

July 6, 2006

Andrew von Eschenbach, M.D., Ph.D. Acting Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

RE: FDA SHOULD REQUIRE GROCERY STORES AND RESTAURANTS TO ADOPT LABELING ON OR NEAR SEAFOOD CONTAINING MERCURY

Dear Dr. von Eschenbach:

Last December, we wrote to you urging that FDA develop a point-of-purchase advisory on seafood containing mercury. Many health-conscious Americans consume seafood regularly as part of a balanced diet. However, seafood is the leading source of mercury in the diet, a chemical that causes neurological harm to an unborn infant if consumed shortly before or during pregnancy. Mercury in fish has been associated with several well-documented poisoning episodes that showed long-term impairment in children of mothers who consumed high does of mercury while pregnant.

In 2004, FDA and EPA issued a joint advisory on mercury in fish and shellfish, urging pregnant women and other high-risk consumers to avoid certain species. CSPI has new evidence documenting that the advisory did not effectively inform the public: many consumers remain unaware of the advisory while others have clearly misinterpreted it. Our survey also confirms that in order to protect high-risk consumers, including pregnant or breastfeeding women and those planning a pregnancy, FDA must give consumers the information where they most need it – at the fish counter or on packages of fish. Consumers have a strong preference for safety information in this format, as demonstrated by our recent random digit-dial telephone survey of 1018 adults conducted between June 22-25, 2006 by Opinion Research Corp.

Our nationally projectable survey showed that one out of three consumers did not know that certain fish and shellfish can be high in mercury and harmful to some people (14% answered NO, 19% answered DON'T KNOW). Twenty-one percent of consumers wrongly believed that salmon, a low-mercury containing fish, was among the fish the government urged high-risk consumers not to eat. That was higher than those who chose swordfish (20%), shark (17%), or king mackerel (15%), fish that are on the government's "DO NOT EAT" list for women who are pregnant, breastfeeding or those planning a pregnancy. Eighty to ninety percent of consumers could NOT correctly identify the fish the government recommends for their low mercury content, including salmon (21% correctly identified), shrimp (20%), catfish (17%) or pollock (11%).

¹ Further highlighting the confusion, another 21% correctly identified salmon as a low-mercury fish.

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Our survey revealed that 31 percent of women who were pregnant, breastfeeding, or planning a pregnancy did not know that certain seafood is dangerous for them to consume (17% answered NO, 14% answered DON'T KNOW). Meanwhile, 18 percent of low-risk consumers may have unnecessarily reduced their fish intake for reasons related to mercury. The FDA/EPA advisory is neither keeping high-risk consumers away from contaminated fish nor is it helping low-risk consumers to secure the health benefits only available at the fish counter. High-risk and low-risk consumers alike need an explicit reminder of which populations the high-mercury advisories target, as well as the fish that are high in mercury. This may bring some consumers back to the fish counter.

Consumers we surveyed expressed a strong preference (60% among high-risk consumers) for more information where they purchase seafood, including right on the package. In fact, these high-risk consumers supported by a margin of 12:1 labels on or near fresh fish with high mercury content as the single best way to inform consumers over the current practice of relying on government or industry websites. (Among all consumers surveyed, support for such labeling was equally strong, with a margin of 14:1.) Media, such as TV or newspapers, was mentioned by only 25% of high risk consumers as the best source of information on mercury in seafood.

This new research demonstrates that FDA should do more to get important health information to the high-risk groups about mercury in seafood, and we urge FDA to mandate the use of labeling at fish counters to do so. Section 201(n) of the FFDCA, 21 U.S.C. 201(n), gives the FDA that authority when it says that in determining if a food is mislabeled, the Secretary shall consider "the extent to which the labeling or advertising fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates . . . or under such conditions of use as are customary or usual." (Emphasis added.)

Clearly, pregnant women and their partners would want to know if a well-documented contaminant in certain seafood species might harm their unborn fetus, thus it is a material fact relating to conditions of use as are customary or usual. We urge that FDA require grocery stores and other retailers to place labeling or signage on or near all fish that FDA has listed among those that pregnant women and other high-risk consumers should avoid. After sufficient time for that policy to be implemented, FDA should prosecute retailers who fail to post or place such information under the "mislabeling" provisions of the Food, Drug and Cosmetic Act.

In 2003, Commissioner McClellan wrote to CSPI regarding the mercury advisory and said that "One of the key needs for an advisory to be successful is for it to be clear and well-communicated. There are many ways that this can be achieved, including the use of printed materials at the point-of-purchase." We hope that CSPI's survey of consumers will shed important light on what printed materials would be most effective and we look forward to working with you to implement this important public-health measure.

Sincerely,

Michael F. Jacobson, Ph.D. Executive Director

Caroline Smith DeWaal Director of Food Safety