

## DOCUMENT RESUME

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Report to Donald Kennedy, Commissioner, Food and Drug Administration; by Albert B. Jojokian, Assistant Director, Human Resources Div.

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A survey of Federal responsibilities for insuring safe and pure fish products assessed: (1) whether actual or potential chemical contamination of fish products warranted a special testing program; and (2) the potential for coordinating Federal and State food inspection efforts. The survey disclosed a need for systematic, comprehensive testing of fish due to the widespread occurrence of toxic chemicals and suspected carcinogens in fish, discovery of concentrated chemical contamination in particular geographic areas, and potential for future chemical contamination problems. The Food and Drug Administration (FDA) plans to implement a special chemical contamination program for fish in fiscal year 1978. The program will contain elements necessary for assessing the health hazards of chemical contamination and should be aggressively monitored to assure timely and effective implementation. There is a potential for maximizing inspection resources by coordinating Federal and State food plant inspections to avoid having FDA and State inspectors at a plant within the same time period. The Commissioner of the FDA should emphasize close coordination with States to maximize resources. (RRS)

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Room 103

Group 3 Report



UNITED STATES GENERAL ACCOUNTING OFFICE

WASHINGTON, D.C. 20548

HUMAN RESOURCES DIVISION

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NOV 3 1977

The Honorable Donald Kennedy  
 Commissioner, Food and Drug  
 Administration  
 Department of Health, Education,  
 and Welfare

File Room 6864  
 code 10876

Dear Dr. Kennedy:

We recently completed a survey of Federal responsibilities for insuring safe and pure fish (excluding shellfish) products. The work included assessing (1) whether actual or potential chemical contamination of fish products warranted a special testing program, and (2) the potential for coordinating Federal and State food inspection efforts.

The work was done at Food and Drug Administration (FDA) headquarters and within the geographic area of FDA's Boston and Baltimore district offices. We also visited the National Marine Fisheries Service in Washington, D.C., and contacted State officials in Virginia, North Carolina, and Mississippi.

The survey disclosed a need for systematic, comprehensive testing of fish due to the

- widespread occurrence of toxic chemicals and suspected carcinogens in fish,
- discovery of concentrated chemical contamination in particular geographic areas, and
- potential for future chemical contamination problems.

We also noted that the opportunity exists for maximizing inspection resources by closer coordination of Federal and State food plant inspections.

CHEMICAL CONTAMINATION

In recent years, chemical contamination of fish and fish products has become an issue of national concern. The environmental impact of chlorinated pesticides, polychlorinated biphenyls (PCBs), and methylmercury in fish

harvesting waters has been frequently publicized. Metals such as cadmium, lead, arsenic, selenium and zinc may also pose harmful threats to the aquatic environment. In many instances, Federal and State programs have provided little foreknowledge as to the severity of chemical contamination problems. However, once these problems were identified, extreme actions, such as prohibiting commercial fishing, often have been required to protect the consumer.

Lake and river bottoms, deltas and ocean banks are prime areas for contaminant concentration. Fish are known to accumulate a contaminant in a higher concentration than the level of the contaminant in their environment. Consequently, fish caught in contaminated areas may present harmful threats to the consuming public. In addition, fish caught outside these prime contamination areas have been found to contain potentially harmful chemicals. For example, several species such as tuna, marlin, and swordfish caught from such diverse areas as the Gulf of Mexico, North and South Atlantic, and the Pacific Northwest have been reported to contain excessive mercury levels.

Environmental contamination has resulted in restricting the use of chlorinated pesticides such as DDT and dieldrin and phasing PCBs out of industrial applications. Even though industries and municipalities are attempting to control industrial waste, the water environment may still contain chemical contaminants. For example, agricultural runoff containing potentially harmful pesticides or naturally occurring contaminants is likely to continue.

Furthermore, limiting the use of chemicals does not reduce their occurrence in fish because some chemicals that have accumulated over the years persist in the water environment. For example, the use of DDT has been drastically limited since the early 1970's. However, FDA general surveillance programs have shown an increasing occurrence of DDT in food products in recent years. Specifically, FDA's draft fiscal year 1974 Pesticides in Foods Program (the most current assessment available during our survey) shows that the relative frequency of DDT, DDT-related chemicals, dieldrin and other such chemical residues in domestic fish increased during fiscal year 1974 when compared to the 1963-1969 period.

Although yearly results cannot be directly compared because of differences in species sampled and locations, a comparison of fiscal year 1974 data for all food commodity classes tested shows that occurrences of pesticide residues

in fish were highest for domestic samples and second highest for imported samples. Overall, during fiscal year 1974 about 80 percent of the domestic and imported fish samples contained pesticide residues and about 65 percent of these fish samples contained multiple pesticide residues.

In addition to widespread occurrences of chemical residues in fish, there are geographically isolated problems. Therefore, we believe there is a need to systematically identify the threat of chemical contamination. Specifically, while determining the national status of chemical contamination, we believe there is an equally important need to collect information at the FDA district level in order to appropriately address regional problems. Such sources of information could be

- input from other Government agencies having knowledge of chemical contamination problems,
- field staff awareness of problems through personal observations and news media coverage of conditions in their geographic areas of responsibility, and
- testing programs designed to identify problems.

FDA has been active in analyzing fish for certain chemical contaminants. In recent years, however, coverage has often taken the form of limited surveys designed to determine the presence of individual contaminants or single classes of contaminants. Past programs either had to be terminated due to higher priority work or have not specifically addressed chemical contamination in fish on a regional basis.

The problems associated with toxic and suspected carcinogenic PCBs illustrate the need for national and regionalized FDA surveillance and intelligence gathering. Industrial applications of PCBs steadily increased from about 1930 to 1970 resulting in persistent and widespread environmental contamination. Subsequently, various regulatory actions were taken and, with the cooperation of the only U.S. producer, the situation was believed to be under control.

By early 1970, FDA's analytical methods for detecting PCBs had become routine and action levels for PCBs in milk, poultry, and fish had been established. However, in 1975, high levels of PCB contamination in fish taken from the Hudson River refocused national attention on the contamination and resulted in stringent curtailing of discharges of

PCBs into the river. We believe a systematic testing program emphasizing regional problems could have identified the severity of the localized as well as national PCB contamination before 1975.

Other problems with regionalized chemical contamination have demonstrated the need for FDA districts to be aware of possible misuses and discharges of pesticides and industrial chemicals in their area. For example, the toxic and suspected carcinogen kepone was manufactured and discharged into the James River for about a year and a half before FDA was told of possible fish contamination. Although FDA's testing programs were not intended to identify kepone, additional FDA emphasis on identifying potential regional problems may have resulted in FDA knowledge of the problem sooner. Subsequent testing disclosed widespread contamination and resulted in the Governor of Virginia closing the river to commercial fishing. The water and sediment contamination persists and there is no indication as to when the river will be reopened for all types of fishing.

In June 1977, the Governor of Virginia banned fishing for human consumption along a 160-mile stretch of three rivers in the Shenandoah Valley because of mercury contamination. The mercury contamination (fish samples showed mercury levels up to four times the safety level) was brought to the State's attention by industry representatives of a company that has not used mercury in its plant operations since 1950. We believe that ongoing regionalized FDA testing geared to identifying potential problems may have uncovered this problem at an earlier date.

Other States have closed fishing waters because of chemical contamination. In addition to the Hudson River in New York, portions of the Housatonic in Connecticut have been closed due to PCB contamination. Further, the Coosa River in Georgia and the area of Lake Hartwell in South Carolina have reportedly been closed because of chemical contamination. There are also fish taken from the Great Lakes surrounding Michigan that cannot be eaten because of chemical contamination.

We understand that FDA plans to implement a special chemical contamination program for fish in fiscal year 1978. The program contains elements that we believe necessary for assessing the health hazards of chemical contamination. For example the program

- is designed to detect emerging problems or potential new sources of contamination in fish,
- allows for attack on geographically isolated problems while determining the national status of chemical contamination in fish,
- allows for redirection of effort to confront newly identified chemical contamination problems,
- considers the commercial significance of various species and past problems such as mercury in several species, and
- provides for coordinating with States and Federal agencies (i.e., the Environmental Protection Agency, the National Marine Fisheries Service, the U.S. Fish and Wildlife Service) that may provide information concerning commercial fishing, pesticide usage, and sites for sampling.

We believe the program should be aggressively monitored to assure timely and effective implementation and coordination. If effectively implemented, the program should provide a better information base for identifying trends on the extent of chemical contamination and the need for additional efforts to assure that safe, pure and wholesome fish is available to consumers.

POTENTIAL FOR COORDINATING  
FEDERAL AND STATE FOOD  
INSPECTION EFFORTS

State food and drug laws are patterned in varying degrees after Federal food and drug laws. As of April 1977, 43 States had enacted food provisions of the Uniform State Food, Drug, and Cosmetic Bill of the Association of Food and Drug Officials which parallels the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301). Among other things, the uniform bill provides for State inspection of food plants.

We believe there is potential for maximizing inspection resources by coordinating Federal and State food plant inspections to avoid having FDA and State inspectors at a plant within the same period of time. In fact, FDA is currently coordinating inspections with officials in Virginia. FDA officials told us they meet monthly with officials of the Virginia Department of Agriculture and Commerce to jointly schedule food (including fish) plant

inspections. By jointly scheduling inspections, both Virginia and FDA officials said they maximize inspection resources because they prevent duplicate inspections.

We did not assess the extent FDA coordinates inspections with all States. However, State officials in North Carolina and Mississippi told us that food plant inspections were not being jointly scheduled with FDA. Officials in both States told us that duplicative or overlapping FDA and State food plant inspections occur.

Although we recognize that States must be willing to cooperate with FDA before close coordination can be achieved, we believe emphasis on coordination at your level could stimulate development of working relationships like those in Virginia. Accordingly, we recommend that you emphasize close coordination with States in the interest of maximizing resources.

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We plan no further reporting on the results of our survey work. We appreciate the cooperation and courtesy extended to us by FDA personnel during our survey and we would appreciate being advised of your views with regard to the matters discussed in this report.

Sincerely yours,



Albert B. Jojokian  
Assistant Director