



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

(82)

Food and Drug Administration
Rockville MD 20857

JAN 31 2001

The Honorable William J. Coyne
House of Representatives
Washington, D.C. 20515-3814

Dear Mr. Coyne:

Thank you for your letter of December 7, 2000, addressed to Jane E. Henney, M.D., former Commissioner of Food and Drugs, regarding the National Academy of Sciences (NAS) report, *Toxicological Effects of Methylmercury* and the Food and Drug Administration's (FDA) reassessment of its consumer guidance and action level for methylmercury in seafood.

FDA shares your concerns about human exposures to mercury and its compounds and believes that the NAS report represents a significant and important contribution regarding the health effects of methylmercury. FDA is carefully reviewing this report, as well as other information that continues to emerge from around the world regarding this important environmental issue.

FDA issued a new fish consumption advisory on methylmercury on January 12, 2001, (copy enclosed). As part of the decision-making process, FDA met with interested parties (consumers, industry, health care providers, etc.) to obtain various perspectives on this important issue. A copy of the questions asked of these groups also is enclosed. FDA also tested different types of messages with consumer focus groups to determine whether these types of messages are clearly understood and how they would be acted upon by consumers. These message tests helped determine the best ways of reaching the public with this important information.

This fiscal year FDA will develop an overall public health strategy for methylmercury in commercial seafood, including a review of the action level. In addition, FDA will need to reconsider the results of any additional studies on methylmercury in fish. This includes the results of the evaluation of the Seychelles Islands cohort study at seven

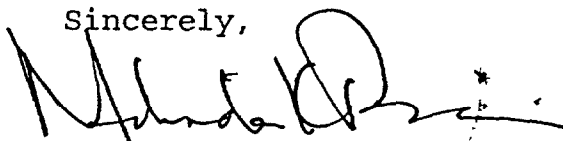
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years, which is expected to be available in the spring of 2001. This information will allow, for the first time, a side-by-side comparison between the Faroe Islands study, which reported results of evaluation of the children at seven years, and the Seychelles Islands study involving children evaluated at the same age using the same battery of neurologic tests. While methylmercury surveillance data has remained relatively stable for most species, FDA will consider additional steps as part of its overall strategy on methylmercury.

In closing, let me reiterate FDA's commitment to protecting the public's health and the environment regarding mercury. Please be assured that FDA will carefully evaluate the NAS report and all other relevant information and take appropriate actions based on that evaluation.

Thank you again for conveying your concerns about this important health issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'Melinda K. Plaisier', with a stylized flourish at the end.

Melinda K. Plaisier
Associate Commissioner
for Legislation

2 Enclosures



CONSUMER ADVISORY

Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration

January 2001

AN IMPORTANT MESSAGE FOR PREGNANT WOMEN AND WOMEN OF CHILDBEARING AGE WHO MAY BECOME PREGNANT ABOUT THE RISKS OF MERCURY IN FISH

Seafood can be an important part of a balanced diet for pregnant women. It is a good source of high quality protein and other nutrients and is low in fat.

However, some fish contain high levels of a form of mercury called methylmercury that can harm an unborn child's developing nervous system if eaten regularly. By being informed about methylmercury and knowing the kinds of fish that are safe to eat, you can prevent any harm to your unborn child and still enjoy the health benefits of eating seafood.

HOW DOES MERCURY GET INTO FISH?

Mercury occurs naturally in the environment and it can also be released into the air through industrial pollution. Mercury falls from the air and can get into surface water, accumulating in streams and oceans. Bacteria in the water cause chemical changes that transform mercury into methylmercury that can be toxic. Fish absorb methylmercury from water as they feed on aquatic organisms.

HOW CAN I AVOID LEVELS OF MERCURY THAT COULD HARM MY UNBORN CHILD?

Nearly all fish contain trace amounts of methylmercury, which are not harmful to humans. However, long-lived, larger fish that feed on other fish accumulate the highest levels of methylmercury and pose the greatest risk to people who eat them regularly. You can protect your unborn child by not eating these large fish that can contain high levels of methylmercury:

Shark
Swordfish
King mackerel
Tilefish

While it is true that the primary danger from methylmercury in fish is to the developing nervous system of the unborn child, it is prudent for nursing mothers and young children not to eat these fish as well.

**Food and Drug Administration's (FDA) Questions to
Interested Parties on Methylmercury**

1. Given the National Academy of Sciences (NAS) report and the emissions standards set by the Environmental Protection Agency, should FDA revise its advisory to consumers (and in particular to vulnerable populations such as pregnant women and women who may become pregnant)? If so, what should the new advisory say?
2. Given the potential nutritional contribution of fish and seafood to a healthful diet, should a consumer advisory be crafted so that it conveys the benefit/risk balance of methylmercury-containing fish? If so, what should be the content of such a message?
3. With additional Seychelles study data expected to be released next spring, what impact, if any, should such new data have on the timing and content of any FDA advisory?
4. What other factors, if any, should impact a decision on whether and how to revise the current consumer guidance?
5. What methods of communication should FDA use to best convey such a consumer advisory?
6. How could FDA measure its success in reaching the consumer audience, including vulnerable populations?