FDA and EPA Development of a Joint Advisory for Methylmercury-containing Fish Consumption for Women of Childbearing Age and Children.

Welcome and Purpose of the Meeting

One of a Series of Meetings Held by FDA and EPA

- Meeting with various groups:
  - Industry
  - Consumers and health professionals
  - States
  - Tribes

Purpose of the Meeting

- To report and inform stakeholders of progress to respond to FAC recommendations re: methylmercury consumer advisory

Purpose of the Meeting

Based on FAC recommendations, we will present information on the following:

- To provide an understanding of the current approach being taken by FDA and EPA in developing a joint advisory
- To provide a brief background on how we got to this point
  - 2001 advisories
  - 2002 FDA Food Advisory Committee
- To present an exposure assessment with various scenarios

Purpose of the Meeting

Based on FAC recommendations, we will present information on the following:

- To address the level of protection based on the exposure assessment
- To describe the elements needed for a joint message
- Describe the process as we move forward from here

Purpose of the Meeting

At a future date, FDA and EPA will seek stakeholder comment and input into the consumer advisory

Today, we are here to provide a progress report and present some important information

Questions of clarification?

FDA and EPA Development of a Joint Advisory for Methylmercury-containing Fish Consumption for Women of Childbearing Age and Children.

Background

Background

2001 – FDA and EPA issued advisories on fish consumption

2002 – FDA Food Advisory Committee made a number of recommendations in relation to the FDA advisory.

Current FDA Advisory for Pregnant Women and Women of Childbearing Age

- Avoid Shark, Swordfish, King Mackerel, Tilefish
- Eat up to 12oz/week of a variety of other fish
- Follow EPA advice for recreationally caught fish
- Prudent for nursing mothers and young children not to eat Shark, Swordfish, King Mackerel, Tilefish

Current 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 methyl mercury 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.

Current Effort and Goal

- To respond to the recommendations from the FAC and incorporate these findings in order
  - To develop a joint FDA and EPA advisory for women of childbearing age and young children that addresses both commercial and recreational fish.

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At Risk Population

At-risk Population

- Current science indicates that the developing neurological system is very sensitive to toxicity of methyl mercury.
- Focus of advisory is on protecting the developing brain from methyl mercury exposure via fish consumption

At-risk Population and Target of the Advisory

- Women of child-bearing age
  - Women who are pregnant
  - Women who could become pregnant
  - Nursing mothers
- Young children

How Effective are we?

- What percentage of the at-risk population is below the reference dose (RfD) of 5.8 µg methylmercury /L blood?
- CDC addressed this question through the National Health and Nutrition Examination Survey (NHANES)

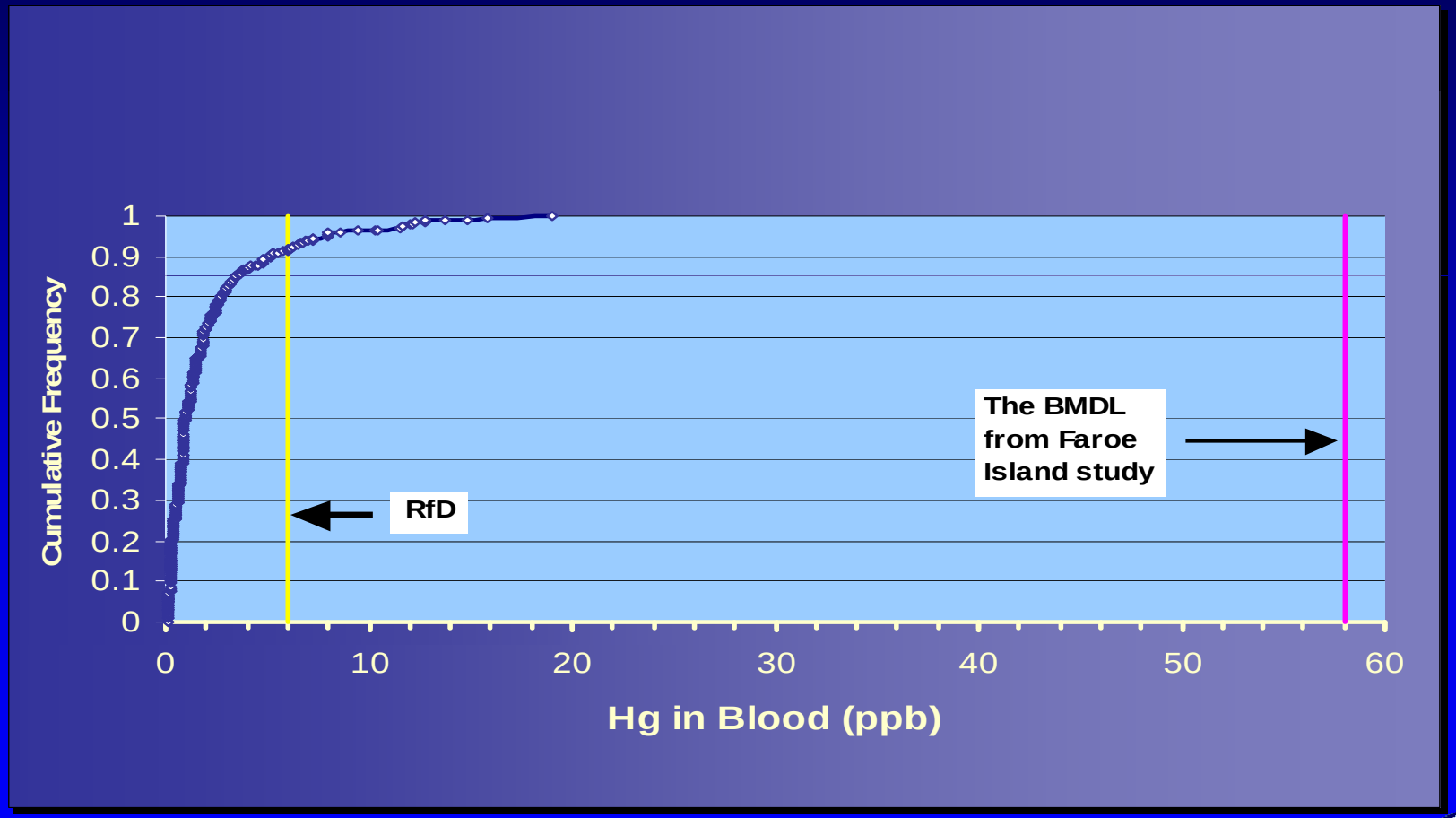
Blood Mercury Levels in US Children and Women of Childbearing Age 1999-2000 [JAMA 2003; 289:1667]

- Subjects:
  - 705 children
  - 1709 women
- Results:
  - Children – mean 0.34 μg Hg/L (95%CI 0.30-0.39)
  - Adults – mean 1.02 μg Hg/L (95% CI 0.85-1.20)

Blood Mercury Levels in US Children and Women of Childbearing Age 1999-2000 [JAMA 2003; 289:1667]

- Results:
  - 7.8% of women had blood mercury levels 5.8 μg/L or higher.
  - Mean blood mercury approximately 4 fold higher in those that ate fish in the past 30 days
  - Otherwise little information about the details of the 7.8%

Blood Mercury levels



Blood Mercury Levels in US Children and Women of Childbearing Age 1999-2000 [JAMA 2003; 289:1667]

- Questions about the 7.8%
  - Geographic distribution
  - Eating habits
  - Commercial vs. recreational fish
  - Source of fish
  - Socioeconomic information
  - Ethnic information
- What other new information could be used to refine and target advisory in the future?

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Estimating Exposure

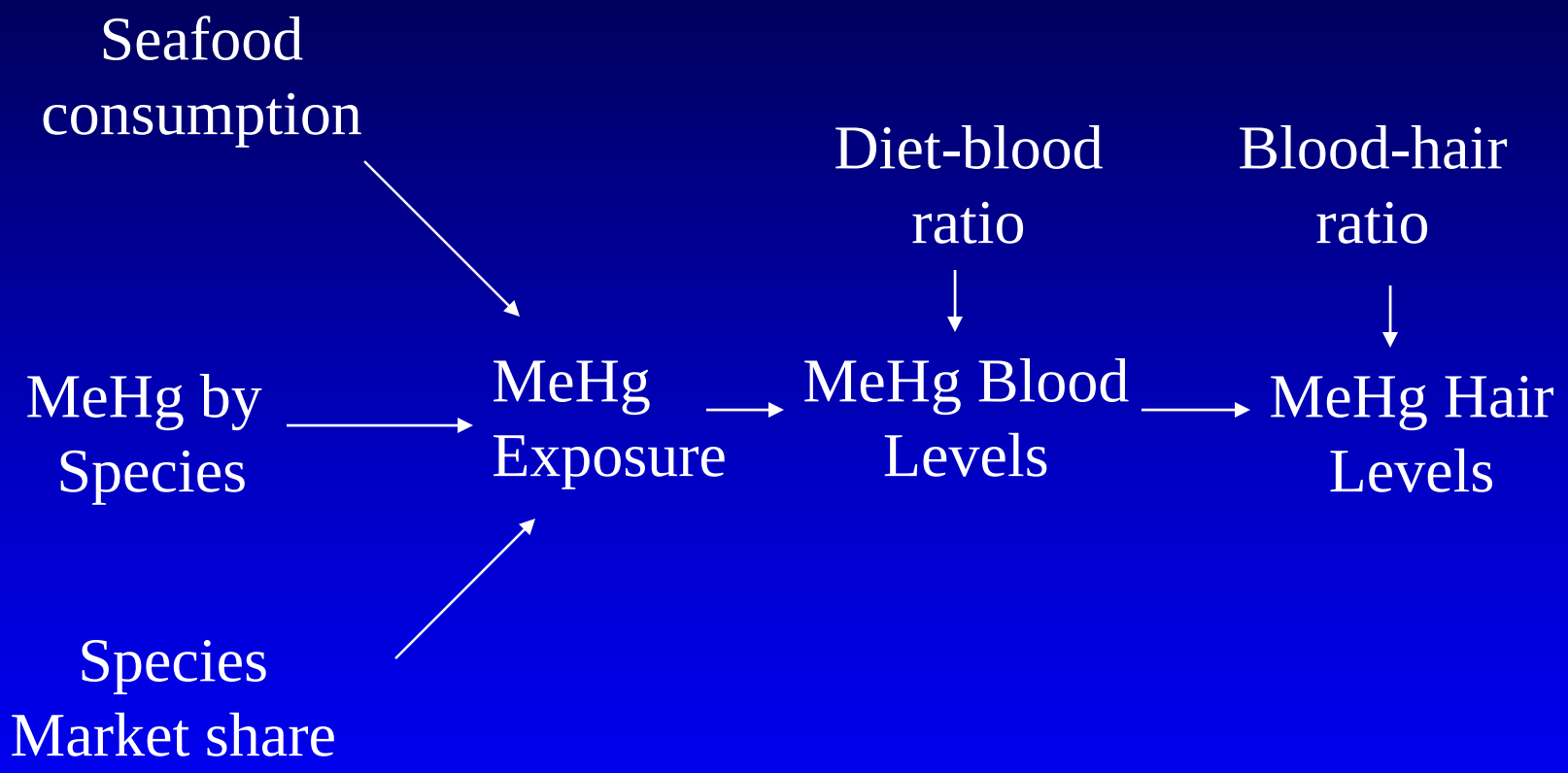
Exposure Assessment Outline

- Methods used
- Consumption/Exposure Scenarios tested
- Results

Methods

- Step 1: estimate of consumption and exposure
  - Age, sex, body weight.
- Step 2: estimate of blood and hair levels
- A probabilistic approach was used throughout

Methods



Exposure Simulation

- Short term consumption (3 day)
- Long-term purchase diaries
- Market share data

		Mean Hg (ppm)
• Shrimp	19.6%	0.02
• Tuna (light)	15.7%	0.13
• Salmon	11.1%	0.02
• Pollock	10.3%	0.07
• Catfish	7.6%	0.08
• Tuna (albacore)	6.5%	0.32
	70.8%	

Scenarios

- Based on the exposure data a number of scenarios were considered
- For the scenarios fish were divided into high, medium and low MeHg
  - High: Swordfish, Shark, Tilefish, King Mackerel
  - Medium: Fish > 0.13 ppm (e.g. Albacore Tuna, Halibut, Tuna steaks, Rockfish, Haddock, American Lobsters)
  - Low: Fish $\leq$ 0.13 ppm (e.g. Light Tuna, Cod, Pollock, Catfish, Shrimp, Salmon, Flatfish, Scallops, Clams, Sardines, Oysters)

Scenarios (weekly consumptions)

1. No dietary exclusions at all
2. **12 oz Unrestricted Medium/Low but No High: Combination of 12 oz from medium and low groups only.**
3. 12 oz variety: Combination of 12 oz from medium and low groups, but not more than 6 oz from the medium group.
4. 12 oz variety or 6 oz albacore: Same as scenario #3 but albacore counts double for purposes of the 12oz limit.
5. 12 oz variety or 6 oz medium: Same as scenario #3 but all medium fish count as double for 12 oz limit.
6. 12 oz low: Only fish from the low group

Results

μg hg/L blood

Scenario	Average	Max	%>RfD
1. No exclusions	1.4	37.7	3.9 (2.9-5.6)
2. 12 oz unrestricted	**1.2**	**14.0**	**1.0 (0.3-2.5)**
3. 12 oz variety	1.2	13.1	1.0 (0.3-1.8)
4. 12 or 6 albacore	1.2	13.3	0.6 (0.2-1.3)
5. 12 or 6 medium	1.1	9.1	0.1 (0.1-0.4)
6. 12 oz low	0.7	3.9	0.0 (0.0-0.0)

Conclusions

- The model closely predicts the NHANES data showing population exceeding Rfd
  - FDA and EPA's Office of Water believe this will therefore be a useful tool in establishing the scientific background for an advisory
  - FDA and EPA's Office of Water are submitting this exposure assessment for peer review
  - FDA and EPA's Office of Water believe the scenarios offer a way to inform the risk management decisions

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Determining the Desired Level of Protection

Desired Level of Protection

Various factors, positive and negative, have to be taken into account, in developing a risk management approach:

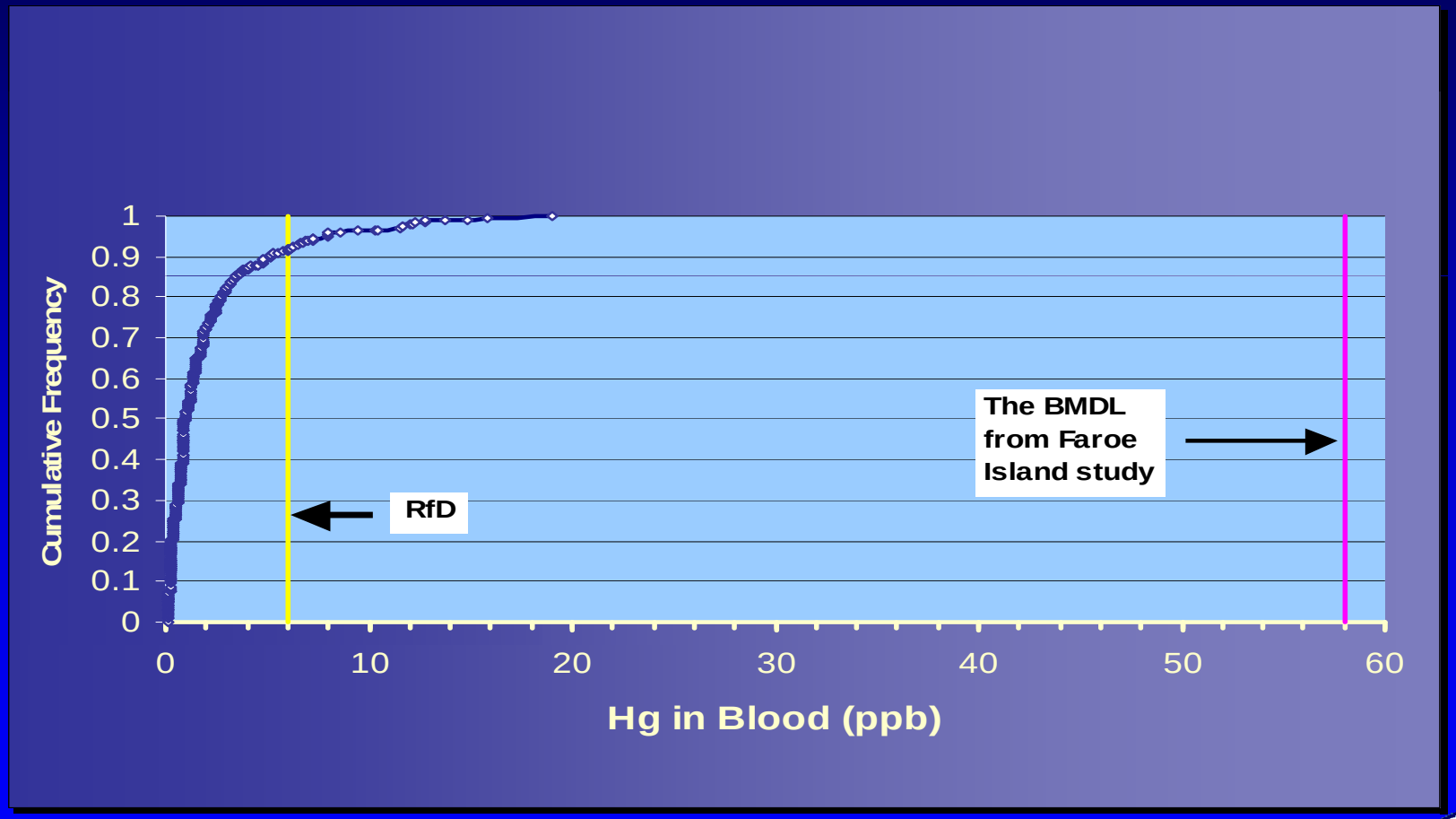
- Fish is a good source of protein
- Fish provides important nutrients
- Fish is generally affordable
- Fish may contain substances that are harmful to health
- Public health message must acknowledge full spectrum of dietary choices for a healthy diet

Risk Management Decision-making

- NHANES indicates approx. 8% of at-risk population above the RfD

- How much can this percentage of the at-risk population be reduced, and still provide consumers with a variety of good sources of protein for a healthy diet?

NHANES Blood Mercury Levels



Establishing a Level of Protection

Two goals:

- Lower the risk of the at-risk population through lowering blood mercury levels
- Maximize the benefits of consuming fish.

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Developing an FDA/EPA Advisory

Current Methylmercury Advisory has Two Main Elements

Risk Message

Consumption Advice

Risk Message

- Who is at risk
- Why they are at risk

Current Consumer Advice

- Do not eat shark, swordfish, King Mackerel, Tilefish
- Eat up to 12 ounces of a variety of fish a week

Current Advice on Non-commercial Fish

- FDA: Check EPA and state advice
- EPA: Check for local advisory. If none, eat non-commercial fish once a week.

FAC Recommendations

- Better define what is meant by “eat a variety of fish”
- Develop specific recommendations for canned tuna
- Bring commercial and recreational fish under the same umbrella
- Specific advice for children

Focus Group Testing of Approaches to Consumer Advice

Upon RM decision, craft joint message(s) and test using focus groups.

Focus groups serve purposes of:

-Understanding message content and associated risk

-Clarity of the information and its content

-Determine if consumers will act on the advice

Questions of clarification

Milestones and Tentative Time Line

Tasks	Dates
Meetings with Stakeholder Groups and Federal Agencies	Week of July 30, 2003
Public Meeting	Fall 2003
Finalize Draft Consumption Recommendations and Implementation Strategy	October/November 2003
Conduct Focus Groups	November 2003
Finalize and Announce New Advisory	December 2003
Implementation of New Advisory	Beginning 2004

Next Steps

- Feedback today on the progress and joint approach taken by FDA and EPA
- How else can stakeholders be involved in this process?

General Discussion