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PANEL ON REVIEW OF BACTERIAL VACCINES AND TOXOIDS

Meeting Change

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announced in a notice published in the FEDERAL REGISTER of February 23, 1976 (41 FR 7973), public advisory committee meetings and other required information in accordance with provisions set forth in section 10(a) (1) and (2) of the act.

Notice is hereby given that the meeting of the Panel on Review of Bacterial Vaccines and Toxoids, scheduled for March 28 and 29, 1976, has been rescheduled to meet on March 27 and 28, 1976, with the open session beginning March 27 at 1:30 p.m.

Dated: February 19, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

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Food and Drug Administration

[Docket No. 76N-0048]

POLYCHLORINATED BIPHENYLS (PCB's) IN CERTAIN FRESHWATER FISH

Statement of Policy

The Food and Drug Administration is stating its policy in regard to the contamination of freshwater fish with polychlorinated biphenyls (PCB's).

Although PCB's may not intentionally be added to food in any quantity, they are, at times, unavoidably present in certain foods as a result of environmental contamination. The Commissioner of Food and Drugs promulgated a regulation under § 122.10(a) (21 CFR 122.10 (a)) in the FEDERAL REGISTER of July 6, 1973 (38 FR 18096) that established limits on the amount of PCB's that may lawfully be present in food as the result of such contamination. Among other things, the regulation set a temporary tolerance for fish of 5 parts per million (ppm) PCB's. Since the July 1973 temporary tolerances were established, additional toxicological data on PCB's have become available. These recently developed data have raised concern that PCB's may be more toxic than previously thought. The need to lower the temporary tolerances in light of these data, particularly the tolerance for fish, is under active consideration. Contemporaneously, sampling programs conducted by Federal and State authorities reveal that PCB's continue to be a significant contaminant of some species of freshwater fish taken from certain rivers and lakes in the United States.

The Commissioner believes that the present situation warrants a statement of the policy of FDA regarding the problem of PCB contamination of freshwater fish and the steps FDA has taken, or may initiate, to deal with the problem. Furthermore, the New York State Department of Environmental Conservation has requested guidance from FDA as to what action, if any, is necessary at this time to protect the public health in light of the recurrence of PCB levels in excess of the 5 ppm temporary tolerance in fish taken from certain waters in New York State. This notice responds to the request from the New York State authorities for guidance and discusses the PCB-in-fish problem generally.

BACKGROUND

PCB's are a class of toxic industrial chemicals that are highly stable, heat resistant, and nonflammable. Prior to 1971, PCB's were used in a variety of applications, primarily because of their excellent chemical and thermal stability. It has been estimated that approximately 40 percent of the PCB's used in the United States prior to 1971 went into applications that resulted in loss into the environment. These applications included use as plasticizers, pesticide extenders, microencapsulation of dyes for carbonless copy paper, and as components of hydraulic fluids and lubricants, surface coatings, inks, sealants, and adhesives. The bulk of the remaining 60 percent use of PCB's was in electrical transformers and capacitors (Ref. 1).

By late 1971, it was apparent that the unique physical and chemical properties of PCB's and their widespread, uncontrolled industrial application had led to their becoming a persistent and ubiquitous environmental contaminant. In 1971, the Monsanto Corp., the sole United States producer of PCB's, restricted sales for use only in closed-system electrical application, e.g., transformers and capacitors. PCB use in the United States today is principally limited to such closed systems, which minimizes but does not eliminate the loss of PCB's into the environment (Ref. 2).

One consequence of the contamination of the environment with PCB's was the indirect contamination of certain foods, principally those of animal origin. Although only limited information on the toxicity of PCB's was available in late 1971 to 1972, there were sufficient data for the Commissioner to conclude that PCB's were a poisonous or deleterious substance, and that their presence in food posed a potentially serious health hazard. As a first step to limit human exposure to PCB's from dietary sources, FDA issued a notice of proposed rule making in the FEDERAL REGISTER of March 18, 1972 (37 FR 5705), indicating the agency's intentions under section 406 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346) to restrict the level of PCB's that could lawfully be present in food. Temporary tolerances for PCB's in fish, milk, dairy products, eggs, poultry, animal feed and feed ingredients, and infant and junior foods became effective in the final regulation of July 6, 1973. These tolerances are listed in § 122.10(a). An action level is also in effect for PCB's in paper food-packaging materials.

In setting the temporary tolerances for PCB's, the Commissioner took into account the extent to which a limit on PCB consumption was necessary for the protection of the public health, other ways in which the consumer might be exposed to PCB's or other poisonous or deleterious substances, and the extent to which PCB contamination of food cannot be avoided. Numerous safety factors were used to assure that the temporary tolerances provided an adequate safety margin for the consumer as long as exposure to PCB's was sporadic and diminished with the passage of time.

Surveillance data gathered by FDA and the U.S. Department of Agriculture subsequent to the effective date of the temporary tolerances (Ref. 3) have shown that, with the exception of certain freshwater fish, the presence of PCB's in those individual foods subject to the tolerances continues to be sporadic, and that there has been an overall and substantial decline in frequency and levels. These data further show that the average daily dietary intake of PCB's is quite low and well within the margin of safety.

PCB CONTAMINATION OF FISH

The Commissioner stresses that most fish intended for human consumption come from salt waters. Sampling programs of FDA reveal that these fish are largely uncontaminated with PCB's (Ref. 3). Fish collected from commercial establishments contained an average of less than 0.2 ppm PCB's, substantially below levels that would pose a risk to health. However, considerably higher levels of PCB's are being detected in various species of freshwater fish—particularly sportfish, e.g., coho and chinook salmon, lake trout—from several areas in the United States. FDA is currently developing information to determine the exact extent of the problem.

The jurisdiction of FDA extends only to food in interstate commerce. For this reason, the agency cannot control directly sportfishing or the consumption of PCB-contaminated fish, unless such fish are being sold or shipped in interstate commerce. Nonetheless, the Commissioner is concerned about the public health implications for sportfishermen and others who may regularly consume fish that are caught from PCB-contaminated waters.

PCB CONTAMINATION OF FISH IN CERTAIN NEW YORK STATE WATERS

On October 9, 1975, the New York Department of Environmental Conservation formally sought the support of FDA with respect to specific actions it contemplated to limit the consumption of PCB-contaminated fish. This request by the Department was based on its finding that various fish species caught in the Hudson River and two species of salmon caught in Lake Ontario contained levels of PCB's well in excess of the FDA tolerance of 5 ppm. Specifically, the New York Department of Environmental Conservation was considering the following actions:

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1. Banning all commercial fishing in the Hudson River;

2. Advising the public not to consume fish from the Hudson River and salmon from Lake Ontario; and

3. Seizing any Hudson River fish in intrastate commerce that contain PCB's in excess of the 5 ppm temporary tolerance.

On October 20, 1975, the New York Department of Environmental Conservation was informed that FDA would initiate seizure of interstate shipments of fish found to exceed the temporary tolerance and would support the State in taking similar action against intrastate shipments. The State was also advised that FDA would need to evaluate fully the results of surveys of fish taken from the Hudson River and Lake Ontario before it could determine the appropriateness of the other suggested actions. At that time, surveys were still being conducted by the State and by FDA. Subsequently, data from these surveys were submitted and have been evaluated by FDA (Ref. 4).

The samples from the Hudson River included 17 species of fish collected from 12 points on the Hudson River between Glens Falls and Alpine, with 13 samples being collected at Glens Falls and 68 samples below Glens Falls. In summary, this evaluation showed that 53 out of the 68 samples of fish collected at or below Fort Edward (approximately 7 miles below Glens Falls) contained PCB's in excess of 5 ppm. The average level of PCB contamination in these 68 samples was 21.3 ppm. In contrast, only trace levels were found in the 13 samples obtained at Glens Falls. A high proportion of finfish and eels from all sampling points below Glens Falls contained PCB levels in excess of 5 ppm. The Fort Edward sampling point had the highest levels for the species examined, with individual samples ranging from 20.1 to 178 ppm.

Twenty-eight of the 32 samples of coho and chinook salmon from Lake Ontario exceeded 5 ppm, with a range from 2.1 ppm to 24.6 ppm. Of the 4 samples of lake trout tested, results were in the range of 10 to 15 ppm. All other species of fish sampled from Lake Ontario were at 5 ppm or less PCB's.

As a result of these findings, the Commissioner has concluded that fish caught in the Hudson River south of Fort Edward are likely to contain excessive levels of PCB's. Similarly, coho and chinook salmon caught in Lake Ontario are likely to contain excessive levels of PCB's. Since there are no data on current levels of PCB's in shad caught in the Hudson River, FDA is unable to make any conclusions about PCB contamination of that fish at this time. However, data obtained by the State of New York for past years, while limited, indicate that shad may contain relatively low levels of PCB's. There are insufficient samples to make any valid conclusions about lake trout caught in Lake Ontario at this time.

The scientific evidence described in the preamble to the July 6, 1973 FDA final regulations on PCB's and in more recent statements by agency officials (Refs. 5 and 6) supports the conclusion that frequent consumption of fish containing PCB's above 5 ppm poses a risk to public health. Therefore, on February 11, 1976 the Commissioner advised the State of New York that FDA fully supports the remaining proposals of the Department of Environmental Conservation. Specifically, the Commissioner concurs with the State of New York in its proposals to:

1. Ban commercial fishing, except for shad, from the Hudson River at or south of Fort Edward.

2. Advise sportsfishermen and other persons not affected by the ban to restrict their intake of fish caught from these waters and to restrict their intake of salmon caught from Lake Ontario.

When implemented, these actions will effectively eliminate the possibility that commercial fish contaminated with PCB's will enter interstate or intrastate commerce from these waters. An advisory to sportsfishermen and others who consume fish caught from these waters is essential to alert them to the potential hazard of consuming such fish, and is necessary since a ban on commercial fishing does not directly protect such individuals. Should additional regulatory actions become necessary in the future, FDA will promptly take all appropriate steps, consistent with its statutory authority, to protect the public from PCB-contaminated fish. Additionally, the State of New York plans to monitor closely the 1976 spring run of shad to determine what additional action may be required for this species of Hudson River fish.

The presence of significant levels of PCB's in freshwater fish is caused by the continued industrial discharge and disposal of PCB's into the environment. The Commissioner emphasizes that the contamination of fish with PCB's will persist unless controls are initiated to curtail pollution of the environment with PCB's. The Commissioner has, therefore, assured the Environmental Protection Agency (EPA) that the full scientific resources of FDA continue to be available to assist in that agency's efforts to control PCB discharges. Similarly, FDA has provided, and will continue to provide, the full range of its scientific expertise in support of individual State actions aimed at controlling industrial pollution of the environment with PCB's (Refs. 5 and 6).

Status of Temporary Tolerances for PCB's in Food

The preamble to the regulations on PCB's in the July 6, 1973 Federal Register states that FDA will periodically review and evaluate the appropriateness of the temporary tolerances for PCB's. On November 21, 1975, it was announced (Ref. 7) at the National Conference on PCB's sponsored by EPA that FDA had initiated such a review. The scope of this review includes an in-depth evaluation of recent scientific reports on various aspects of the toxicity of PCB's. These reports were formally presented at the National Conference on PCB's (Ref. 8). The purpose of the FDA evaluation will be to determine if the information contained in these reports indicates that a reassessment of the temporary tolerances is warranted. As part of its current activity, the agency is also gathering and reviewing data from different sources on the extent to which PCB's occur in fish and other foods. This information is necessary since section 406 of the act requires assessment of the impact on both human health and the food supply that would result from any lowering of the current temporary tolerances.

Additionally, on November 21, 1975 the Environmental Defense Fund and the National Resources Defense Council petitioned FDA to reduce gradually all PCB temporary tolerances for PCB's in fish to zero. This petition and supporting information will be given full consideration and are included in the current review activities of the agency.

If, on the basis of these reviews, lowering any of the temporary tolerances is warranted, the Commissioner will issue a proposal to amend the existing PCB regulations in the Federal Register, and allow time for public comment prior to implementing any revision.

References

A copy of each reference document on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, and may be seen during working hours, Monday through Friday.

1. World Health Organization, International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man," Vol. 7, 1973.

2. Statement by Russell E. Train, Administrator, Environmental Protection Agency, at Press Conference on PCB's, Monday, December 22, 1975, Washington, DC.

3. "Levels of PCB's in the U.S. Food Supply," C. F. Jelinek and F. E. Cornelissen, Bureau of Foods, Food and Drug Administration, November 20, 1975.

4. "Polychlorinated Biphenyls Residues in Fish from Lake Ontario and the Hudson River," Bureau of Foods, Food and Drug Administration, December 17, 1975.

5. Testimony of Albert C. Kolbye, Bureau of Foods, Food and Drug Administration, before the Department of Environmental Conservation, State of New York, October 7, 1975.

6. Testimony of Henry Roberts, Minneapolis District Office, Food and Drug Administration, before the Department of Natural Resources, State of Wisconsin, August 8, 1975.

7. "FDA Regulation of PCB's in Food," John R. Wessel, Office of the Assistant Commissioner for Compliance, Food and Drug Administration, November 21, 1975.

8. "Health Effects and Human Exposure," Session I of the National Conference on PCB's, November 19 through 21, 1975, Chicago, Illinois.

Dated: February 12, 1976.

A. M. Schmidt,
Commissioner of Food and Drugs.

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