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United States Tuna Foundation

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December 8, 2000

Mr. Joseph Levitt
Director, Center for Food Safety
and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Dear Joe:

During our meeting of November 22 I agreed to furnish you with the results of our focus group studies and the paper we had requested from ENVIRONS regarding fresh tuna consumption. Attached you will find these documents, entitled "Impact of Mercury Statement on Seafood/Tuna Consumption" and "Usual Intake of Fresh Tuna by Women Age 15-44."

In addition, I have sent you a copy of a paper we have prepared entitled "Revised Methyl Mercury Fish Advisories." This paper sets forth our understanding of FDA's past practice regarding "advisories" and our concern that FDA appears to be taking a different approach to the proposed "fish advisory."

Finally, we have attached a "Draft Interim Advisory," which we submit should be considered in the present situation. We believe that the advisory should be interim, in order to delay any final decision on such an advisory until the concerns raised over the Faroes Island study and the final report of the Seychelles Child Development study have been satisfactorily addressed.

We appreciate your willingness to take our views into consideration before making any final determination on this very important matter.

Very truly yours,

DAVID G. BURNEY

Attachments: 1. Impact of Mercury Statement on Seafood/Tuna Consumption
2. Usual Intake of Fresh Tuna by Women
3. Revising Methylmercury Fish Advisories

December 8, 2000

USTF/NFI Memo on Revising Methylmercury Fish Advisories

Based on a United States Tuna Foundation (USTF) and National Fisheries Institute (NFI) joint evaluation on methylmercury in fish advisories, we believe it is premature to adopt the Environmental Protection Agency's (EPA) reference dose (RfD) as a basis for consumer advice. Recently, a committee of the National Academy of Sciences (heretofore referred to as the NAS Committee) concluded that an RfD of 0.1 ìg/kg/day for methylmercury (MeHg) is a scientifically justifiable level for the protection of public health. Soon thereafter, the Food and Drug Administration (FDA) indicated that it is considering issuing a new methylmercury in fish advisory for sensitive subpopulations. Findings from the Seychelles Child Development Study (Seychelles study) are expected this coming spring as well as initial findings from the fourth National Health and Nutrition Examination Survey (NHANES) mercury exposure study (now under review by Federal agencies). These important studies need to be included as part of a thoughtful science-based process before issuance of a new advisory.

Although the NAS Committee has issued its report, its conclusions do not necessarily represent consensus in the public health community:

- The Agency for Toxic Substances and Disease Registry (ATSDR) reviewed essentially the same studies considered by the NAS Committee and concluded that findings from the fish-eating population in the Seychelles Islands rather than from the whale-eating community in the Faroes Islands (relied upon by the NAS Committee) provided a more appropriate basis for addressing risk among U.S fish consumers. ATSDR concluded that a minimum risk level (MRL) of 0.4 ìg/kg/day (4 times higher than the EPA RfD) was justified based on findings in the Seychelles study. ATSDR reduced this value to 0.3 ìg/kg/day in consideration of "missing data" from the Seychelles study (which is expected in spring 2001) that will allow developmental outcomes in the Faroes and Seychelles studies to be compared directly.

- The World Health Organization concluded that numerous confounding factors in the Faroes study should be reassessed in order to determine the role of MeHg in the adverse effects.

EPA's RfD and ATSDR's MRL both describe MeHg exposure levels without appreciable risk. They should **not** be considered to be thresholds for adverse effects. Higher exposure levels may also be without risk. As noted in ATSDR's analysis of the Seychelles study, no adverse effects were observed in this fish-eating population, even among offspring from mothers in the highest quartile where exposure averaged about 15 times higher than the RfD. Clearly, the EPA RfD should not be used as a bright line to construe that a large number of offspring of U.S. consumers who exceed the RfD will be

at risk to adverse developmental effects. It is possible that the numbers at risk of developmental effects among U.S. consumers is zero.

FDA, with its responsibility for assuring the safety of the seafood supply, is the biggest stakeholder in this public health debate. One must wonder why FDA feels compelled to act at a time when the risk of probable harm from exceeding the RfD by U.S. consumers has yet to be clearly demonstrated. FDA has taken no formal position regarding the merits of available science yet appears ready to proceed with actions that could have significant impact on the consumption of seafood and the perceived safety of the food supply. FDA should include the expected findings from the Seychelles study and NHANES in an analysis before proceeding.

Over the years of dealing with MeHg, FDA has relied on Section 402(a)(1) of the Federal Food Drug and Cosmetic Act (the Act) for determining whether MeHg constitutes an added poisonous or deleterious substance that "*may*" render food injurious to health. Interestingly, the court in the Anderson Seafood case instructed FDA that "*may*" connotes a reasonable probability and does not require an absolute assurance that no one, even under extreme circumstances, could be harmed:

> "Nothing in the Act or legislative history suggests that Congress intended to proscribe a food simply because it was physically possible for one to consume enough of it to harm oneself."

FDA should explain what portion of the population they intend to protect with their action level for MeHg and what portion of the population requires special advice because the action level may not provide sufficient protection. FDA should also indicate whether they have issued advisories for other contaminants with action levels.

It appears that FDA typically uses mean and 90th percentile exposure figures as the basis for assessing and managing risks. One reason for this is because when dealing with food consumption surveys, potential errors in the levels beyond the 90th percentile become problematic due to the small number of individuals represented. Higher exposed groups might be considered if acute effects are likely. When FDA set its tolerance for PCBs in fish, risk to consumers was examined at the 90th percentile. Regulatory approaches for lead (ceramic glazes, lead crystal, bottle capsules, and can solder) also relied on 90th percentile exposure figures for risk assessments and determining what levels of exposure may render the food injurious. If FDA is going to rely on mean and 90th percentile exposure figures for assessing and managing the risks of MeHg in seafood, available exposure data can be used to judge whether there is a reasonable likelihood that intake guidelines are being exceeded and whether any actions are warranted at this time.

EPA's Mercury Study Report to Congress concluded from an analysis of dietary intake figures that only about 7 percent of women of childbearing age exceed their RfD of 0.1 ìg/kg/day. If FDA used this conclusion alone, there would be no need for FDA to change their advisory or defect action level (DAL) since exposure levels at the 90th percentile would be below the RfD.

A number of recent studies using biological measurements of exposure are supportive of EPA's exposure conclusion:

- An ATSDR study of 320 licensed Lake Ontario anglers showed only 23 percent had hair mercury concentrations exceeding 0.25 ppm and the 90th percentile figure was 1.0 ppm.
- A general population study conducted in the Great Lakes states under EPA sponsorship (National Human Exposure Assessment Survey-NHEXAS) yielded hair samples for 182 participants. Analysis for total mercury levels revealed mean hair levels of 0.28 ppm and a 90th percentile level of 0.53 ppm. For the 59 women of childbearing age, the mean was 0.35 ppm and the maximum level was 1.6 ppm.
- A New Jersey study of hair samples from 189 pregnant women who were randomly selected throughout the state found a mean level of 0.48 ppm and the 90th percentile at 1.1 ppm.

Although the foregoing data are not nationally representative (such national data are expected from NHANES), they do suggest that current exposure levels around the 90th percentile are below the RfD, at least 3 times lower than the MRL, over 4 times lower than FDA's tolerable daily intake (TDI), and 15 times lower than the highest exposed group in the Seychelles study (which exhibited no adverse effects).

Based on this analysis, it seems fair to conclude that an urgent public health situation requiring FDA's immediate response does not exist just because of the NAS Committee report. FDA should delay its planned update of its advisory and revisit this issue later next year when data from the Seychelles study and NHANES can be considered.

Impact of Mercury statement on Seafood/Tuna Consumption

KEY FINDINGS

- Nearly one-half of all people who consume canned tuna would reduce their consumption as a result of eith Advisory A or Advisory B.
- Canned tuna consumption could decline by 19% (Advisory A) to 24% (Advisory B).
- A significant reduction in consumption would occur for all categories of consumers measured.

ADVISORY TESTED

Advisory for shark/swordfish/fresh and canned tuna (A)	Advisory for swordfish/shark/fresh tuna (B)
"The United States Food and Drug Administration warns pregnant women and women of childbearing age not to eat shark, swordfish and fresh tuna more than once a month and not to eat more than 6 ounces of canned tuna per week. These fish have much higher levels of methylmercury, which can cause neurodevelopment defects".	"The United States Food and Drug Administration warns pregnant women and women of childbearing age not to eat shark, swordfish and fresh tuna more than once a month. These fish have much higher levels of methylmercury, which can cause neurodevelopment defects".

Impact on Consumption among Rep. Sample & Female 18-44 aged

	Rep. Sample		Female 18-44 aged	
	Advisory A	Advisory B	Advisory A	Advisory B
- No Impact on Consumption	58	57	49	45
Would Impact	39	39	49	52
- Reduce by 1/4	10	8	12	11
- Reduce by half	9	10	12	20
- Reduce by 3/4	5	7	4	5
- Stop eating	16	15	22	17

- Total Canned Tuna market could decrease by 24% when using Advisory A and by 19% when using advisory B. Advisory A has a higher impact on Canned Tuna consumption since it directly communicates negative effect regarding eating canned tuna, and affect on higher proportion heavy users of the category.

Impact on Canned Tuna Consumption among different frequency of eating Canned Tuna

	Advisory A			Advisory B		
	Regular users	Occasional users	Light users	Regular users	Occasional users	Light users
	Once a week or more often	Once every 2/3 Weeks	Once a month or less	Once a week or more often	Once every 2/3 Weeks	Once a month or less
- No Impact on Consumption	58	67	56	63	57	57
Would Impact	40	33	42	36	43	39
- Reduce by 1/4	14	11	8	14	11	6
- Reduce by half	12	9	10	9	24	7
- Reduce by 3/4	4	3	7	4	5	10
- Stop eating	12	11	17	8	4	16

DRAFT INTERIM ADVISORY

Fish is an important source of high-quality protein, vitamins and minerals. Fish consumption offers strong health benefits, and the American Heart Association recommends that people include fatty fish such as tuna or salmon as a regular part of their diets.

Mercury occurs naturally in the environment. Nearly all fish contain trace amounts of methyl mercury, some more than others. FDA believes that eating a variety of commercial seafood, as part of a well-balanced diet does not put any one at risk from being exposed to excess amounts of mercury. However, since the fetus may be more susceptible than others to the adverse effects of methyl mercury, FDA advises pregnant women and women of childbearing years to limit the consumption of fish that have higher levels of methyl mercury.

Specifically, FDA advises pregnant women and women of childbearing age, to limit their consumption of shark and swordfish to no more than once a month. For all other species of commercial fish, FDA advises that pregnant women and women of childbearing years, should limit their consumption to moderate levels, thus ensuring that fish is consumed as part of a well balanced diet. Current evidence indicates that pregnant women and nursing women may safely consume up to 11.65 ounces or 4.7 servings of commercial seafood (other than shark and swordfish) per week, without exposing a fetus to any risk from methyl mercury.

For the rest of the U.S. population, commercial seafood is safe to consume. However, this does not mean that people should overindulge in those fish that contain the highest levels of methyl mercury, such as shark and swordfish. Taking into account the types of fish normally eaten, the levels of methyl mercury present in these species of fish and the amounts of fish normally consumed at each eating occasion, most consumers are not at risk from the levels of mercury found in commercial seafood.

Some fresh-water species caught recreationally, such as pike and walleye, also have elevated mercury levels, particularly in areas where mercury levels in the local environment are elevated. FDA suggests sports fishers check with state or local governments for advisories about water bodies or fish species. These advisories provide up-to-date public health information on local areas and warn of areas or species where mercury (or other contamination) is of concern.