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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum of Meeting

Date: October 20, 2000

Place: Center for Food Safety and Applied Nutrition, Washington, D.C.

Participants:

Industry

Richard Gutting, President, National Fisheries Institute (NFI)
Robert Collette, Vice-President, Science and Technology, National Fisheries Institute

FDA

Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, HFS-1
Louis J. Carson, Acting Director, Food Safety Initiative, HFS-32
Marjorie Davidson, Education Lead, Food Safety Initiative, HFS-32
Tamar Nordenberg, Editor/Writer, Food Safety Initiative, HFS-32
Marylynn Datoc, Consumer Safety Officer, Office of Enforcement, Division of Compliance Policy, HFC-230
Philip Spiller, Director, Office of Seafood, HFS-400
Brenda Derby, Math Statistician, Office of Scientific Analysis and Support (OSAS), HFS-727
Alan Levy, Senior Consumer Research Scientist, Consumer Studies, Office of Scientific Analysis and Support, HFS-727
Michael P. Bolger, Director, Division of Risk Assessment, Office of Plant and Dairy Foods and Beverages, HFS-355

Subject: Methylmercury in Seafood

CFSAN Director, Joseph A. Levitt, opened the meeting by explaining that FDA is consulting with stakeholders to help reach the most reasoned outcome on the issue of methylmercury in seafood following the National Academy of Sciences' (NAS) methylmercury report. He noted that the decision about whether to issue a revised consumer advisory is the short-term focus, but that this decision could impact others down the line, affecting, for example, determinations regarding action levels and tolerances.

Richard Gutting was the main speaker for the National Fisheries Institute (NFI) and first distributed a written summary of NFI's talking points (attached). He began by emphasizing two "fundamental points": FDA has the opportunity to be a leader among federal agencies by making independent decisions based on science untainted by environmental politics; and NFI is viewing the issue of changing the advisory as a very serious issue with a tremendous impact on his industry. A 60-day deadline is politics, not science, he said.

NFI does not support revising the consumer advisory. Mr. Gutting acknowledged that the NAS study changed the landscape on methylmercury, but said there were too many unanswered scientific questions remaining, and that NAS's numbers were unsupported and didn't get the experts to consensus.

NFI discussed its talking points. FDA discussed several points and thanked NFI for sharing its views.

Louis J. Carson

Attachment:

NATIONAL FISHERIES INSTITUTE

1901 North Fort Myer Drive, Suite
Arlington, VA 22
(703) 524-8880 • Fax: (703) 524-4
www.nfi.

Revising The FDA Consumer Advisory
On Methylmercury in Fish

1. The NFI encourages FDA to undertake a scientifically sound reevaluation of its present consumer guidance regarding methylmercury in fish.

2. FDA should not revise its consumer advisory at this time because of the EPA utility determination and the NAS study.

   - FDA credibility is undermined if the timing and substance of its food safety decisions are dictated by an EPA air pollution announcement and not by its own independent scientific judgment.
   - The NAS report raised (fails to address) scientific concerns
     - The report raises issues that the NAS panel says should be answered, including neurodevelopment effects of continuous versus peak exposures.
     - The World Health Organization has concluded that the numerous confounding factors in the Faroe Island study cited by the NAS report, such as the confounding effects of in utero PCB and other POP exposure, "should be reassessed in order to determine the role of methylmercury in the adverse effects reported in this study."
   - FDA and state authorities already have issued guidance to the subpopulations identified as being at risk in the NAS report.
   - There is no scientific consensus that action is needed now. NAS's theoretical extrapolations concerning U.S. children based on debatable assumptions and unsupported by epidemiological evidence are not sufficient.
   - No adverse effects are found in the Seychelles study despite exposure levels that exceed those in the U.S. (Mean levels in the Seychelles study exceed the 99th percentile consumer in the U.S.)
   - Arbitrary deadlines should not preempt science-based decision-making.

3. FDA should consider the benefits of consuming fish in crafting any consumer advisory.

   - Fish is a good source of high-quality protein, is low in fat and contains Omega-3s that experts say provides health benefits. Randomized clinical

trials show improved retinal and neural maturation for term and pre-term infants supplemented with Omega-3s.

- Consumer advice to a subpopulation will harm public health if it scares the general public away from eating a nutritional food that poses no risk.
- Recent nutritional advice from FDA encourages fish consumption.
- The American Heart Association's "Eating Plan for Healthy Americans" recommends that consumers "enjoy at least 2 servings of baked or grilled fish each week"
- Mixed messages from FDA and other authorities will confuse consumers and undermine FDA credibility.
- To be effective, consumer advice should be clear and consistent over time.

4. Additional information from the Seychelles study this spring should be considered before any revision of FDA's consumer guidance.

   - This information will allow for the first time a direct comparison of outcomes from identical test batteries in the Faroe and Seychelles Island studies.
   - The Seychelles population is not exposed to the unique risks posed by the episodic consumption of whales in the Faroe Islands population that has confounded analysis.
   - Seychelles and U.S. exposures are both through fish consumption.
   - New information may draw into question the validity of the Faroe Island study.
   - FDA's credibility is undermined if it supports research but acts without considering the results.

5. FDA should consider these other factors in deciding whether and how to revise its current consumer guidance:

   - Whether the agency has a clear and consistent rationale and process for issuing consumer advisories concerning unavoidable contaminants.
   - The precedent that would be established for issuing FDA advisories for other food-borne risks.
   - The need to precisely define the distribution of exposures for sub-populations especially any at-risk subpopulation using information from the NHANES mercury exposure study.
   - Whether methylmercury levels in fish are changing over time.
   - Support of stakeholders and public health professionals in assisting FDA communicate its advice to consumers.
   - **The impact any advisory would have upon FDA's current defect action level for methylmercury and the impact of any lower DAL upon the future supply of food, FDA resources, and the economy.**