DEPARTMENT OF HEALTH & HUMAN SERVICES



Office of Foods Food and Drug Administration Silver Spring, MD 20993

September 26, 2011

John Kaneko, MS, DVM Symposium Secretariat Hawaii Seafood Council 1130 N. Nimitz Highway Suite A-263 Honolulu, HI 96817

Dear Dr. Kaneko:

Thank you for your December 16, 2010 letter to Commissioner Hamburg, co-signed by 35 of your colleagues, in which you urge the U.S. Food and Drug Administration (FDA) to update its fish consumption advice to pregnant women, women who might become pregnant, nursing mothers and young children.

The fish consumption advice you refer to was issued in 2004 jointly with the U.S. Environmental Protection Agency (EPA). You express concern that the recommended limitation for pregnant women of twelve ounces, or two servings of fish per week, is not consistent with recent research in which more than this amount has been associated with improved cognitive development in children. Because FDA has said that it will not consider updates to the consumption advice until it considers comments and completes work on an assessment of risks and benefits of eating commercial fish, you encourage FDA to complete this work at the earliest time possible.

We agree with you that research published since 2004 has enhanced our understanding of the benefits and risks of fish consumption to the point where updating the consumption advice is now warranted. You are correct that neurodevelopmental benefits have been associated with fish consumption during pregnancy in studies published since the consumption advice was issued. While health benefits from fish were generally recognized in 2004, that particular benefit had not yet been identified in research focusing on fish consumption. Updated consumption advice should continue to be protective against neurotoxic effects from methylmercury in the developing fetus and young children, but also enable them to obtain the maximum neurodevelopmental benefits that fish can provide.

The assessment of risks and benefits of eating commercial fish was published in draft form in 2009. It has been under further development and revision since then to take into account comments from the public, government agencies, and scientific peer reviewers. It also incorporates additional risk and benefit modeling as recommended by many

commenters. FDA is currently consulting with EPA on it. The revised assessment will assist FDA and EPA in evaluating the 2004 advice and in determining appropriate updates or modifications based on the best science available.

FDA and EPA plan to issue revised draft consumption advice this year for public comment. Before finalizing it, the agencies will consult with other stakeholders and the public through a transparent process in which all views will be thoroughly considered.

We thank you for your thoughtful letter on this important subject, and apologize for the delayed response. We would be grateful if you would distribute this response to your cosignors.

Sincerely,

Michael R. Taylor

Deputy Commissioner for Foods