

FDA and EPA Development of a Joint Advisory for Methylmercury-containing fish and shellfish for Women of Childbearing age and Children.

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Purpose of the FAC meeting

The purpose of the FAC meeting was to provide a report of how FDA has responded to the FAC recommendations in developing a revised joint advisory with EPA that addresses both commercial and locally caught fish.

Structure of the presentations

1. Status report of how FDA has responded to the previous FAC recommendations.
 - Description of the process involved in developing a revised advisory based on the recommendations.
2. Review of the exposure assessment
3. Discussion of focus group testing of the revised advisory.
4. The final draft advisory – post focus groups
5. FAC comments

Status Report

Outline

- Background of relevant recent history in relation to the current advisory
- Process involved in responding to the six primary recommendations from the 2002 Food Advisory Committee meeting
- Response to the recommendations
- Question to the 2003 Food Advisory Committee

Background

- 2001 FDA and EPA issued advisories on fish consumption.
- 2002 FDA Food Advisory Committee asked to evaluate the advisory.

2001 - FDA Advisory

- Avoid Shark, Swordfish, King Mackerel, Tilefish
 - Aimed at women of childbearing age and young children.
- Eat up to 12oz/week of a variety of other fish
 - Aimed at women of childbearing age
- Follow EPA advice for recreationally caught fish

2001- EPA Advisory

- Limit consumption of freshwater fish caught by family and friends to one meal/week
 - Adult -- 6 ounces cooked, 8 ounces uncooked
 - Child --2 ounces cooked, 3 ounces uncooked
- Applies to areas where states have not provided advice about untested waters
- Check with state or local health department for advice on waters where friends /family fish
- Target -- women who are of child-bearing age and children
- Follow FDA advice for ocean, commercial fish

FAC 2002 - Charge

The Committee was asked to evaluate whether the FDA's consumer public health advisory on methylmercury provides adequate protection for pregnant women and women of childbearing age who may become pregnant

FAC 2002 - Recommendations

1. Better define what is meant by "eat a variety of fish",
2. Work with other federal and state agencies to bring commercial and recreational fish under the same umbrella,
3. Publish a quantitative exposure assessment used to develop the advisory,

FAC 2002 - Recommendations

4. Develop specific recommendations for canned tuna, based on a detailed analysis of what contribution canned tuna makes to overall methyl mercury levels in women,
5. Address children more comprehensively in the advisory,
6. Increase monitoring of methyl mercury to include levels in fish and the use of human biomarkers.

Process to address the
recommendations

Key Process Milestones

- Fall 2002: EPA Administrator and Secretary of HHS exchange letters agreeing to collaborate and “bring commercial and recreational fish under the same umbrella advisory”.
 - Follow-up meeting held between Director of FDA’s Center for Food Safety and Applied Nutrition and EPA’s Assistant Administrator for the Office of Water
- Feb 2003: Set up joint working and leadership group from FDA/EPA
 - Staff and managers from FDA/EPA

Key Process Milestones (con)

- 2002-03: FDA undertakes exposure assessment
- April 2003 to present: Weekly meetings and joint work between FDA and EPA
 - Planned and completed independent external peer review of exposure assessment and revised exposure assessment,
 - Planned and held 4 stakeholder meetings,
 - Planned and produced draft joint advisory,
 - Planned and held 8 Focus Groups in 4 different locations across the U.S. and revised draft advisory on basis of Focus Group input,
 - Planned and prepared materials for this FAC

Key Process Milestones (con)

- July 2003: Stakeholder meetings
 - EPA/FDA met with industry, consumers and health professionals, States and Tribes and reported on progress in responding to FAC recommendations of July 2002
 - Shared with Stakeholders a tentative timeline that included Focus Group testing of a draft advisory in November and a public meeting in Fall of 2003

Key Process Milestones (con)

- July 2003: Stakeholder meetings (con)
 - Key messages from Stakeholder meetings included:
 - Need to continue research, bring new data and science into future revisions; but, important to move forward now
 - Some concern about accuracy of tissue data in model
 - Concern about balanced message vis-à-vis fish in diet
 - Proposed timeline seems ambitious; important to have Focus Groups and time for States to be on board
 - Effective outreach and implementation to get the message out are critically important to achieving public health goals

Key Process Milestones (con)

- September/October 2003: Developed draft joint advisory
 - Initial draft advisory was 2 and ½ pages in length
- November 2003: Focus Group testing and real time revisions
 - 8 Focus Groups in 4 different locations
 - Testing of advisory resulted in substantial revisions after first Focus Group in Calverton, Maryland: message not received
 - Lesser refinements occurred after subsequent Focus Groups

Key Process Milestones (con)

- December 2003: Public meeting/presentation at FDA FAC
 - Presenting “final” draft advisory (post Focus Groups)
 - Looking for concurrence on readiness to move forward

Response to Recommendations

Response to recommendations

1. Better define what is meant by “eat a variety of fish”

- Consider a variety of methods
 - Lists of fish
 - Expanded language
 - Shorter explicit language
- Tested some of these in focus groups

Response to recommendations

2. Work with other federal and state agencies to bring commercial and recreational fish under the same umbrella,

- Close collaboration between FDA and EPA to develop a single joint advisory concerning commercial and recreationally caught fish,
- Interacted with States during this process through Stakeholder meetings.

Response to recommendations

3. Publish a quantitative exposure assessment used to develop the advisory

- Quantitative exposure assessment developed in early 2003.
- Presented publicly as a poster in March 2003
- External peer review in August 2003
- Revised exposure assessment December 2003
 - New data on mercury levels in fish
 - Comments from the peer review

Response to recommendations

4. Develop specific recommendations for canned tuna, based on a detailed analysis of what contribution canned tuna makes to overall methyl mercury levels in women

- Canned tuna comprised of two main types.
 - Albacore/white
 - Light
- Canned tuna is one of the most frequently consumed fish in the United States
- Exposure assessment scenarios address tuna specifically
- New data on levels of mercury in canned tuna
- Specific statement regarding canned tuna added to the advisory

Response to recommendations

5. Address children more comprehensively in the advisory

- FDA and EPA determined that there was no scientific consensus to define a specific age or weight in the revised advisory.
- More emphasis on young children in the revised advisory
 - In the title
 - In the text
 - Not limited to the “Do Not Eat” list
- Statement added indicating children should eat less than the 12oz because they are smaller.

Response to recommendations

6. Increase monitoring of methyl mercury to include levels in fish and the use of human biomarkers.

- Two new assignments to measure mercury in fish in United States commerce completed in 2003
 - 12 different species of fish – total of 224 samples
 - Canned tuna
 - 170 samples of albacore/white
 - 119 samples of light

Question to the FAC

- Given the enormous interest and expectations from all perspectives on this issue, the one important point we believe all agree on, is that we move forward and begin our education program.
- As we learn more from scientific findings, population demographics, NHANES and receive results from the education effort on consumer behavior, we may need to refine the approach.
- We believe that this activity is best conducted concurrently with an outreach and educational program that in the interests of public health should commence as soon as possible . We therefore seek the Committee's concurrence.