

**MINUTES**  
**Of the**  
**Food Advisory Committee**  
**METHYL MERCURY**  
**Meeting**  
**December 10–11, 2003**  
**Hotel Washington**  
**Washington, DC**

*Members present:* Sanford A. Miller, Ph.D., Chairman; Alex Acholonu, Ph.D.; Marion Aller, D.V.M.; H. Vas Aposhian, Ph.D.; Douglas L. Archer, Ph.D.; Frank Busta, Ph.D.; Patrick S. Callery, Ph.D.; Annette Dickinson, Ph.D.; Goulda A. Downer, Ph.D.; Richard A. Durst, Ph.D.; Johanna Dwyer, Ph.D.; Jean M. Halloran; Douglas C. Heimbürger, M.D., M.S.; Norman Krinsky, Ph.D.; Daryl B. Lund, Ph.D.; Mark F. Nelson, Ph.D.; Linda Reed, Food Advisory Committee, Acting Executive Secretary; Robert M. Russell, M.D.; Clifford Scherer, Ph.D.; Carolyn I. Waslien, Ph.D., R.D.

*Food and Drug Administration (FDA) representatives: (Center for Food Safety and Applied Nutrition – CFSAN)* Mr. Joseph A. Levitt; David Acheson, M.D.; Bob Buchanan, Ph.D.; Clark Carrington, Ph.D.; Marjorie Davidson, Ph.D.; Ms. Catherine DeRoever; Ms. Jeanne Latham; Kathleen Jones, Ph.D.; Mr. Richard Bonnette; Mark Hepp, Ph.D.; Ms. Sylvia Washington; Ms. Linda Hayden; Ms. Carolyn Jeletic

*Environmental Protection Agency (EPA) representatives:* Ms. Denise Keehner; Mr. Jim Pendergast; Rita Schoeny, Ph.D.; Mr. Jeff Bigler

*Public speakers:* Dr. Roger Clemens, on behalf of the International Formula Council (IFC); Ms. Sally Fallon, The Weston A. Price Foundation; Dr. William C. MacLean, on behalf of the IFC; Ms. Susan W. Marmagas, Physicians for Social Responsibility; Dr. David Wallinga, Institute for Agriculture & Trade Policy; Ms. Caroline Smith DeWaal, Center for Science in the Public Interest; Ms. Carol Stroebe, Children’s Environmental Health Network; Mr. Robert Collette, National Fisheries Institute; Dr. Edward Groth III, Consumers Union of the U.S.; Mr. Michael T. Bender, Mercury Policy Project; Dr. Susan Boehm, New York Academy of Science; Ms. Jane Houlihan, Environmental Working Group; Dr. Rhona Applebaum, National Food Processors Association; Dr. Diana Zuckerman, National Center for Policy Research for Women & Families; Dr. Joshua Cohen, Harvard Center for Risk Analysis; Dr. John Stiker, Bumble Bee Seafood; Dr. Lillian Beard, Pediatrician and Associate Clinical Professor of Pediatrics, George Washington University School of Medicine and Asst. Professor, Howard University College of Medicine.

**1. Welcome and Introduction**

Dr. Sanford Miller, Chairman, Food Advisory Committee (FAC), called the meeting to order at 9:40am, Wednesday, December 10, 2003.

**2. Conflict of Interest Statement: Linda Reed, Acting Executive Secretary, FAC**

**3. Opening Remarks**

Dr. Bob Buchanan, Senior Science Advisor, (CFSAN) presented for Joseph A. Levitt, who had been delayed. When Mr. Levitt arrived, he reported that he would retire from CFSAN at the end of the year; Dr. Robert Brackett will become CFSAN director in January 2004 and thanked the members for their service on the food advisory committee.

**4. Subcommittee Reports**

*a. Infant Formula*

Ms. Jeanne Latham reviewed the minutes of the November 2002 Ad Hoc Task Force meeting on this topic; the committee had no questions.

Public speakers:

Dr. Roger Clemens, representing the Infant Formula Council, presented the industry's perspective and guidelines as to when a new or changed infant formula requires documentation of nutritional adequacy and clinical or other testing.

Committee questions/concerns:

?? Infant development on breast milk versus formula (growth patterns associated with breast milk are known to be different).

?? Total development versus just growth in height and weight (this is being discussed but no standards have been identified).

Sally Fallon, The Weston A. Price Foundation, reported on studies finding toxins added or formed during the processing of soy for infant formulas, and associating soy formulas with autoimmune reactions and other harmful physical phenomena.

Committee questions/concerns:

?? Had this been discussed during the group meeting (no specific formula types had been distinguished).

?? These recommendations' difference from American Academy of Pediatrics (AAP) recommendations (the studies are recent and the AAP has not yet responded to the

foundation's reports or requests to meet).

- ?? Long-term (presenting after 6 months) impacts on infant development.
- ?? The amount of data supporting these findings.
- ?? The statistical significance of a JAMA study that was reported as supporting soy formula (not significant; study small and flawed).

**b. Contaminants and Natural Toxicants (CNT)**

Dr. Frank Busta and Ms. Jeanne Latham reviewed the minutes of the March 2003 CNT subcommittee meeting on *Enterobacter sakazakii* in powdered formula.

Committee questions/concerns:

- ?? Which infants are at risk (those born prematurely).
- ?? The robustness of *E. sakazakii* (can live in dry formula, but postprocessing contamination is an issue).
- ?? *E. sakazakii* source (traced to processing plant environments, suggesting a potential intervention).
- ?? Infants in Africa and other developing regions (sterilized liquid formula not logistically feasible; hotter water to rehydrate the formula could destroy nutrients).
- ?? What the committee does with the subcommittee's report and recommendations (review these and decide what recommendations to make to FDA).
- ?? What the FDA is doing on this issue (preparing advisory documents, consulting with the U.S. Centers for Disease Control and Prevention [CDC], World Health Organization [WHO], Food and Agriculture Organization [FAO], Codex Alimentus, and other relevant organizations).
- ?? The need to inform doctors and food programs working with immunosuppressed infants.
- ?? U.S. formula producers' impact on the world market.

Public speakers:

William MacLean, representing the IFC, reported on the infant formula industry's response to the *E. sakazakii* issue, noting a relatively low incidence of *E. sakazakii* infections relative to other pathogens, and advocating better formula handling rather than eliminating powdered formulas.

Committee questions/concerns:

- ?? Infants in developing countries (HIV-positive mothers are increasingly medicated to minimize vertical HIV transmission and therefore their infants are less likely to have compromised immune systems; the role of water contamination and other improper handling).
- ?? Reference for the industry's testing methods, and the industry's role in advising practitioners (the industry will cooperate with both).

***c. Dietary Supplements***

Dr. Johanna Dwyer and Ms. Jeanne Latham reviewed the minutes of the March 2003 Dietary Supplements Subcommittee meeting, which focused on the definition of "metabolite."

Committee questions/concerns:

- ?? Discussion of safety in the definition (subcommittee considered this to be a legal issue, beyond their charge and covered by existing regulations).
- ?? Reason for definition (clarification for the legal definition of "ingredient").
- ?? Expansion of the definition beyond humans (beyond the subcommittee's charge); specification of humans in the definition.
- ?? Toxic metabolites of nontoxic substances (the subcommittee had only been charged to define metabolite).
- ?? Why "increased" production and flux (Dwyer referred the committee to expert testimony in the meeting transcript).
- ?? Efficacy, stereospecificity.
- ?? Purpose of committee discussing subcommittee findings in depth.

***d. Additives and Ingredients***

Dr. Johanna Dwyer and Mr. Richard Bonnette reviewed the minutes of the August 2003 Additives and Ingredients Subcommittee meeting, which focused on food-mediated latex allergy.

Committee questions/concerns:

- ?? Other allergenic components in gloves (composition varies widely).
- ?? Evidence weak but connection plausible; make recommendation?

- ?? Industry response to the issue.
- ?? Ranges and threshold for latex allergies.
- ?? Cross-allergies to various foods and the need to control for these.
- ?? The content and value of a public education campaign.
- ?? Restaurants' possible responses (e.g., "latex-free" signs).
- ?? Existing state regulation in face of low incidence and scant evidence; should the committee make recommendations.

***e. Food Biotechnology***

Dr. Frank Busta and Dr. Kathleen Jones reviewed the minutes of the September 2003 Food Biotechnology Subcommittee meeting.

Committee questions/concerns:

- ?? The Codex Alimentus is clear on the need for risk assessment; why did the subcommittee pass this over? (There is no indication of data outcome or how this fits into food safety.)
- ?? Researchers might find a toxin or allergen gene that could be turned on (but changes without effects are common; this might not be an efficient way to identify new hazards but could be a basis for further study).
- ?? New equipment can detect individual proteins in a product.
- ?? The possibility of industry sharing its data on what it alters and why (not all companies are forthcoming).
- ?? Translocation (both natural and man-made) likely to have an effect; gives some idea where to look.
- ?? Is FDA actively involved in biotechnology? (Reviewing and advising Codex Alimentus.)

The committee recommended that the committee report be amended to indicate the extensive discussion of the usefulness.

***f. Allergenicity***

This was not discussed, because due to an oversight the report was not included in the briefing book.

**5. Status Report and Response to FAC's Recommendations on Methylmercury**

## **(MeHg) in Fish and Shellfish**

### **6. FDA and EPA Development of Joint Advisory**

CFSAN's Chief Medical Officer, Dr. David Acheson and EPA's Denise Keehner reviewed the background and progress to date in the FDA's and EPA's development of a joint advisory regarding the consumption of MeHg-containing fish and shellfish by women of childbearing age and children.

Committee questions/concerns:

- ?? Which type of canned tuna has the greater market share (light).
- ?? The age and reliability of some FDA data, and will older data be merged with the new.
- ?? NHANES data.
- ?? The possibility of accessing industry data and its validity.
- ?? The difference between mercury and MeHg.
- ?? The role of geographic distribution.
- ?? The public's current perception of the mercury question and whether the FDA is working with the media.
- ?? Naming issues (a commercial fish name may cover multiple species; a single fish species may have multiple commercial names).

### **7. Exposure Assessment and Peer Review**

EPA's Dr. Rita Schoeny reviewed the quantitative exposure assessment used to develop the draft advisory, and how this was submitted to external peer review.

The Committee had no questions or concerns.

### **8. Exposure Assessment**

CFSAN's Dr. Clark Carrington reviewed the fish consumption scenarios used to project MeHg exposure and recommended consumption limits.

Committee questions/concerns:

- ?? The difference between the average population and specifically vulnerable subpopulations, and which group to consider when setting levels.

- ?? A study linking lower mercury excretion levels with autism, and ongoing issues concerning mercury in vaccines.
- ?? Analogies to the sector's experience with perinatal alcohol consumption, and phenylketonurics and aspartame.
- ?? The definition of medium versus low mercury levels.
- ?? The model's data source.
- ?? The public's perception of the mercury issue, and the danger that people will avoid fish and thereby sacrifice various nutrients.

## **9. Focus Group Testing**

CFSAN's Dr. Marjorie Davidson reviewed the findings of focus groups asked to review the draft advisory.

Committee questions/concerns:

- ?? The educational and other demographic features of the focus group participants.
- ?? The need to reach possibly isolated ethnic and other groups with different dietary patterns.
- ?? The focus group process and its validity.
- ?? The process of behavior change, and the need to plan how to do this.
- ?? The possibility of multiple advisories, each customized for a specific subpopulation.

## **10. The Draft Joint Advisory**

CFSAN's Dr. David Acheson and EPA's Jim Pendergast reviewed the current draft advisory.

Committee questions/concerns:

- ?? Whether the message, in being made comprehensible, has been simplified beyond meaning and science.
- ?? How the draft advisories were presented in the focus groups.
- ?? The danger that people will interpret "limit" as "avoid," and the possibility of adding text recommending "good" fish and referring to additional information.
- ?? The need to balance risks and health benefits.

- ?? Confusion over portion sizes and fish names.
- ?? The possibilities of lists ranking fish according to safety.
- ?? The legal implications of text “guaranteeing” following these guidelines will avoid risk and reap benefits.
- ?? Whether the message, and the media through which it will be distributed, are accessible by less-educated women, immigrants, ethnic groups, and other subpopulations.
- ?? The need to state up front the message the FDA wants the public to get.
- ?? The possibility of involving restaurants, grocery stores, and other commercial interests.
- ?? NHANES data.
- ?? The implications for regions without significant nonfish protein sources.

**a. Public speakers:**

Ms. Susan W. Marmagas, of Physicians for Social Responsibility, reported on her organization’s concerns regarding the advisory in its present form.

The committee had no questions or concerns.

Dr. David Wallinga, of the Institute for Agriculture & Trade Policy, reported on his organization’s *Smart Fish Guide*, a brochure on perinatal and childhood fish consumption. He also reported on a study by Jane M. Hightower that found symptoms associated with mercury poisoning in adults who were heavy fish consumers.

The committee had no questions or concerns.

Ms. Caroline Smith DeWaal, of the Center for Science in the Public Interest, reported on her organization’s concerns regarding the advisory in its present form.

The committee had no questions or concerns.

Ms. Carol Stroebel, of the Children’s Environmental Health Network, reported on her organization’s concerns regarding the advisory in its present form.

Committee questions/concerns:

- ?? Whether Stroebel’s projected number of children at risk wasn’t conservative.

Mr. Robert Collette, of the National Fisheries Institute, reported on his organization’s concerns regarding the advisory in its present form.

The committee had no questions or concerns.

Dr. Ned Groth , of the Consumers Union, reported on his organization's concerns regarding the advisory in its present form.

The committee had no questions or concerns.

Dr. Michael Bender, of the Mercury Policy Project, reported on his organization's concerns regarding the advisory in its present form.

The committee had no questions or concerns.

Dr. Susan Boehm, of the New York Academy of Science (NYAS), reported on her organization's studies of mercury levels in sport-caught fish.

Committee questions/concerns:

- ?? Had the NYAS geographically mapped high- versus low-mercury fish.
- ?? Is dental amalgam mercury a significant source of aquatic mercury (ambient mercury cannot be traced to specific sources; in the New York/New Jersey area industrial wastewater and its treatment are known to be a major source).

Ms. Jane Houlihan, of the Environmental Working Group, reported on her organization's concerns regarding the advisory in its present form, based on her study of the focus group transcripts.

Committee questions/concerns:

- ?? The possibility of requiring the use of standardized, scientific fish names.
- ?? Whether to take a "guilty until proven innocent" attitude where there is little data.
- ?? Possible better sources than food surveys to assess what the public is eating.
- ?? The value of comprehensive, ongoing testing to track MeHg levels over time, and whether or not to delay issuing the recommendations to accommodate more data.
- ?? The possibility of issuing a list of fish believed to be safe based on current data.
- ?? The possibility of low-mercury fish later being found to contain significant PCB levels.

Dr. Rhona Applebaum, of the National Food Processors Association, reported on his organization's concerns regarding the advisory in its present form.

Committee questions/concerns:

?? The possibility of the food industry collaborating on a mercury database.

?? Whether a government recommendation has ever successfully changed public behavior.

?? The risk of a simple message confusing the public regarding a larger issue.

Dr. Diana Zuckerman, of the National Center for Policy Research, reported on her organization's concerns regarding the advisory in its present form.

Committee questions/concerns:

?? The possibility of different advisories, designed for different groups, and the risk that this might be a source of confusion.

Dr. Joshua Cohen, of the Harvard Center for Risk Analysis, reported on an ongoing risk analysis study of mercury in seafood by his organization.

Committee questions/concerns:

?? When this study would be available (probably in 1 year).

?? The value of special advisories for specific populations.

?? Any forecasts of how this study would impact the current consensus.

?? Any forecasts of the advisory's impact on broader public health.

Mr. John Stiker, of Bumble Bee Seafood, reported on his company's concerns regarding the advisory in its present form.

Committee questions/concerns:

?? The relative Omega-3 contents of albacore versus light tuna (4.5–5 times more in albacore).

?? The impact on the tuna industry if the final recommendation emphasized light tuna over albacore.

?? Albacore's actual share of the U.S. tuna market.

Dr. Lillian Beard, a pediatrician, reported on her concerns regarding the advisory in its present form, citing anecdotal reports from her medical practice.

The committee had no questions or concerns.

## 11. FAC Discussion and Comments

The committee had no objections to the subcommittees' reports.

Dr. Miller reviewed the recommendations from the Food Advisory Committee, July 2002 that committee had been charged to review. The committee agreed that FDA substantially met the recommendations made by the committee.

In reference to the new joint advisory, the Committee has the following questions/concerns:

- ?? The exposure assessment, especially in relation to particularly vulnerable groups.
- ?? The value of individual advisories for specific groups (including clinicians, to help them work with their patients).
- ?? The use of scientific fish names to bridge regional and ethnic variations and aliases.
- ?? The value of the language on consuming a "variety" of fish.
- ?? Specifications regarding bodyweight, especially for children.
- ?? The need to specify serving guidelines and sizes.
- ?? The need to clarify the tuna advisory.
- ?? The need for better data and continuous testing, particularly more species and more samples of each species.
- ?? The wording of the message and the need to minimize the risk of any unintended consequences.
- ?? The need to better assess consumption patterns, especially among ethnic and other subgroups.
- ?? The issue of how the public will understand and act on the message.
- ?? The value of presenting specific behavioral steps.
- ?? The possibility of posting the current version of the recommendation on the FDA's Web page as a draft for comment.
- ?? The possibility of drawing on industry and state MeHg data.
- ?? The possibility of the FDA hiring communication experts to work on the advisory.
- ?? The need for objective criteria to define high-, mid-, and low-mercury fish, and a protocol

for adding and deleting fish to the “do not eat” list as more data are received.

- ?? The need to educate the public on the difference between albacore and light tuna.
- ?? The possibility of adding a disclaimer that the recommendations are based on extant data and may change as more data are collected.
- ?? The possibility of an “eat freely” (very-low–mercury) list of fish.
- ?? The value of including ranges and statistical analysis, and references to Web pages with more information.
- ?? The possibility of a single advisory, but multiple outreach formats and media, tailored to specific subgroups.
- ?? The importance of focus group testing of different versions.
- ?? The importance of developing related educational materials.

Because of time constraints, the committee did not have time to vote on which recommendations should be forwarded to the FDA/EPA as the highest priority. The members agreed to review the meeting transcript and afterwards decide on this.

## **12. Adjourn**

The meeting was adjourned at 4:00pm on Thursday, December 11, 2003.

Respectfully Submitted:

Linda L. Reed  
Acting Executive Secretary  
Food Advisory Committee

Certified:

Sanford A. Miller, Ph.D.  
Chairman  
Food Advisory Committee