

Harvard Center for Risk Analysis



November 1, 2000

The Honorable Jane Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney,

I am writing in regard to the suggested FDA action warning against consumption of fish due to concerns about methyl mercury. I have been consulted by the National Food Processors Association and will accompany them next Monday when they meet with Mr. Levitt. In advance of the meeting, however, I urge you to suspend judgement until the risks of reductions in fish consumption have been compared to the potential risks from methylmercury contamination.

As a risk analyst and public health professional I believe it is important to make sure that in public health actions we "first, do no harm." It is important for us to remember that risk management interventions, like medications, can have side effects. These foreseeable consequences can offset, or even outweigh, the risk reduction achieved by the intervention. The identification and evaluation of these risk/risk tradeoffs is a growing area in public health*.

I am concerned that a focus on the potential risk of methylmercury in fish will not consider the risks to health of reducing consumption of this nutritious source of protein. These would include,

* For examples see Graham, J.D. and Wiener, J.B. (1995) Confronting Risk Tradeoffs in *Risk vs. Risk* (Graham, J.D., and Wiener, J.B. eds.) Harvard University Press; Gray, G.M., and Hammitt, J.K. (2000) Risk/Risk Trade-offs in Pesticide Regulation: An Exploratory Analysis of the Public Health Effects of a Ban on Organophosphate and Carbamate Pesticides. *Risk Analysis* 20:665-680; Cohen, J.T., Beck, B.D., Rudel, R.A. (1997) Life years lost at hazardous waste sites: Remediation worker fatalities vs. cancer deaths in nearby residents. *Risk Analysis* 17:419-425.; Toy, E. and Graham, J.D. (2000) Fueling Heavy-Duty Trucks: Diesel or Natural Gas? Risk in Perspective (Volume 8, Issue 1) Harvard Center for Risk Analysis, Boston, MA; Anderson, P.D. and Wiener, J.B. (1995) Eating Fish in *Risk vs. Risk* (Graham, J.D., and Wiener, J.B. eds.) Harvard University Press; Comparative Dietary Risks: Balancing the Risks and Benefits of Fish Consumption (1999) <http://www.tera.org/news/project%20descriptions/diet%20jp.htm>

in addition to the potential reduction in nutrients, the well-established relationship of increased risk of coronary heart disease with decreased fish consumption. The risks of substitute sources of protein would have to be considered (*e.g.*, increases in saturated fat consumption) including the potential contamination of these foods with other substances. In fact, there is evidence that fish consumption may be beneficial to the developing fetus, due to ω -3 fatty acids, when consumed by a pregnant woman. Clearly, there are risk/risk tradeoffs associated with any action that might induce people to consume less fish that must be weighed if we are to ensure that the policy helps, rather than harms, public health.

These comparisons cannot be carried out with existing regulatory risk values (*e.g.*, RfDs) as reflected in the U.S. EPA's IRIS database or the National Research Council's recent report suggesting 60,000 children at risk from methylmercury[#]. Regulatory risk assessment procedures were developed primarily for the purpose of setting standards, safe levels of exposure to hazardous materials. Codified in these methods was the concept of conservatism: deliberately making assumptions and choices, in the face of uncertainty, that make risks look greatest. Examples from the case of methylmercury include reliance on only the Faroe Island epidemiologic data and some of the specific methods for estimating exposure to methylmercury in fish. Risk comparisons are seriously compromised by the use of conservative risk assessment methods since many countervailing risks, for example the increased risk of heart disease with decreased fish consumption, are not estimated conservatively. The scientific basis for any estimate, especially the 60,000 children at risk, must be clearly explained. It is necessary that comparative risk assessment strive for best estimates, rather than "conservative" estimates, to make sound comparisons.

In closing, the FDA has a long history of careful risk comparisons to inform decisions. I hope that in the case of methylmercury in fish you will take the time for explicit analysis of risk tradeoffs to ensure that policies do not inadvertently increase net health risk.

Sincerely,



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[#] <http://www.epa.gov/iris/>; National Research Council (2000) Toxicological Effects of Methylmercury. National Academy Press, Washington, D.C.