

REPRINTED — Not to be used for other than the original
purpose for which printed, or the purpose of the original
By the Office of Engineering Research, Research, and Development
By the Distribution Section, Publications Branch, GPO

089695

~~204.06~~

77 0027

RELEASED



REPORT TO THE COMMITTEE
ON COMMERCE
UNITED STATES SENATE

27
29
9
12

BEST DOCUMENT AVAILABLE

Total Diet Study And Other Pesticide
And Residue Surveillance Programs

B-164031 (2)

Food and Drug Administration
Department of Health, Education,
and Welfare

W
164031 (2)

FILE COPY - OHSR, GFDL

BY THE COMPTROLLER GENERAL
OF THE UNITED STATES

~~204591~~
10896951

FEB. 23, 1972



COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20348

B-164031(2)

BEST DOCUMENT AVAILABLE

Dear Mr. Chairman:

Pursuant to your request on June 18, 1971, this is our report on the Food and Drug Administration's total diet study program to monitor pesticide and other residues contained in the diet of an average young adult male. The report also contains information on other pesticide and residue surveillance programs of the Food and Drug Administration.

We plan to make no further distribution of this report unless copies are specifically requested, and then we shall make distribution only after your agreement has been obtained or public announcement has been made by you concerning the contents of the report.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "James P. Braxton".

Comptroller General
of the United States

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

5 2300

C o n t e n t s

	<u>Page</u>
DIGEST	1
CHAPTER	
1 INTRODUCTION	3
2 OPERATION OF TOTAL DIET STUDY PROGRAM	5
Objectives	5
Program procedures	6
Sample analysis	10
Use made of results	11
3 OTHER PESTICIDE AND RESIDUE SURVEILLANCE PROGRAMS	15
Pesticide-monitoring program	15
Wholesale fish survey	16
Mercury in canned tuna survey	17
Mercury in swordfish survey	18
Mercury in foods survey	18
Cadmium in spinach survey	19
PCB in food and food-packaging material survey	20
APPENDIX	
I Letter dated June 18, 1971, from the Chairman, Senate Committee on Commerce	21

ABBREVIATIONS

EDRO	Executive Director for Regional Operations
FDA	Food and Drug Administration
GAO	General Accounting Office
NCA	National Canners Association
NOAA	National Oceanographic and Atmospheric Administration
PCB	Polychlorinated biphenyl
USDA	United States Department of Agriculture

- 1 Food and Drug Administration 148
2 Department of Health, Education, and Welfare 22
B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

The General Accounting Office (GAO) reviewed the Food and Drug Administration's (FDA's) total diet study program at the request of the Chairman of the Senate Committee on Commerce.

Background

The program--began in 1961--originally was intended to determine the amount of radioactivity in a sample diet. Subsequently FDA decided to analyze the sample for other contaminants, such as pesticides, and for essential dietary elements, such as vitamins. Later the analysis for radioactivity and dietary elements was ended. About 22 man-years are spent in implementing the program at a cost of \$510,000 annually.

FINDINGS AND CONCLUSIONS

What is the program's purpose?

The objective of the total diet study program is to determine the levels of pesticide and other residues in the American diet on a seasonal and geographical basis. The program is designed primarily for information gathering and does not serve as a basis for regulatory action against specific products. (See p. 5.)

How is this done?

Market baskets, each containing 117 food items, are collected six times a year by FDA inspectors in four areas of the United States. According to FDA, however, the program is not intended to be statistically valid or representative of the typical diet of the general population. For example, the collection of market baskets by the Baltimore, Maryland, District Office does not provide coverage of States that are south of Virginia. (See p. 9.)

FDA's shopping guide is based on a recommended diet for an adolescent male--usually the biggest eater in the general population. The recommended diet was derived from two publications of the Department of Agriculture--the Household Food Consumption Survey, 1965-1966, and the Family Food Plans, Revised, 1964. (See p. 6.)

According to the Department of Agriculture, however, the diet recommended for adolescent males differs from the diet they actually consume. The quantities

of food recommended exceeded the quantities of food consumed, except for meat, poultry, and fish. (See p. 9.)

How are the samples analyzed?

The market baskets collected by the FDA district offices are sent to the Kansas City, Missouri, District Office laboratory, where they are divided into 12 groups and are analyzed for pesticides, arsenic, cadmium, mercury, and polychlorinated biphenyls. (See p. 10.)

What use is made of the results?

The results of the market basket analysis are sent by the laboratory to FDA's Bureau of Foods in Washington, D.C., where they are tabulated and published annually in the Pesticides Monitoring Journal. The results also are compared with the acceptable daily intake guidelines established by the United Nations' Food and Agriculture Organization and World Health Organization. (See p. 11.)

FDA also uses the results to establish trends on the extent of pesticide and other residues in persons' food consumption. These trends determine which pesticide or other residues should receive increased monitoring by FDA. (See p. 12.)

Since September 1970 the Kansas City FDA laboratory has identified and traced abnormally high residues in eight specific products. In seven of the eight cases, the residue problem was referred to other surveillance programs or a special survey was initiated to determine the extent of the problem. In the remaining case a subsequent analysis of the product showed no residue problem. (See p. 12.)

Other surveillance programs

FDA, in addition to conducting the total diet study program, has a national pesticide-monitoring program and several special surveys to monitor residues in food. The special surveys generally are initiated on an as-needed basis and result primarily from adverse findings in the total diet study or national pesticide-monitoring programs.

Since the beginning of fiscal year 1971, FDA has established the following special surveys to regulate and monitor residues: the wholesale fish survey, mercury in canned tuna survey, mercury in swordfish survey, mercury in foods survey, cadmium in spinach survey, and polychlorinated biphenyl in food and food-packaging material survey. (See p. 15.)

CHAPTER 1

INTRODUCTION

The Food and Drug Administration, a constituent agency of the Department of Health, Education, and Welfare, is responsible for administering the Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 301), which is intended to prevent the manufacture, distribution, and sale of adulterated or misbranded foods, drugs, devices, and cosmetics through interstate commerce. The act states that any food in its raw or natural state containing pesticide residues is deemed unsafe unless (1) the pesticide chemical has been exempted from the requirement of a tolerance or (2) a tolerance has been established for the particular pesticide on the specific food and the residue does not exceed the established tolerance.

The total diet study program, administered by FDA, is designed to provide information on the levels of pesticide and other residues in the dietary intakes of persons in the United States.

FDA initiated the total diet study program in May 1961. The study originally was intended to determine the amount of radioactive substances contained in a sample diet. Subsequently FDA decided that it would be of value to analyze the sample diet for other contaminants, such as pesticide residues, and for essential dietary elements, such as certain vitamins. FDA's decision was based, in part, on a 1963 report on the use of pesticides published by the President's Science Advisory Committee, which contained a recommendation that FDA place increased emphasis on pesticides. Later the analysis for radioactivity and dietary elements was deleted from the program.

About 22 man-years are spent by FDA in implementing the total diet study program at a cost of about \$510,000 annually.

We reviewed the legislation authorizing FDA to monitor pesticides and other residues in foods and FDA's policies and procedures relating to the conduct of the total diet

study program. Our review was performed primarily at the FDA headquarters in Rockville, Maryland, and at the FDA Bureau of Foods in Washington, D.C. Visits were made to the Baltimore and Kansas City FDA District Offices for observation of the market basket collection and the sample analysis, respectively.

CHAPTER 2

OPERATION OF TOTAL DIET STUDY PROGRAM

Program guidelines are the means employed by FDA to communicate the objectives and scopes of its various programs to FDA district office employees. Guidelines contained in program FH-10, dated September 15, 1970, and issued by the Bureau of Foods, implement the total diet study program. Basically the program is designed to have five FDA district offices collect certain food items in four geographical areas of the United States for pesticide and other residue analysis by the Kansas City FDA District Office laboratory.

The Bureau of Foods is responsible for (1) writing the program, subject to the approval of the Associate Commissioner for Compliance and the Executive Director for Regional Operations (EDRO), (2) summarizing the analytical results received from the Kansas City FDA District Office laboratory, and (3) determining the methodology to be used in the program. EDRO is responsible for planning and coordinating the work of the district offices involved in the program, and the Associate Commissioner for Compliance determines the depth of the program coverage and acts as an overseer for all aspects of the program.

OBJECTIVES

The objective of the total diet study program is to determine the levels of pesticide and other residues in the American diet on a seasonal and geographical basis. The program is designed primarily for information gathering and does not serve as a basis for regulatory action against specific products. A secondary purpose of the total diet study program is to identify possible problem areas for increased monitoring. We noted that FDA had several surveillance programs for monitoring pesticide and other residues. (See p. 15.)

PROGRAM PROCEDURES

Sample collection

Under the program market baskets, each containing 117 food items, are collected six times a year by FDA inspectors in five FDA district offices in four geographical areas of the United States. The collecting districts are Boston, Massachusetts (northeastern area); Baltimore, Maryland (southeastern area); Kansas City, Missouri, and Minneapolis, Minnesota (central area); and Los Angeles, California (western area). The program guidelines instruct each collecting district to visit as many retail outlets as necessary to collect all items specified for the market basket.

The program instructions indicate that, for each market basket, each district should collect specified quantities of each of the 117 food items from one of the six population areas listed in the program. According to the instructions a different population area is to be used for each market basket collection. These areas are designated as follows:

<u>Population category</u>	<u>Actual population</u>
1	1,000,000 or more
2	500,000 to 1,000,000
3	250,000 to 500,000
4	100,000 to 250,000
5	50,000 to 100,000
6	Less than 50,000

FDA instructed the districts which did not have metropolitan areas within one of the above categories to substitute the area nearest to the desired category. In addition, each collecting district was instructed to visit a different supermarket chain or outlet for each market basket collected.

Selection of sample diet

On the basis of data contained in the U.S. Department of Agriculture (USDA) Household Food Consumption Survey and of discussions with USDA employees, FDA established a food shopping guide for collection of a market basket representing the recommended 2-week diet of an adolescent male for

each of the four regions of the country in which it is collected. A program analyst in the Bureau of Food's Office of Compliance stated that this diet had been selected because a teen-age male consumes the largest amount of food within the general population and that the diet therefore provided coverage for a greater variety of food. In this manner FDA believes that the diets of most persons receive coverage through the program.

The selected 2-week diet is based primarily on data published by the Consumer and Food Economics Research Division, Agricultural Research Service, USDA, in its 1965-66 Household Food Consumption Survey. USDA has made periodic surveys of food consumption since 1936.

The survey contains information on food consumption by approximately 15,000 households having one or more members. The households were selected scientifically to represent metropolitan areas, cities of various sizes, and rural areas in all parts of the United States except Alaska and Hawaii. The report covers four geographical areas of the country, and data was collected during each of the four seasons of the year.

Experienced interviewers collected the data in the USDA survey from members of the households, generally the homemakers. A detailed food list was used to aid the homemakers in recalling the kinds, quantities, and costs of foods used at home during the 7 days preceding the interviews as well as to obtain other household data--such as age, education, and employment--about members of the households who consumed the food.

The USDA survey states that food consumption is measured at the level at which the foods come into the kitchen and that therefore the data in the reports should be considered as economic consumption data rather than actual food consumption data. The spring portion of the survey included data on a day's food intake of persons, in addition to the regular household food consumption data.

Using the Spring 1965 Household Food Consumption Survey as a base, USDA prepared a list of food items divided into 11 homogeneous groups and listed the foods within each

group in descending order of consumption. The proportion of each item within a group to the group total was recorded for each grouping.

USDA then extracted data from USDA's Family Food Plans, Revised, 1964, to determine the weekly quantities of food which should be purchased on a moderate-cost basis for an adolescent male. The food plan for the adolescent male is based on foods that are recommended to provide a nutritionally adequate diet. The quantities listed in the plan were doubled to cover a 2-week period. The proportions obtained from the Household Food Consumption Survey were applied to the doubled quantities, which represented the 11 homogeneous food groups. USDA then converted the amounts to grams as requested by FDA.

We were advised that USDA and FDA officials had jointly determined which foods should remain on the list and had taken into consideration shifts in food use between 1955 and 1965, the two latest USDA food consumption surveys, the nature of foods increasing in use, and the practicability of adding certain foods. FDA also made revisions in the list to reflect changes in geographical locations and seasonal variations.

We were unable to obtain information from the files of FDA or USDA headquarters on the revisions that reflected changes in geographical locations and seasonal variations. Officials of both agencies advised us that they did not keep such records.

Representativeness of shopping guide

We found that FDA's shopping guide for collecting the market baskets for analysis of pesticide and other residues was based on (1) an estimate of purchases made by a moderate-income household and (2) the recommended diet for an adolescent male.

The Deputy Associate Commissioner for Compliance informed us, however, that the total diet study program was not intended to be statistically valid or representative of the typical diet of the general population.

We noted, for example, that the collection of market baskets in the southeastern sector of the United States by the Baltimore FDA District Office to monitor the amount of pesticides and other residues being consumed in the sector did not provide coverage of States that are south of the State of Virginia. An FDA inspector technician from the Baltimore District Office informed us that his office had never collected market baskets outside of the Maryland, District of Columbia, Delaware, Virginia, and West Virginia area.

Further, according to USDA, the quantities of food in the recommended diet for male adolescents differ from the quantities of food they actually consume. A USDA official provided us with the following schedule which compares actual intake, based on data collected in 1965, with the recommended diet for male adolescents from urban households of all incomes.

	Actual intake (grams)	Recommended diet (grams)
Milk and milk products (milk equivalent)	713	975
Meat, poultry, and fish	276	235
Eggs	40	44
Dry beans, peas, and nuts	32	35
Grain products	129	292
Potatoes	85	207
Citrus fruit and tomatoes	109	175
Dark green and deep yellow vegetables	15	37
Other vegetables and fruit	210	341
Fats and oils	42	73
Sugar and sweets	52	73

As shown in the schedule, variances exist between actual intake and the recommended diet. We noted, however, that the quantities of food recommended exceeded the quantities of food consumed, except for meat, poultry, and fish.

SAMPLE ANALYSIS

After the market baskets are collected, they are packed by the five FDA collecting district offices for shipment by air freight to the Kansas City FDA District Office laboratory for analysis. The collecting districts use dry ice to maintain frozen foods, meats, and dairy products. Prior to 1970 the collecting districts were responsible for analyzing their market baskets.

Upon receipt of the market baskets in Kansas City, the food is separated into (1) items to be prepared by a dietician to represent the food items as they would be served (e.g. cooked, broiled, etc.) and (2) items which do not require preparation. The Kansas City District Office has contracted with St. Mary's College near Leavenworth, Kansas, for preparation of the market baskets at a rate of \$50 a basket, or about \$1,500 annually.

The 117 food items collected in each of the market baskets are separated into the following 12 commodity groups for analyses.

<u>Composite</u> <u>group</u>	<u>Items</u>
I	Dairy products
II	Meat, fish, and poultry
III	Grain and cereal products
IV	Potatoes
V	Leafy vegetables
VI	Legume vegetables
VII	Root vegetables
VIII	Garden fruits
IX	Fruits
X	Oils, fats, and shortening
XI	Sugar and adjuncts
XII	Beverages (includes drinking water)

The food items within each composite group are combined until they form a homogeneous slurry--a uniform mixture of similar food commodities. Each composite then is measured into as many 100-gram portions as necessary for analysis, and the portions are labeled and frozen until analysis is begun.

Containers of surplus food items and composite portions are stored in case abnormally high residues are noted in any composite and follow-up analysis is necessary. The labels and code numbers of the food items, if available, are retained so that products containing abnormally high residues can be traced to either the manufacturer or the packer. The district offices' collection reports are filed to enable FDA to trace a market basket to the store where the food items were purchased.

The Kansas City laboratory uses analytical methods for detection of the following nine residue groups.

- Organochlorine residues
- Organophosphorus residues
- Polychlorinated biphenyl (PCB) residues
- Chlorophenoxy acid residues
- Carbaryl residues
- Ortho-phenylphenol residues
- Arsenic residues
- Cadmium residues
- Mercury residues

The analytical method used for the detection of the organochlorine and organophosphorous residues, commonly referred to as the multiresidue method, permits the examination of a composite for about 60 to 80 pesticide residues. The analysis, which includes both identifying and measuring the residues, is made by gas-liquid chromatography. The other residue groups are analyzed by using separate analytical methods.

USE MADE OF RESULTS

The results of the market basket analysis are sent by the Kansas City District Office laboratory to the Bureau of Foods in Washington, D.C., where they are tabulated and published annually in the Pesticides Monitoring Journal.¹ The

¹This journal is published quarterly by the Division of Pesticide Community Studies of the Environmental Protection Agency, under the auspices of the Working Group on Pesticides and its Panel on Pesticide Monitoring, as a source of information on pesticide levels relative to man and his environment. The working group and its panel comprise representatives of the Environmental Protection Agency and the Departments of Agriculture; Commerce; Defense; the Interior; Health, Education, and Welfare; State; and Transportation.

results also are compared with the acceptable daily intake guidelines established by the United Nations' Food and Agriculture Organization and World Health Organization.

A program analyst in the Bureau of Food's Office of Compliance stated that the results were used to establish trends on the extent of pesticide and other residues in persons' food consumption. He informed us that such trends were used to determine which pesticide or other residues should receive increased monitoring through FDA's nationwide pesticide-monitoring program or through a special survey program. (See p. 15.)

Follow-up action on high residues

Total diet study program instructions dated September 1970 state that follow-up analysis of individual food commodities should be made when abnormally high residues are noted in any composite. Prior to this date follow-up analysis was not required under the program.

Follow-up analysis is intended to identify individual food commodities which warrant increased monitoring by FDA because they contain excessive pesticide or other residues. When such problem areas are detected, FDA generally initiates on a larger scale a special survey to determine the extent of the residue problem.

Our review showed that from September 1970 the Kansas City FDA laboratory identified eight commodities in which the residue levels warranted additional follow-up action.

The following schedule summarizes data on each of the commodities.

<u>Residue and commodity</u>	<u>Parts per million (p.p.m.) detected</u>	<u>Date collected</u>	<u>Collecting district office</u>
Mercury in halibut	0.50 to 0.56	12-70	Kansas City
" " canned tuna	.83 to .90	1-71	Boston
Cadmium " spinach	1.48	1-71	Minneapolis
Mercury " canned bonita	.72 to .90	1-71	"
" " red snapper	1.52	5-71	Los Angeles
" " canned tuna	.56 to .62	5-71	Minneapolis
PCB in shredded wheat	25.0 ^a	5-71	Boston
Mercury in carrots	.08 to .35	8-71	Kansas City

^aApproximate.

Our review showed that, for seven of the eight commodities, the residue problem had been referred to other surveillance programs or a special survey had been initiated to determine the extent of the problem.

In two of the eight cases--cadmium in spinach and PCB in shredded wheat--we found that FDA had conducted follow-up investigations; however, no seizure or recall actions to remove these products from the market had been taken because, according to FDA, it did not have sufficient knowledge on the health hazards related to the residues to warrant such action. Both of these cases also were referred to the Bureau of Foods for consideration in special surveys, and in both cases special surveys were initiated. (See pp. 19 and 20.)

In another case--mercury in carrots--FDA collected a sample of the same brand of carrots and found no mercury residue.

In five of the eight cases, the residue levels detected exceeded FDA's guideline limiting the amount of residue permitted in food. According to the FDA guideline, the five cases all involve mercury in different species of fish, which cannot exceed 0.5 p.p.m.

We found that in two of the five cases--mercury in halibut and mercury in red snapper--FDA attempted to collect samples of the products. In the first case FDA determined the warehouse from which the halibut had been purchased by the retailer; however, the remainder of the lot already had been distributed when FDA attempted to take samples at the warehouse. In the second case FDA could not determine the source of the fish. Both of these cases were referred to the Bureau of Foods and were included in a special survey. (See p. 16.)

In three of the five cases--two involving mercury in canned tuna and another involving mercury in canned bonita--we found that the Bureau of Foods had been notified of the problem because they had information on code distribution and import code sampling and analysis. As in the other instances, these three cases were included in special surveys. (See p. 17.)

For the canned tuna and bonito cases, however, representatives of the Offices of the Associate Commissioner for Compliance, EDRO, the Bureau of Foods, and the Kansas City District Office laboratory were unable to provide us with information as to what action, if any, had been taken by FDA to trace the specific products involving mercury in tuna and mercury in bonito to the manufacturers or shippers of the products.

CHAPTER 3

OTHER PESTICIDE AND RESIDUE SURVEILLANCE PROGRAMS

FDA has a national pesticide-monitoring program and several special surveys, in addition to the total diet study program, to monitor residues in food. The special surveys generally are initiated on an as-needed basis and result primarily from adverse findings in the total diet study program or in the national pesticide-monitoring program. Since the beginning of fiscal year 1971, FDA has established the following special surveys to regulate and monitor residues: the wholesale fish survey; mercury in canned tuna survey; mercury in swordfish survey; mercury in foods survey; cadmium in spinach survey; and PCB in food and food-packaging material survey.

PESTICIDE-MONITORING PROGRAM

The Deputy Associate Commissioner for Compliance informed us that the pesticide-monitoring program was the primary regulatory program for pesticide surveillance. This program is conducted on a continuing basis at all 17 FDA district offices, and samples of food commodities are collected at the grower or shipper level to provide for effective regulatory follow-up action when necessary.

The objectives of the pesticide-monitoring program are to:

1. Determine the pesticide residue levels of individual food commodities on a geographical basis through the use of gathered intelligence on pesticide use and misuse and through a statistically based sampling plan.
2. Survey certain food commodities of interest on a nationwide basis to obtain a broad overview of the pesticide residue levels in these commodities.
3. Provide coverage of the pesticide residue problem at a sampling level where the compliance follow-up may be instituted most effectively.

According to FDA 8,769 samples--comprising 6,717 domestic and 2,052 import samples--were analyzed in this program during fiscal year 1971. The Deputy Associate Commissioner for Compliance informed us that about 12,000 samples were planned for collection and analysis in fiscal year 1972.

WHOLESALE FISH SURVEY

In January 1971 FDA initiated the wholesale fish survey to:

1. Determine the current status of mercury contamination of the leading commercial fish species in the United States.
2. Institute appropriate compliance action where mercury residues were at guideline levels or higher.

Program instructions stated that five samples of each of the following types of fish and shellfish were to be collected.

Bonita	Whitefish	Crabs
Halibut ¹	Cod	Lobster
Flounder	Haddock	Trout
Ocean perch	Scallops	Hake
Snapper (Pacific or red) ¹	Mackerel	Sardines
Salmon (Pacific)	Oysters	Herring
	Clams	

All FDA district offices collected samples at the wholesale level, such as supermarket distribution warehouses, public storage warehouses, and wholesale fish dealers. Each district office was responsible for analyzing the samples.

¹ Halibut was added to the wholesale fish survey as a result of a finding of mercury at a level of 0.50 to 0.56 p.p.m. in the total diet study program. Red snapper in which mercury was detected in the total diet study program at a level of 1.52 p.p.m. already was included in the wholesale fish survey.

The program instructed the district offices to submit, for seizure consideration, information on all lots where analysis showed the samples to contain mercury levels of 0.5 p.p.m. or higher. The program was terminated in July 1971. In October 1971 the Director of the Bureau of Food's Office of Compliance stated that no seizures had been made as a result of the program.

MERCURY IN CANNED TUNA SURVEY

This survey, implemented in December 1970, was to provide nationwide coverage of imported and domestically packed tuna on a priority basis. The survey was conducted by FDA in cooperation with the National Cannery Association (NCA) and the Department of Commerce's National Oceanographic and Atmospheric Administration (NOAA).

NCA was given prime responsibility for analyzing for mercury residues all lots of domestically packed tuna on the market and all raw tuna to be canned. The survey instructions stated that NCA would arrange for voluntary removal of all lots from the market that were found at or above the 0.5-p.p.m. guideline.

NOAA was charged with conducting studies to determine various parameters of the mercury residue problem and to attempt to identify the source of the problem. NOAA was charged also with analyzing various other fish and fish products to determine whether the problem involved species of fish other than tuna.

FDA's responsibility, in addition to monitoring the program, was to analyze all imported canned tuna on the market as well as raw tuna which was being offered for entry into the country.

As of December 1971 FDA still was evaluating data from this program.

MERCURY IN SWORDFISH SURVEY

The purpose of this survey, which began in January 1971, was to provide coverage of imported and domestically caught swordfish for contamination with mercury. The survey guidelines instructed the district offices to sample and analyze all lots of imported swordfish, in any form, that were offered for entry at ports within their districts. In addition, in districts where domestic fresh swordfish was being harvested, samples were to be collected and analyzed.

The survey guidelines stated that, if imported swordfish was found at mercury levels of 0.5 p.p.m. or higher, entry into the country should be denied. If domestic swordfish was detected at the level of 0.5 p.p.m. of mercury or higher, the FDA districts were to request the cooperation of local and State officials to curtail the distribution of the fish by placing a local embargo.

According to the Deputy Associate Commissioner for Compliance, FDA terminated this program in February 1971 because FDA had sampled a large portion of swordfish on the market and had found excessive mercury residue levels which resulted in the voluntary recall of most marketed swordfish and in the virtual elimination of the swordfish market.

MERCURY IN FOODS SURVEY

As a result of data accumulated by FDA and other Government agencies on mercury in fish, FDA, to determine whether there were other foods that contribute significant amounts of mercury to the diet, initiated a mercury in foods survey in October 1970.

A program was established calling for a survey of 10 selected food commodities to determine whether a problem existed with mercury contamination.

Each FDA district office was instructed to collect two samples of the 10 selected commodities and to send the samples to a designated district laboratory for analysis. Each sample collected was to be from a different manufacturer.

The 10 selected commodities were:

Wheat flour	Chicken breasts
Nonfat dry milk	Shrimp
Cane sugar	Beef liver
Potatoes	Shell eggs
Raw ground beef	Fluid whole milk

As of December 1971 data obtained from the program was being evaluated by FDA.

CADMIUM IN SPINACH SURVEY

In March 1971 the FDA Kansas City District Office laboratory, in analyzing market baskets collected in the total diet study, detected cadmium at a level of 1.48 p.p.m. in canned spinach. Follow-up action on the product, which was traced to a company in the San Francisco, California, area, found spinach from one grower at a level of 1 p.p.m. An FDA toxicologist considered this level of cadmium to be high and recommended that additional follow-up action be taken.

In May 1971, as a result of the recommendation, FDA implemented the cadmium in spinach survey by instructing each FDA district office to collect two samples each of canned and frozen spinach. The samples were to be collected at the wholesale level, and preference was to be given to spinach packed in the collecting district or packed under labels of distributors in the collecting district.

Samples collected were analyzed by the Kansas City District Office laboratory, and the range of cadmium detected was zero to 0.8 p.p.m. In addition, the San Francisco District Office investigations uncovered no evidence of application of cadmium compounds or cadmium in irrigating waters.

In July 1971 FDA concluded, as a result of the survey, that naturally occurring cadmium in soil might be the source of cadmium in spinach.

PCB IN FOOD AND FOOD-PACKAGING
MATERIAL SURVEY

In June 1971 PCB was detected by the Kansas City District Office laboratory at a level of 24 p.p.m. in shredded wheat biscuits and of 497 p.p.m. in the package's cardboard dividers. Follow-up by the FDA Cincinnati District Office revealed high residues of PCB in paperboard manufactured by a company in Ohio which supplied paperboard to a number of container manufacturers and food firms. These results provided the background for the nationwide survey of PCB in food and food-packaging material. Guidelines for this program were issued by FDA's Bureau of Foods on September 14, 1971, and, as of December 1971, the program was still in process.

BEST DOCUMENT AVAILABLE

WARREN G. MAGNUSON, WASH., CHAIRMAN
 JOHN O. PASTORE, R.I.
 VANCE HARTKE, IND.
 PHILIP A. HART, MICH.
 HOWARD W. CANNON, NEV.
 RUSSELL B. LONG, LA.
 FRANK E. MOSS, UTAH
 ERNEST F. HOLLINGS, S.C.
 DANIEL K. INOUE, HAWAII
 WILLIAM B. SPONG, JR., VA.

NORRIS COTTON, N.H.
 WINSTON PROUTY, VT.
 JAMES B. PEARSON, KANS.
 ROBERT F. GRIFFIN, MICH.
 HOWARD H. BAKER, JR., TENN.
 MARLOW W. COOK, KY.
 MARK O. HATFIELD, OREG.
 TED STEVENS, ALASKA

United States Senate

COMMITTEE ON COMMERCE

WASHINGTON, D.C. 20510

FREDERICK J. LORDAN, STAFF DIRECTOR
 MICHAEL PERTSCHUK, CHIEF COUNSEL

June 13, 1971

The Honorable Elmer B. Staats
 Comptroller General
 General Accounting Office
 Washington, D.C.

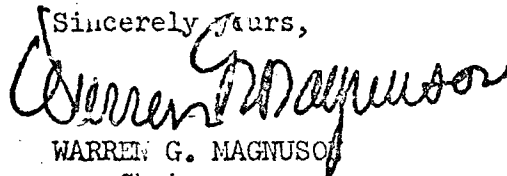
Dear Mr. Comptroller General:

The Senate Commerce Committee is interested in obtaining information on the Food and Drug Administration's total diet study program to monitor pesticide and other residues contained in the diet of an average young adult male. The program involves the testing of certain food commodities purchased by the agency at the retail level.

Specifically, the Committee would appreciate the General Accounting Office supplying it with data relating to the (1) objectives of the program; (2) procedures which the agency employs to accomplish the objectives; (3) information obtained from the program and, to the extent possible, its validity; and (4) use made of the information obtained.

I would appreciate receiving your report on the total diet study program at your earliest convenience.

Sincerely yours,



WARREN G. MAGNUSON
 Chairman

WGM:ltd