been revised or which has not been included in the final report

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF THE INSPECTOR GENERAL
WASHINGTON D C 20250

September 20, 1972

Mr Richard J Woods
Assistant Director
Resources & Economics
Development Division
General Accounting Office
Room 6639-South Agriculture Building
Washington, D C

Dear Mr Woods

We regret the delay in transmitting this Department's response to the draft report entitled "An Incident of Contamination of Livestock Feed and Certain Consumer Products, B-164031(2)

The attached letter signed by the Administrator, Francis J Mulhern, APHIS, and dated August 8, 1972, sets forth the Department's position.

Sincerely

L J ROTH
Assistant Inspector General
Analysis and Evaluation

Attachment

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
WASHINGTON D C 20250

AUG 8 1972

Mr Richard J Woods, Assistant Director
Resources and Economic Development Division
United States General Accounting Office
Washington, D C 20548

Dear Mr Woods

We appreciate the opportunity to review and comment on your draft report relating to an incident of PCB contamination of livestock feed and certain consumer products (B-164031(2)) We agree generally with the recommendation that the Departments of Agriculture (USDA) and Health, Education and Welfare (HEW) should establish procedures which provide for coordinating future investigations and for exchanging information needed by each Agency in its respective area of responsibility

USDA houses a number of component agencies with regulatory or investigatory responsibilities which can become involved in a coordinated effort with HEW or any of the other elements of the Federal structure These component agencies (USDA) have highly specialized functions They have developed operational modes and reporting techniques which are uniquely tailored to their needs Information as developed and reported by one Agency frequently does not meet, fully, the needs of another Incompatibility of information gathering systems becomes even more pronounced when the exchange must occur between Departments in a limited time span

This does not deny the need for developing a more effective system for exchanging information between all governmental units, but we believe the problem to be more complicated and pervasive than is generally recognized

Contacts between representatives of Animal and Plant Health Inspection Service (APHIS) and the Food and Drug Administration (FDA) have been both increased and their quality improved These contacts reflect a continuing exchange of information between the Meat and Poultry Inspection Program (MPI) residue, microbiology and laboratory staffs and representatives of FDA In addition, work contacts are being made at the regional level In a further effort to correct past deficiencies, APHIS has designated a formal contact between MPI and FDA, Dr Harry Mussman, Acting Deputy Administrator for Scientific and Technical Services We fully expect these steps to result in improved coordination of joint operations and exchange of information.

Sincerely,

F. J Mulhern
Administrator