

April 21, 2009

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Quantitative Risk and Benefit Assessment of Commercial Fish Consumption Report
Docket [FDA-2009-N-0018]

To whom it may concern:

Consumers Union submits these comments regarding the recent risk assessment and modeling described in the FDA Report, "Quantitative Risk and Benefit Assessment of Commercial Fish Consumption," Docket [FDA-2009-N-0018]. Although this report was issued on January 15, 2009 - prior to the beginning of this Administration - we wanted to make the new FDA leadership aware of our concerns. We are concerned that because of the significant limitations, this study could be misconstrued to serve as an erroneous basis for the FDA to weaken its fish consumption advice in ways that could increase mercury risks, especially for vulnerable populations. The link between fish consumption and exposure to the neurotoxin, methylmercury is well established. The ability of methylmercury to traverse the placenta exacerbates potential harm to the developing fetus. Therefore, Consumers Union respectfully requests that the new leadership at FDA focus on how to strengthen and refine public health advice around seafood consumption, especially for the most sensitive populations, rather than weakening the significance of the problem as suggested by this report.

While Consumers Union does recognize the benefit of omega-3 consumption, especially by susceptible populations including women of childbearing age, infants and children, we do not believe consumption of fish high in mercury, or with variable significant mercury levels, is necessary. Our understanding of the current science is that the neurodevelopmental and cardiac health benefits of omega-3 consumption, would be even greater with lower mercury consumption.^{1,2} Our advice, based on FDA measurements of mercury in specific fish, is for pregnant women to take precaution and avoid all forms of tuna altogether and to continue to avoid king mackerel, swordfish, tilefish and shark. We also recommend that children under the age of six significantly curtail consumption of fish that could contain high levels of mercury, including tuna.³

¹ Oken E, et al. Maternal fish intake during pregnancy, blood mercury levels, and child cognition at age 3 years in a US cohort. *Am J Epidemiol.* 168(2):236, 2008.

² Stern, A.H., A review of the studies of the cardiovascular health effects of methylmercury with consideration of their suitability for risk assessment. *Env Res.* 98:133, 2005.

³ Consumer Reports, Mercury in tuna: New safety concerns, June 2006
(http://www.consumerreports.org/cro/babies-kids/child-safety/food/mercury-in-tuna/tuna-safety/overview/0607_tuna_ov.htm)

While we understand that the purpose of the FDA report may have been in part to address concerns outlined in the Institute of Medicine's (IOM) report, "Seafood Choices: Balancing the Benefits and Risks," we do not believe that this report fulfills the IOM request for "consolidated advice that brings together different benefit and risk considerations," nor that it "is tailored to individual circumstances, to better inform consumers." Instead, the FDA report is based on an average exposure level across all types of commercial seafood, and is not tailored to any sensitive populations, including the significant percentage of women of childbearing age who already harbor significant mercury levels and /or eat diets high in fish. The report therefore does not adequately reflect the heterogeneity and wide variability in the degree of consumption of specific types of fish.

The report calculates an average of mercury exposure for all types of commercial fish consumption based on the average mercury levels found in specific fish types. However, in the case of chunk light tuna, for example, the average level calculated is not indicative of what a consumer may purchase from the store. In fact, FDA's own data of mercury levels measured in chunk light tuna show widely varying levels, where almost 6% of cans tested contained problematic levels of mercury that far exceed the average calculated. Consumers Union published our analysis of FDA's data on chunk light tuna in the June 2006 issue of *Consumer Reports* (see ref 1).

While we understand that this report was likely produced under the auspices of prior leadership, we believe that there are many problems with the risk assessment and mathematical modeling conducted by FDA in this report. Consumers Union supports the detailed technical analysis of the FDA report, submitted by Edward Groth, Ph.D. on behalf of the Mercury Policy Project.

Without specific considerations and tailored analysis to specifically vulnerable populations, the findings in the report are misleading, severely limited and should not serve as any basis for FDA risk communication to the public on seafood consumption. Consumers Union urges the new FDA leadership to reject this flawed report as a credible basis for establishing a quantitative risk and benefit assessment for commercial fish consumption. FDA should focus on helping the most sensitive populations make better and safer overall food choices to gain the health benefits of eating omega-3 fatty acids without the unnecessary risks of mercury exposure. FDA has done little to educate the public about what fish offer the benefits with minimal risks. FDA may also want to consider measures like enforcing its action level of 1ppm of mercury in fish, to keep the highest mercury fish off the market.

Sincerely,

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