



United States Tuna Foundation

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October 31, 2000

Mr. Joseph A. Levitt
Director, Center for Food Safety
and Applied Nutrition (6815 FB8)
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Dear Joe:

Attached is a copy of the statement that I made at our September 25, 2000 meeting concerning methylmercury in fish. I apologize for the delay in getting it to you, but the original was accidentally destroyed, and I have attempted to recreate it the best that I could. I have taken the liberty of incorporating concerns that have been raised after more careful consideration of this important matter.

We understand that any new consumption advisory will, to a large extent, be based on the reference in the NAS Committee report to the possibility of 60,000 children being at risk. We do not believe that this 60,000 number is scientifically justifiable nor has it been properly documented or explained. A full explanation of this number and its reliability should be considered a priority matter before any change in the current advisory is agreed upon.

We continue to have great concern over the potential negative impact of any seafood advisory generally and even greater concern over any advisory that specifically references canned tuna. Our concerns are multiple and serious. They include the effect that an advisory will have on:

- the current FDA defect action level,
- the eating habits of the U.S. population and the alternatives to fish consumption,
- consumers and the health benefits lost if they do not consume seafood,
- international trade in seafood products, and
- international fisheries conservation efforts.

We are confident that the trace levels of mercury in canned tuna products are at levels that are safe for all segments of the U.S. population. We believe that any public policy review on this critical issue must include full weight being given to the Seychelles Child

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Development Study, the most definitive study of its kind. In addition, full consideration should be given to the health benefits that are known to be directly linked to fish consumption. These benefits were recently emphasized by the American Heart Association's statements encouraging consumption of at least two fish meals per week as a cardiac benefit.

I would like to meet with you to discuss the concerns that I have set forth above. They are real concerns and should be considered in any policy review. Please advise of a time and date that we can discuss these critical issues.

Very truly yours,



DAVID G. BURNEY

Attachment



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STATEMENT REGARDING THE ISSUANCE OF A NEW CONSUMER GUIDANCE ON METHYLMERCURY IN FISH

The U.S. canned tuna industry is greatly concerned over recent reports that the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) are considering the issuance of a new consumer guidance on methylmercury (MeHg) in fish. We understand that the advisory will be based on the recently released National Academy of Sciences Committee report on the Toxicological Effects of Methylmercury (NAS Committee report). Furthermore, we understand that the primary scientific basis for the guidance will be the Faroe Islands study (Faroes study), the study of a fish and whale-meat eating population that is quite dissimilar to seafood consumers in the United States.

We have been told that FDA may take action before the results of the most recent testing in the Seychelles Child Development Study (Seychelles study) are published. Such an action by the FDA could have an irreparable negative impact on American dietary habits, resulting in significant segments of the population turning away from the proven health benefits of fish consumption. It would be a serious disservice to public health to base any U.S. fish consumption guidance on the Faroes study or to ignore the outcomes of the Seychelles study, the most definitive study ever conducted on the association between prenatal exposure to MeHg through fish consumption and the cognitive functioning of the postnatal children.

In our science presentation today we have set forth many reasons why the NAS Committee report should not be the sole basis for any new consumer guidance on MeHg in fish. The NAS Committee report, along with the comprehensive Report on the Workshop on "Scientific Issues Relevant to Assessment of Health Effects from Exposure to Methylmercury" (organized by the White House -- Office of Science and Technology Policy's Committee on Environmental and Natural Resources) raised numerous questions that need answering before any change is made to the current public policy on this important subject. We agree with the NAS Committee report when it concluded that critical additional work is necessary to, "better address the risk assessment process."

We were pleased that the NAS Committee report finally recognized that the Iraq contamination study should no longer be used as the basis for the EPA reference dose. We do not agree, however, that the Faroes study should now replace the Iraq study as the basis for a U.S. reference dose, and we certainly do not believe that this study should be used to establish U.S. consumer guidance on MeHg in fish.

A number of eminent toxicologists and risk assessors, including those at the Agency for Toxic Substances and Disease Registry (ATSDR) and FDA have expressed

serious concerns regarding the use of the Faroes study as the basis for U.S. consumer guidance on MeHg in fish. Concerns have been raised regarding the episodic intake of MeHg, PCBs and other persistent organic pollutants (POPs) through the consumption of whale meat by the Faroes cohort. Concerns have also been expressed over the method used in this study to calculate the levels of PCBs and other POPs found in the cohort and the confounding role they play in efforts to determine the effect of the MeHg intake by this population, since PCBs and POPs would influence the findings.

The NAS Committee report recognized these concerns and stated that "Thus, it is possible that the more episodic exposure pattern in the Faroe Islands, with heavier doses per occasion" (MeHg and POPs in whale meat and blubber), "has a more adverse impact on neuronal development than the gradual exposure in the Seychelles" (MeHg in fish). Regarding exposure to PCBs in the Faroe Islands cohort, the NAS Committee report stated, "Whereas, PCB concentrations in the Seychelles are among the lowest observed anywhere in the world, the portion of the Faroes population that eats whale blubber accumulates unusually high PCB body burdens." The NAS Committee report went on to state, "The potential for confounding by PCBs exposure is of some concern for the Faroe Islands Study."

Subsequent to the release of the NAS Committee report, Dr. D.C. Bellinger (Harvard Medical School), a member of the NAS Committee, co-authored a report published by the World Health Organization (WHO -- Geneva, 2000), which questioned the reliability of the methodology used in the Faroes study to estimate PCB levels. This report concluded that "the confounding role of PCBs and persistent organic pollutants should be reassessed in order to determine the role of methylmercury in the adverse effects reported in the study."

There is no reason to issue new consumer guidance on MeHg in fish until the concerns regarding the Faroes study are addressed satisfactorily and the results from the latest testing of the Seychelles cohort are published. The publication of the latest Seychelles testing is expected sometime during the spring of 2001. The early indications are that the results of this testing will answer the specific questions raised by the NAS Committee report and corroborate earlier findings by the investigators that there is no evidence of any relationship between maternal exposure to MeHg during pregnancy (at even the higher MeHg levels found in the cohort) and adverse developmental outcomes.

The NAS Committee report recognizes that fish and seafood products cannot be regarded merely as a source of exposure to MeHg. The report acknowledges that seafood is an integral part of the American diet and, as such, plays a valuable role in the nutritional status and general health of the population. Fish and seafood products offer nutritional benefits that are simply not available through alternative foods. Canned tuna in particular is an affordable source of these benefits to low-income families.

Fish and seafood products contain substantial amounts of protein and many essential vitamins and minerals. They contain low concentrations of fat, saturated fat, and cholesterol. Fish is an excellent source of selenium, a known antioxidant, and omega

3 fatty acids, essential during the fetal period and infancy for full neurologic and vascular tissue development. Also, omega 3 fatty acids have been found to reduce the likelihood of cardiovascular disease and mortality in adults (see attachment).

The canned tuna industry is proud of its efforts to produce an affordable and safe seafood product. The low levels of MeHg in canned tuna products are significantly below international standards for mercury in fish and seafood and are also well below the levels of MeHg found in other U.S. seafood that currently have advisories in place.

We are greatly concerned that any advisory aimed at canned tuna will open the door for spurious lawsuits and irreparably damage the category in the U.S. marketplace. Our concerns over the effects of an advisory on canned tuna are legitimate. The media attention is always drawn to canned tuna anytime that an advisory for seafood products is contemplated or announced. The attention is totally disproportionate to the relative mercury levels of the various seafood products under consideration. Canned tuna becomes the headline even when efforts are made to minimize the risk level associated with the product.

Canned tuna is the number one seafood category in the United States. Because of its popularity and recognized health benefits, approximately 77 percent of all retail grocery stores in the United States "promote" canned tuna. In fact, 54 percent of all canned tuna sold in the U.S. retail market is sold through a grocery store promotion and at an average price discount of 31 percent. Thus, U.S. households, including low-income families, are provided with an affordable source of high quality protein that contains many of the essential vitamins and minerals and is low in fat and cholesterol.

It is reasonable to expect that the U.S. retail trade will re-examine its promotion policy regarding commercial seafood and consumers will significantly reduce their consumption of seafood, including canned tuna, if the trace levels of mercury contained in these products becomes the basis of a new seafood advisory. Obviously, our concern is based on the fact that a new advisory is simply not necessary.

We requested this meeting today for two important reasons. First, is the matter of Federal jurisdiction over seafood safety. We implore the FDA to retain this jurisdiction, including any public policy review or risk assessment of the effects of mercury on U.S. consumers of fish and seafood products.

Secondly, we submit that the public policy on this important matter should be solely based on the best and most relevant scientific evidence available. There are too many important questions currently being answered by the Seychelles study investigators and too many remaining concerns to be addressed by the Faroes study investigators before the public policy can be effectively settled. We are confident that once the questions and concerns have been answered, canned tuna will again be confirmed to be a safe and nutritionally valuable source of high quality protein.

It would be a disservice to public health to ignore the recognized health benefits associated with fish consumption and rush to judgment on the need for a new advisory. The final decision on a new advisory should be postponed until the critical and more relevant Seychelles study report is published next year and the serious concerns raised regarding the Faroes study have been satisfactorily addressed.