



**North Carolina Department of Health and Human Services**

2001 Mail Service Center • Raleigh, North Carolina 27699-2001

Tel 919-733-4534 • Fax 919-715-4645

Michael F. Easley, Governor  
H. David Bruton, M.D., Acting Secretary

A. Dennis McBride, M.D., M.P.H.  
Assistant Secretary for Health and State Health Director

February 7, 2001

Ms. Betsy Southerland, Director  
Standards and Health Protection Division  
US Environmental Protection Agency - 4305  
Room 515B - West Tower  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

Mr. Bernard A. Schwetz  
Acting Principal Deputy Commissioner  
US Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857-001

Dear Ms. Southerland and Mr. Schwetz:

I am writing in response to the January 12 national fish consumption advisories on methylmercury in fish issued by US Environmental Protection Agency (EPA) and the US Food and Drug Administration (FDA). North Carolina supports EPA and FDA's decision to increase the public awareness of the risks of methylmercury found in seafood to the developing fetus and possibly to children. North Carolina would like to work with both agencies in this public awareness campaign.

My staff and I have reviewed both advisories and would like for both agencies to consider the following comments:

**1. Question for US FDA**

**Is the FDA advisory for fish bought from stores and restaurants only or does it include recreationally caught fish?**

It is unclear from the FDA advisory if the no consumption advice for shark, swordfish, king mackerel, and tilefish and the limited consumption advice (12 ounces per week) applies to fish from stores, restaurants, or to recreationally caught fish. According to the enclosed EPA advisory fact sheet, the FDA limited fish consumption advice is for fish bought from stores or restaurants. In order to reduce confusion, it is recommended that this be clarified in the FDA advisory.

**2. Question for US FDA**

**If the FDA advisory is for fish bought from stores and restaurants only, then did FDA base the advisory on methylmercury levels found in fish classes that are routinely processed for restaurants and stores? What are the average methylmercury levels of shark, swordfish, tilefish and king mackerel that are bought nationwide by consumers from stores and restaurants?**



829

On March 23, 2000 North Carolina, South Carolina, Georgia, and Florida jointly issued an advisory for king mackerel following the sampling of 181 king mackerel caught off the coasts of all four states (112 were collected off North Carolina coast from 1998 to 1999). This advisory was issued for recreationally caught king mackerel and not for commercially caught king mackerel sold in restaurants or stores.

The advisory issued for all four states is as follows:

King Mackerel > 39 inches (from the nose to where the tail forks) should not be consumed. The methylmercury levels for this size class were routinely greater than 1.5 ppm.

King Mackerel 33 to 39 inches (from the nose to where the tail forks) should be limited. Children and women of childbearing age should eat no more than 1 meal a month; all other adults eat no more than 4 meals a month. The methylmercury levels were, on average, between 0.5 to 1.5 ppm.

King Mackerel < 33 inches (from the nose to where the tail forks) had, on average, less than 0.5 ppm of methyl mercury and no advisory was issued for this size class.

This advisory was for recreational marine fishermen only and did not include commercial king mackerel from restaurants and stores. According to the North Carolina Division of Marine Fisheries, the king mackerel size class routinely processed by North Carolina processors for restaurants and stores is 33 inches or less. The average methylmercury level for this size class was approximately 0.5 ppm or less. If the FDA no consumption advisory is for fish consumed from stores and restaurants, then the advisory should be based on methylmercury levels expected in commercially consumed fish.

3. **Questions for US FDA and US EPA**

**Which species of tilefish and shark were tested that served as a basis for issuing this advisory? What were the locations and sizes of the king mackerel, shark, swordfish and tilefish sampled?**

There are at least six species of tilefish (including golden, blueline, and sand) and more than 50 species of sharks that are harvested along the east coast of the United States. North Carolina does not have adequate methylmercury data for sharks, swordfish, and tilefish to assess the risk from exposure.

4. **Question for US EPA**

**If the FDA advisory is for commercially available fish only, are recreational fishermen protected? Is EPA considering issuing an advisory for recreationally caught king mackerel or other saltwater species?**

For example, the methylmercury levels in the king mackerel size class routinely caught recreationally was of most concern in North Carolina. The methylmercury levels for king mackerel of 33 to 39 inches, a size more typically taken by recreational fisherman, ranged from 0.5 to 1.5 ppm. The largest size class of king mackerel tested (> 39 inches) had

methylmercury levels consistently above 1.5 ppm. This largest size class is predominantly harvested by recreational fishermen. Commercially harvested king mackerel was expected to have levels on average less than or equal to 0.5 ppm, well below the FDA action level of 1 ppm.

5. **Question for US FDA**

**Why doesn't the FDA no consumption advice specifically include women who are or may become pregnant, nursing women and young children?**

Under question 2 of the attached FDA advisory, the populations that are to follow the no consumption advice for shark, swordfish, king mackerel, and tilefish are not clearly identified. FDA does advise women to protect unborn children by not eating the four species and further states that it is prudent for nursing mothers and young children to not eat these fish. A woman who may not be aware of her own pregnancy or pregnant woman may not understand the advisory. In order to reduce confusion, it is recommended to include all groups that are of concern together. For example, the wording might be "FDA advises that pregnant women, women who may become pregnant, nursing women and young children not eat shark, swordfish, king mackerel, or tilefish."

6. **Question for US FDA**

**Why doesn't the FDA limited consumption advice specifically include women who are or may become pregnant, nursing women and young children?**

Under question 3 of the attached FDA advisory, FDA advises women who are pregnant or who may become pregnant can safely eat 12 ounces per week of cooked fish. The FDA no consumption advice included nursing women and children. The groups need to be the same in both advisories. The risk to nursing infants and children are expected to be lower than to fetuses, but there is much we do not know about the risks to infants and children. Because of the uncertainty in the risk to infants and children, it is recommended to include nursing mothers and children in the limited consumption advice. Furthermore, US EPA includes all of these groups in their national freshwater fish consumption advisory. This is confusing. Consistency would be helpful to the states in delivering these messages. "Children" should be defined (by age), and FDA should provide the recommended meals per week for children.

7. **Question for US FDA and US EPA**

**Why do FDA and EPA recommended meal sizes differ for women who are pregnant or may become pregnant?**

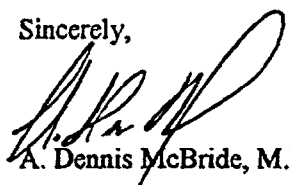
Regardless of whether the fish comes from a store, restaurant, or freshwater; the methylmercury levels should be similar with the exception of those species that are under advisory. The FDA advisory recommends twice the meal size of EPA's (12 verses 6 ounces per week) for pregnant women or women who may become pregnant. This is confusing to state health officials and may be confusing to the public. The EPA advisory

states that if, in a given week, a woman eats 12 ounces of cooked fish from a store or restaurant, then she should not eat fish caught by your family or friends that week. This is not the message from FDA. The FDA advisory states that there is no harm in eating more than 12 ounces of fish in one week as long as you don't do it on a regular basis. Consistency would be helpful to the states, again, in delivering these messages.

8. **Question for US FDA and US EPA**  
How are US FDA and US EPA going to communicate these messages to the public and will states be involved in this process? North Carolina is interested in working with FDA and EPA in communicating health risks to the public with regard to fish consumption.

Please do not hesitate to contact my office at 919-715-3730.

Sincerely,



A. Dennis McBride, M.D., M.P.H.

ADM:lw

- c: Dr. Steve Cline, Section Chief for Section of Human Ecology and Epidemiology  
Dr. Louis Daniel, North Carolina Division of Marine Fisheries  
Mr. Mark Hale, North Carolina Water Quality Section  
Mr. Jeff Hayward, Toxicologist, North Carolina Division of Air Quality  
Mr. Bill Pate, Head of Medical Evaluation and Risk Assessment Unit  
Mr. Preston Pate, Head of North Carolina Division of Marine Fisheries  
Mr. Joe Reardon, NC Food and Drug Protection Division  
Dr. Bill Tynan, Head of Occupational and Environmental Epidemiology Branch  
Mr. Bruce Williams, Head of North Carolina Food and Drug Protection Division  
Dr. Luanne Williams, Scientific Advisor to NC State Health Director