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The Commonwealth of Massachusetts
Executive Office of Human Services
Department of Public Health

Bailus Walker, Jr., Ph.D., M.P.H.
 Commissioner

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Center for Health Promotion and
 Environmental Disease Prevention

MEMORANDUM

TO: Commissioner Walker and Members of the Public Health Council

THRU: Gerald S. Parker, P.E.
 Assistant Commissioner

FROM: Nancy Ridley, M.S., Director
 Division of Food and Drugs

RE: Request for Authorization to Proceed to Public Hearing on Regulations to Enact an Action Level of Two Parts Per Million for PCBs in Fish Products

DATE: April 17, 1985

This memorandum sets forth the recommendation of the Division of Food and Drugs (DFD) with regard to a food tolerance for polychlorinated biphenyls (PCBs) in fish and shellfish caught in Massachusetts waters. The federal Food and Drug Administration (FDA) tolerance, effective August 20, 1984, is 2 parts per million (ppm) PCBs in fish and shellfish in interstate commerce. FDA requested that state and local governments consider their own actions to protect the public against PCB exposure from fish and shellfish in intrastate commerce. There are essentially three options for the Commonwealth in designating a tolerance for PCBs in fish and shellfish. The options are to adopt the 2 ppm FDA tolerance, to adopt some other tolerance level, or not to adopt any tolerance. The DFD accepts the risk analysis and the determination of appropriate balance between public protection and economic cost which was made by the FDA. The DFD therefore recommends that the FDA tolerance of 2 ppm PCBs in fish and shellfish be adopted. The proposed regulations are in the form of amendments to 105 CMR 515, and are attached as "Exhibit A".

HEALTH EFFECTS

PCBs are a class of toxic industrial chemicals that have become persistent and ubiquitous environmental contaminants due to past widespread and uncontrolled industrial usage and disposal. They accumulate preferentially in fat tissue. Tremendous bioconcentration can therefore occur in fatty marine species. Humans can absorb PCBs through the lungs, skin, or gastrointestinal tract.

PCBs have a low acute toxicity. Because these compounds are stored in body fats, however, cumulative exposures can lead to symptoms of toxicity, such as chloracne.

Most scientists and regulatory agencies share the opinion that PCBs pose a carcinogenic risk to those exposed. This is due to data from animal bioassays which have demonstrated carcinogenic and neoplastic responses. Human evidence of carcinogenicity cannot as yet be confidently affirmed or denied. Nonetheless, worrisome findings in human studies exist.

An extensive literature exists on PCB reproductive toxicity in various animal species. Adverse effects on reproductive capability are generally more pronounced in higher animals. Reproductive dysfunction has been seen in nearly all animal species when the doses are increased sufficiently. Of particular concern are the findings with Rhesus monkeys, which showed markedly depressed levels of conception and reduced numbers of live births at levels of 2.5 and 5.0 ppm PCBs in their diet. Because of a lack of information on the effects of PCB consumption on human reproduction, and because a no adverse effect level cannot be demonstrated, the nature of the risks to the infant and to a woman's reproductive capability is not known.

BASIS FOR FEDERAL TOLERANCE

Due to uncontrolled disposal of PCBs, unavoidable contamination of certain foods, such as fish and shellfish, milk and dairy products, and poultry has occurred. In 1973, the FDA established temporary tolerances for PCBs in those foods (38 FR 18006, July 6, 1973). By law, the FDA must set the tolerances at a level which protects the public health while avoiding excessive food losses to the consumers.

The temporary tolerance established for PCB residues in fish and shellfish was 5.0 ppm. In determining this level, FDA took into consideration both human exposure data from the Yusho poisoning incident in Japan (where PCBs leaked from a transformer into rice oil, which was eventually consumed) and animal exposure data from chronic feeding studies (see attached summary of health effects of PCBs).

In the Yusho poisoning incident, an average daily intake of PCBs resulting in the development of symptoms was estimated (symptoms included lesions of the skin and mucous membranes, vomiting, hair loss and abnormalities of growth and development). FDA then calculated a total allowable exposure from the average doses which caused overt symptoms, and applied two safety factors of ten - one to account for variation within the human population and one to account for variation in exposure periods (see discussion, 42 FR 17688, April 7, 1977).

At the time of announcing the temporary tolerances, the FDA expected PCB levels in the food supply would show a continual decrease over the next few years and that it would then be possible to decrease the tolerances. PCB levels did indeed decrease in all categories of food monitored, with the exception of fish. FDA's concern over the continued presence of PCBs in fish as well as new toxicity data on PCBs led to a proposed reduction in the tolerance.

The revised tolerance of 2 ppm for fish and shellfish was proposed by the FDA in 1977 and promulgated in 1979. New information on the chronic effects of PCB toxicity, specifically cancer and reproductive risks (see attached summary of health effects of PCBs) had surfaced.

"...there is little genuine dispute over the fact that exposure to PCBs must be considered to pose a risk of serious, chronic toxic effects in humans. The toxicological judgment that flows from this fact - i.e., that a reduction in human exposure to PCBs will reduce the risk - was an important part of the agency's rationale for proposing to reduce the fish tolerance. Nothing in the comments and nothing discovered during FDA's reassessment of the toxicity data alters the validity of that fundamental judgment. The agency therefore concluded that it is important as a matter of public health protection to minimize human exposure to PCBs."
(44 FR 38332, June 29, 1979)

To arrive at a tolerance of 2 ppm, FDA considered the following: national per capita fish consumption, the fish species in which PCBs are routinely found, the levels of contamination, and the percentage of the US population which eats the twelve species in which PCBs are routinely found. Cancer risks from consumption were estimated for tolerances of 1.0 ppm, 2.0 ppm, 5.0 ppm, and no tolerance. FDA concluded that the optimum tolerance for public health protection was 1.0 ppm, the lowest enforceable level. FDA is, however, required by law to balance health risks with food loss. They are also required to consider the extent to which a contaminant is unavoidable. The 2 ppm level was promulgated and represented a balance between public health protection and economic impact.

The implementation of this revised tolerance was stayed in the courts before it was to go into effect. Objections were based not on the health effects information, which FDA, drawing upon a large data base, concluded showed PCBs to pose a serious health threat, but on the magnitude of the food loss that would occur as a result of the lower tolerance. A formal evidentiary hearing was held in 1981 to collect more information on the economic impact of the revised tolerance. In May 1984, the Commissioner of the FDA announced that the appropriate tolerance, taking into account food loss, should remain at 2.0 ppm.

"I have concluded above that the annual dockside human food loss is \$13.5 million...I have further concluded that the risk assessment supporting the final rule continues to be valid in light of newly submitted scientific information. The only question that remains is whether a balancing of the unchanged public health considerations and the increased human food loss yields a tolerance greater than 2 ppm. I conclude that the answer is no...

"...I believe that we should keep in mind the fact that total annual domestic landings of fish are also \$1.6 billion. Thus, the total human food loss is less than 1% of all domestic landings." (49 FR 21519, May 22, 1984)

SPECIES AFFECTED IN MASSACHUSETTS

The tolerance will be established for commercially available fish and shellfish. In Massachusetts, species that have been detected with high PCB levels are the lobster in some estuaries, the bluefish, the striped bass, and Housatonic River species, such as trout, bass, sunfish, and perch. Only the lobster, bluefish and striped bass are sold commercially. Tolerances imposed on sportsfish are not enforceable.

Limited data exists on levels of PCBs found in fish and shellfish in Massachusetts waters other than the New Bedford harbor. From that data, it appears that PCB levels in fish and shellfish caught in Massachusetts generally do not exceed the 2 ppm level. There may, however, be certain areas which may be affected.

MARKET IMPACT

It is useful to draw upon FDA's analysis of possible market impact. The FDA did an extensive analysis of the national food loss resulting from lowering the tolerance. In its 1979 final rule, FDA said the reduction would result in an estimated loss of a minor percentage of marine fish (approximately 0.2%). This figure was arrived at by assuming all fish containing PCBs above the tolerance would be removed from both intra- and interstate commerce.

Furthermore, FDA noted that with the exception of some anadromous species (species that spend time in both salt and freshwater, such as salmon), all ocean fish contain an average of considerably less than 1 ppm PCBs. The average PCB levels for most species were less than 0.5 ppm for whole fish and the levels in edible portions were lower still, the majority having an average of a few tenths of 1 ppm.

According to the 1984 FDA analysis, the economic effects of lowering the tolerance to 2 ppm on a national basis is a dockside loss of about \$13.5 million. Of that figure, about \$8 million is lost nationally of species that can be found in Massachusetts waters.

FDA considered multiplying that dockside loss by some factor to derive the retail value of the catch. In FDA's view, however, the dockside value was the most appropriate measure for human food loss. This is because the fisherman who can't sell his catch loses what he would have received were it not for the tolerance. Persons further on in the marketing chain are not as fixed in the short run. Consumers can shift consumption patterns. Processors can buy from another source. FDA therefore concluded that "a lower tolerance level will not have a direct effect on those sectors of the economy and the value that would have been added by processing, distributing, and retailing to the landed value of fish that violate the lower tolerance should not be considered" (49 FR 21516, May 22, 1984).

Thus, the impact of a lower tolerance on the commercial fishing industry in Massachusetts may be minimal, except in areas where heavily contaminated waters have led to heavily contaminated fish. The lower tolerance is not expected to affect the catch of sportsfish since the tolerance on these fish is not enforceable. In areas where high levels of PCBs in sportfish might be found due to contaminated waters, a public health advisory might be issued. It is difficult to estimate the impact this type of advisory might have on sportsfishing in that area. ✓

CONCLUSION

The Division of Food and Drugs requests permission to proceed to public hearing on the proposed regulation. We expect that in the course of the public hearing process the potential effects of the proposed regulation on the Massachusetts fishing industry and other concerned actions will be fully discussed, as well as the health benefits which can be expected from the regulation's adoption.