Food and Drug Administration Guidelines for Contaminants in Fishery Products

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One need only be a reader of the newspapers to realize that the fishing industry has had a very rocky time over the past few years. There have been a number of health related problems — botulism, mercury, pesticides, industrial contaminants — which have generated disproportionate publicity. I would like to try and put some of these problems in perspective while telling you a little about the Food and Drug Administration's (FDA) regulatory and research activities in the areas of fisheries products. Perhaps I might also offer some insights into some of what FDA feels may be the emerging health problems associated with fisheries.

Traditionally, the FDA approach to fisheries products has related to microbiological quality, generally to in-plant sanitation. In the 1960s, public health attention was focused on the virus threat posed by the consumption of raw oysters and clams. Fortunately, no more major outbreaks have occurred involving this disease, although this potential public health problem remains as a reminder to all of us to maintain our established sanitary controls. The 1970s have caused us to reassess the potential health hazard presented by the vast array of industrial and toxic waste materials dumped daily into our waterways. The question of how these chemicals affect the quality of our aquatic food supply has taken on new proportions and many scientists and public officials are searching for answers. Quite predictably, the effects upon fish, shellfish and clam resources have been severe. It would seem that the public, regulatory officials and the fishing industry itself need to consider a few very basic facts about fisheries products when considered against the rest of the foods we eat in order to anticipate problems before they assume crisis proportions.

Fish are grown and harvested in a relatively uncontrolled environment when compared to our other protein sources. While fish roam wide areas in search of food, meat is produced in the confines of a pasture or a feed lot. Everything that a meat animal eats is decided by the producer. A few years ago serious pesticide problems in animal feeds which carried over into milk were discovered. The problem was corrected in a short period of time by more careful selection of feed and changed spraying practices. When pesticide residues in fish occur, however, solution is difficult and a long time coming. I think as a society we are being very unrealistic in being surprised that our fisheries are hurt by problems caused by careless or purposeful disposal of our land wastes.

The FDA has had an active fresh-water fish pesticide analysis program for a number of years. In fiscal year 1971, 600 samples of fish were analyzed for pesticides. As might be expected almost all contained some residue level of DDT and its analogs. (558 residues of DDE, 447 of DDT and 392 of TDE). Every widely used chlorinated pesticide was also detected but not as frequently. These included aldrin, dieldrin, endrin, heptachor and heptachor epoxide, toxaphene and BHC. PCB (1254) which is not a pesticide but an industrial contaminant was also found in 346 samples. As I have said before, the majority of these fish were

fresh water fish. There have, however, been some federal seizures of kingfish which contained more than 5 parts per million (ppm) DDT and its analogs. While truly adequate pesticide surveys of ocean fish species need to be undertaken, information from our total diet studies would indicate pesticide levels in ocean fisheries products are generally below any level of serious public health significance.

As I mentioned before, PCB residues have been found at some level in 346 of 600 fish samples examined. This would be strictly from environmental contamination. Much of the recent publicity about PCBs related to accidental industrial contamination of fish meal from leaks in heat transfer equipment in a plant. This type of contamination is easily handled. The source of the contamination is simply eliminated. Would that the environmental problems were as easily solved.

Man's various activities during recent years, ranging from wide-spread burning of fossil fuels to the careless dumping of millions of pounds of mercury contaminated wastes, have undoubtedly increased the concentration of mercury in many productive areas of our surface waters to the extent that a significant segment of the world's food resources has been affected.

In March 1970, the Canadian Food and Drug Directorate announced that Lake St. Clair, an international boundary lake, was being closed to commercial fishing. Industrial plants at Sarnia, Ontario and nearby, have discharged enough mercury over a period of many years to seriously pollute not only Lake St. Clair and the St. Clair River, but also most of the western basin of Lake Erie. The microbiological flora of these streams had converted the mercury discharge to methyl mercury which had found its way up the food chain until finally concentrated at dangerous levels in certain species of fish flesh. This triggered a great deal of state and federal activity which had great impact on the fishing industry.

On our part, the FDA initiated a Compliance Program in April 1970. Since fish were found contaminated with mercury residues from industrial wastes and other sources discharged into fishing areas, there was a need for the FDA to determine the extent of this problem. The concern in the U.S. with respect to tuna began in December 1970. The canned tuna program analyzed the entire canned tuna supply of the U.S. This included all domestic and imported canned tuna on the market between December 16, 1970 and February 1, 1971. When the survey of the entire tuna pack was published in February 1971, less than 4% of all the tuna examined exceeded the guideline. Species and size were the determining factors in predicting which fish might be at or above the guideline.

On December 23, 1970, Commissioner Edwards announced that the precautionary program of sampling tuna for mercury was being extended to another deep water fish; i.e., swordfish. Since December 26, 1970, all of the swordfish in cold storage and offered for entry into the U.S. has been examined for mercury. On May 6, Commissioner Edwards announced that test results showed only 42 of 853 swordfish samples to be within FDA's 0.5 ppm guideline and 53% exceeded 1 ppm. Therefore, at this time he issued a public warning against the consumption of swordfish.

After the smoke had cleared and some of the analytical resources of our laboratories were freed, a statistically valid analysis program of the 19 most commercially important fish was undertaken by FDA. The results of this survey indicated that while the mean mercury level in saltwater fish was quite low, approximately 0.09 ppm of mercury, certain species such as snapper, bonito and

mackerel would have a number of fish above the 0.5 ppm mercury action level established by FDA. Of over 1,000 lots examined, it has been necessary to initiate seizure or recall actions against 14 lots of snapper, 3 lots of bonito and 3 lots of mackerel. Other predator type fish have also been implicated but not in commercially significant quantities.

The National Canners Association, the Japanese Canned Food Association, the National Fisheries Institute, the American and Japanese Tuna Packers and the halibut industry of the Pacific Northwest have all instituted quality control programs which will go far toward minimizing the necessity for regulatory action on the part of the federal government.

I know that as fishermen you are questioning the necessity ot such activities. You are saying, "Where are the people injured from eating fish? Look at the people injured by smoking or consumption of alcohol!" While I can sympathize with this feeling, the responsibility of the FDA with respect to this problem is quite clear. We must continue to monitor the whole of the nation's food supply, identifying and isolating the problem areas while taking positive action to remove from the channels of commerce those foods found to contain excessive mercury residues. In order to meet this responsibility our basic philosophy is to seek control measures maximizing the safety to humans, based on the best available data, both animal and human. In properly carrying out this assigned task relative to mercury in fish, one should not see any direct cause and effect relationships in our population relative to mercury poisoning from this source.

There are no formal tolerances for mercury in food products. The registered uses of mercurial compounus as pesticides or fungicides are on a no-residue basis. The FDA has established certain "Administrative Guidelines" covering the presence of mercury treated seed in wheat intended for food and also covering mercury residues in fish, shellfish and other aquatic organisms. The guidelines allowed for legal action on wheat when 10 or more pink kernels, each containing greater than 1.0 ppm mercury, were found per 500 grams of wheat. Legal action will be instituted against fish when 0.5 ppm or more of mercury is found in the edible portions. The mercury in fish guideline has been the subject of tremendous controversy during the past several months. Various consumer groups and individuals representing themselves as consumer advocates have asserted that the figure is too high and should be lowered to assure that the public health will not be endangered. Other voices, primarily from the various industries directly involved, have maintained that the guideline level is too low.

Let us examine this guideline and how it was established. The types of data available at the time the FDA guidelines for mercury in fish were established were derived from: (1) Minamata Episode (used in the original Swedish evaluation), (2) intake of methyl mercury in man from contaminated fish and blood levels of mercury and (3) studies in the distribution and excretion of Hg-203 labelled mercury in human volunteers, in conjunction with data in brain levels of mercury in test animals and human autopsy cases.

Consideration of this data led to the establishment of the 0.5 ppm mercury in fish guideline. This guideline is under continuous review. The conclusion of a ten scientist study group to Sweden and Finland, in August 1970, where a great deal of work had been done in this area, was that the FDA guideline of 0.5 ppm mercury in fish is, for the present, a sound basis for the protection of the public health. The mercury in fish guideline was again reviewed in April 1971 by an Ad Hoc Committee of scientific and medical experts from this country and Canada with respect to the high levels of mercury found in swordfish. The Committee

expressed support (11 of 13 non-FDA members) for the maintenance of the 0.5 ppm guideline.

In May 1971, four members of the Bureau of Foods visited Japan. The most recent Japanese data reaffirmed and reinforced the present FDA guideline for mercury in fish.

Therefore, controversy notwithstanding, the consensus of the scientific community with expertise in the area of mercury toxicity is that the 0.5 ppm mercury figure is adequate, appropriate and necessary for the protection of the consuming public.

If anyone can bring forth hard scientific facts necessary to demonstrate that this level is either too high or too low, we stand ready to change this action level. Mind you, I said *facts* and not *opinions.*

Another related area of concern is the concentration of metals besides mercury in our foodstuffs. FDA and the Public Health Service have had a metals in shellfish program in operation since 1966. Many shellfish growing areas in the U.S. have been classified and shellfish analyzed for metals content. The metals included in this survey are cadmium, lead, chromium, zinc, copper, cobalt, nickel, iron and manganese. These metals arise in shellfish from both natural sources, the weathering of rocks, and also from industrial discharges and airborne contamination of rivers and streams. When baseline data of this type is available, meaningful alert systems can be devised. Abatement of the source pollutants can be attempted when metals levels rise by statistically significant amounts.

It has been well-known to medical scientists for a number of years that oysters contained large amounts of cadmium when compared with other foods. Cadmium can produce a wide range of adverse effects in man and animals when the intakes are in excess of typical population exposures. Based on present knowledge of dietary intakes of cadmium we can see no particular problems resulting with regard to oysters.

These are some of the regulatory problems we are concerned with at FDA. We have not touched on the problems associated with oil spills in food producing areas, the problems associated with processing in smoked fish which may contain botulism spores, or nitrosamine formation when nitrites are used in fish processing. There is a common trend with all the problems we face now or anticipate in the future. There is a common deficiency of knowledge to adequately define problems. We need a great deal more toxicological, analytical and engineering information before we can come close in every case to the goal of industry and government, a pure wholesome and safe fisheries product.

Definite positive steps are underway, however, to solve many of the major fisheries problems, at least as they relate to FDA. While the scope of many of these problems is very broad, FDA stands ready to work with anyone, individuals, firms or trade associations, in achieving our goal of consumer protection through product integrity.