

DEPARTMENT OF HEALTH AND HUMAN SERVICES

(35)

MEMORANDUM OF MEETING

Date: November 6, 2000

Place: Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition, Washington, D.C.

Participants:

Industry

John R. Cady, National Food Processors Association (NFPA)
Rhona Applebaum, National Food Processors Association (NFPA)
Don Binotto, Starkist, H.J. Heinz
Dennis Mussell, Chicken of the Sea International
Chris Lischewski, Bumble Bee
Jim Heimback, ENVIRON
F. Jay Murray, Murray and Associates
George M. Gray, Harvard Center for Risk Analysis, Harvard School
of Public Health
James R. Coughlin, Coughlin & Associates
Ted Smyth, H. J. Heinz

FDA

Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition
(CFSAN), HFS-1
L. Robert Lake, Director, Office of Regulation and Policy, HFS-4
Philip C. Spiller, Director, Office of Seafood, HFS-400
Philip M. Bolger, Director, Division of Risk Assessment, Office of Plant Dairy
Foods and Beverages, HFS-355
Louis J. Carson, Acting Director, Food Safety Initiative Staff, HFS-32
Marjorie L. Davidson, Education and Outreach Team Leader, Food Safety
Initiative Staff, HFS-32
Richard A. Williams, Jr., Director, Division of Market Studies, Office of Scientific
Analysis and Support, HFS-725
Brenda M. Derby, Food Safety Initiative Staff, HFS-32
Tamar Nordenberg, Editor/Writer, Food Safety Initiative Staff, HFS-32
Ellis M. Norris, Policy Analyst, Executive Operations Staff, HFS-22

Subject: Methylmercury in Seafood

This was one in a series of consultations that CFSAN held with various stakeholder groups to get their views on what FDA's response should be to the National Academy of Sciences' (NAS) report on methylmercury in seafood. The primary purpose of these meetings was to obtain stakeholder input regarding whether the Agency should issue a new advisory on seafood and, if one is needed, what should that advisory be.

Representatives of industry stressed the point that FDA should not attempt to make a judgement on the issue of methylmercury in seafood without having all of the pertinent scientific data. They stated that there are other data, especially the results of the Seychelles Island study, that need to be considered in efforts to determine the risk associated with methylmercury in seafood. They recommended that FDA wait until the Seychelles Island data are available, which should be early in the spring of 2001. Also, representatives of industry suggested that it is now widely recognized that there are problems with the NAS study and that it tends to raise more questions than it answers.

During the meeting representatives of industry made presentations related to the NAS report, risk/risk tradeoffs related to seafood consumption, and the potential impacts of a revised seafood advisory on seafood consumption and the economic health of the canned tuna industry. The following were among the major points made during these presentations:

1. Use of the Faroe Island study to estimate risk for U.S. consumers is highly controversial because the type of seafood and pattern of consumption is different than that in the U.S. The major source of exposure in the Faroe Island is through the consumption of whale meat and blubber and the pattern is high/short-term exposure. There is also the possibility that the results of the Faroe Island study is confounded by the presence of high levels of PCBs and other organic pollutants in whale meat and blubber consumed in the Faroe Island. Industry representatives also pointed out that the World Health Organization's (WHO) Joint Expert Committee on Food Additives (JECFA) has called for a reevaluation of the results of the Faroe Island study.
2. While the NAS report concluded that over 60,00 children are born each year at risk for adverse neurodevelopmental effects due to in utero exposure to methylmercury, it does not explain the basis for that estimate. Industry believes that this is a bad number that is scientifically indefensible. In addition, they noted that the NAS report does not explain what "at risk" means nor does it clearly identify the "neurodevelopmental effects" that are expected to occur in children who are considered to be at risk.
3. To this point, the results of the Seychelles Island study have not shown adverse neurodevelopmental effects from the consumption of seafood with

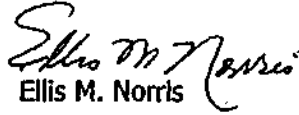
higher methylmercury levels higher than that consumed by Americans. Representatives of industry indicated that, if FDA decides to reevaluate its advisory on seafood, it would be critical that the results of the Seychelles study be taken into consideration because the fish consumption patterns are more like those in the United States. Also, they could see no sound scientific basis for the NAS rejecting the available results from this study simply because it did not find any adverse effects.

4. There are significant health benefits associated with seafood consumption that need to be considered. Industry representatives emphasized that fish are a good source of protein, lipids (e.g., omega-3 fatty acids), and other essential nutrients that produce healthful benefits, including decreased risk of heart disease, enhanced immune and nervous system development, reduced risk of stroke and arthritis, and enhanced neural development of fetuses and children. They stated that canned tuna in particular is an especially convenient, inexpensive source of high quality protein. In addition, they believe that the foods consumers are likely to consume instead of seafood will tend to be less healthful.
5. The economic impact of an advisory based on the NAS report is likely to be devastating to the seafood industry. Industry representative reported that they have been conducting focus groups to test the impact of several advisory messages. They indicated that, depending on the type of message used, the preliminary results indicate that 18% to 65% of consumers would probably discontinue eating seafood.
6. A change in the advisory on seafood will be seen by some as an admission that seafood has been unsafe in the past. Industry is concerned that there is a good possibility that this could lead to law suits filed by those who will try to link neurodevelopmental problems in their children to methylmercury in seafood.

Mr. Levitt thanked the industry representatives for their presentations. He asked representative of the tuna industry if they would be willing to share the results of the focus group testing with the Agency. They agreed that they would.

Mr. Levitt explained that the Center would consult with a number of other stakeholder groups, including the NAS study group and consumer groups, to obtain their views on this issue. He also indicated that plans have been made to have

discussions with a representative of the Seychelles study via telephone. Mr. Levitt assured the representatives of industry that the Center would do its best to make a rational presentation of all the various stakeholder views on this issue to the Commissioner.


Ellis M. Norris