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November 6, 2000

Dr. Jane Henney  
Commissioner  
Food and Drug Administration  
5600 Fisher Lane  
Rockville, MD 20857

Dear Commissioner Henney:

We are writing in response to the scheduling of meetings among U.S. Food and Drug Administration (FDA) officials and selected groups to discuss issues associated with methylmercury contamination in commercial fish.

We would like to commend FDA for beginning to address the very important issue of human exposure to potentially hazardous concentrations of methylmercury in commercial fish. A recent National Academy of Sciences (NAS) report, Toxicological Effects of Methylmercury, indicates that more than 60,000 children may suffer from exposure to methylmercury while in utero. Therefore, in the near future, FDA should establish a public-health-based standard for seafood to protect women and children from these effects. Specifically, FDA should establish a new action level and consumer advisory as soon as possible that responds to the findings of the NAS.

There is wide consensus among experts that the existing FDA consumer advisory is severely inadequate both in terms of its content and distribution and is based on outdated information. Moreover, the recommendations in the NAS report reveal fatal flaws in the methodology used by FDA to establish its action level for methylmercury in commercial fish. Initiating this discussion is a welcome start to what we hope will be a productive dialogue concerning our many procedural and substantive concerns.

Our substantive concerns relate to the scope and content of the advisories themselves, the information needed to adequately and effectively implement an appropriate advisory and the need to address other aspects of FDA policy related to methylmercury in commercial fish. We agree that the existing advisory needs to be revised. Information provided by FDA to the public about methylmercury in commercial fish needs to reflect the findings of the NAS report. It also needs to be issued and presented in a way that reaches all consumers--particularly those most at risk.

**Mercury Policy Project**  
**November 6, 2000**

We also believe that in order to give people at risk--particularly women of child-bearing age--the most useful and health-protective advice about fish consumption, it is important to help them select fish that are not contaminated with methylmercury, so that they may obtain the benefits of fish consumption without incurring the risks of exposing their children to methylmercury. This requires more testing and better information about concentrations of methylmercury in fish than is available at this time. A plan to greatly expand the information about methylmercury in fish is needed to provide women of childbearing age with the information they need to make healthful and informed choices.

Clearly, the issues that need to be addressed by FDA go beyond the advisories themselves. Given the report of the NAS on the health risks posed by even very low concentrations of methylmercury to children in utero, FDA's action level for methylmercury in fish needs to be revised to reflect current science and to be more compatible with the guidance provided by the U.S. Environmental Protection Agency.

FDA's failure to include a broad group of stakeholders in ongoing discussions on this topic is unfortunate given the importance of the issues at hand. In addition to the undersigned organizations, countless others--including businesses, Native American tribes and governmental and nongovernmental agencies--are concerned about this issue. For example, at least twelve states have issued public warnings about methylmercury levels in marine fish that are sold through interstate commerce. Given these state actions and their concerns, knowledge and expertise, they would undoubtedly be a valuable resource to your agency as you move forward to address this important issue.

As with any government action, there are a variety of potential outcomes, some intended and some unintended. The issues, which the FDA is considering, have a wide variety of implications for the diverse communities across the United States who will be impacted. Clearly, the message concerning the safety of fish consumption will have a very different impact on the occasional consumer than on families who depend heavily on consuming fish as an integral part of their diet for economic or cultural reasons. Health risk communications must clearly alert vulnerable persons to the risks associated with fish consumption. FDA, however, has failed to include the broad base of groups who could provide the input necessary to maximize the effectiveness of FDA actions while minimizing unintended, negative outcomes.

In closing, we appreciate the efforts that you are making to begin to address concerns related to methylmercury in commercial fish. We hope to work with you in developing and implementing a process both that provides the opportunity for widespread public involvement and addresses all issues of concern, so that we can protect consumers, especially children, from harm from methylmercury-contaminated commercial fish.

**Mercury Policy Project  
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Sincerely,

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**Mercury Policy Project  
November 6, 2000**

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cc U.S. Senator Patrick Leahy  
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U.S. Senator Jim Jeffords,  
U.S. Representative Frank Pallone  
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