DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 15, 2005

Jane Houlihan
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Environmental Working Group
1436 U Street, N.W. Suite 100
Washington, D.C. 20009

Dear Ms. Houlihan:

This letter is in response to the Environmental Working Group (EWG) Information Quality Act Request (Request) of the draft advisory, "Advice For Women Who Are Pregnant, Or Who Might Become Pregnant, And Nursing Mothers, About Avoiding Harm To Your Baby Or Young Child From Mercury In Fish And Shellfish" (2003 Draft Advisory). The 2003 Draft Advisory was made public on December 10, 2003.

The U.S. Food and Drug Administration's (FDA) Guidelines for Ensuring the Quality of Information Disseminated to the Public provide that when the agency disseminates information in draft form, the agency may consider the request in connection with agency comment procedures. Thus, rather than responding immediately to your Request, FDA considered EWG's Request as a comment on the 2003 Draft Advisory and took EWG's Request into account when we refined the 2003 Draft Advisory into the 2004 Advisory[1] entitled, "What You Need to Know About Mercury in Fish and Shellfish" (2004 Advisory) in response to the many comments made by your organization, the Food Advisory Committee, and others. The 2004 Advisory is available at www.cfsan.fda.gov/~dms/admehg3.html. Below we provide some background and a discussion of EWG's specific recommendations.

BACKGROUND

The Request

The Request alleges that FDA failed to meet the utility and objectivity requirements of the information quality guidelines set forth in the Information Quality Act. Specifically, EWG made the following recommendations:

1. FDA should conduct an updated, comprehensive sampling program for seafood.
2. FDA should provide consumption advice that consumers can follow without appreciable risk to their health.
3. FDA should provide specific advice on canned tuna.
4. FDA should provide specific advice on how much seafood young children can safely consume.
5. Calculations of risk on "exceedences" of the reference dose for the last half of the third trimester of pregnancy should be consistent with interpretations of the National Academy of Sciences (NAS) 2000 report.

[1] The 2004 advisory was released by FDA on March 19, 2004.

6. FDA should develop and make public documentation of a scientific assessment conducted in correcting the 2003 Draft Advisory.

Development of the 2003 Draft Advisory

The FDA and the Environmental Protection Agency (EPA) worked jointly to develop and review the 2003 Draft Advisory and the 2004 Advisory. The language in both advisories was developed in consultation with, and reviewed by, experts in the subject matter, including the FDA Food Advisory Committee (FAC), stakeholders, the general public, and other interested parties.

The 2003 Draft Advisory had its origins in an advisory on the subject of methylmercury in fish that FDA issued in the mid 1990's. New information had become available since the 2001 Advisory was issued. Specifically, in July 2002, FDA asked the FAC to provide recommendations on ways in which the then current advisory (the 2001 Advisory) could be improved. The background materials, transcripts, and meeting minutes, including the FAC recommendations, are provided on the web (http://www.fda.gov/ohrms/dockets/ac/cfsan02.htm) . The FAC recommended that FDA clarify the language of the 2001 Advisory, develop a quantitative exposure assessment, and increase monitoring for methylmercury, including levels in fish, and the use of human biomarkers. The FAC also recommended that FDA and EPA issue a joint advisory to address both commercial fish and fish caught by sports fishermen.

The agencies addressed the 2002 FAC recommendations as follows:

- FDA and EPA jointly held four stakeholder meetings between July 29 and July 31, 2003, (http://www.cfsan.fda.gov/%7Edms/mehg703.html) regarding methylmercury in fish. The meetings consisted of a series of formal presentations from FDA and EPA, followed by a general discussion in which participants provided comments on the progress toward a joint advisory;
- FDA conducted focus group testing in November 2003 to assess consumers' understanding of the then current draft of the advisory;
- The exposure assessment that FDA conducted underwent a peer review in August 2003; and
- FDA collected additional fish monitoring data from 2002 to 2003.

Revisions were made to the 2001 advisory in response to the above information and the FAC's prior recommendations. The 2003 Draft Advisory was issued on December 10, 2003. On March 10, 2004, the FAC provided additional recommendations for the FDA and EPA to consider, as follows:[2]

- Include a list of fish that have low levels of mercury and a list of common names of fish;
- Clarify the portion size to make it easier to understand;
- Make portion size consistent between variety and frequency of consumption;
- Include a website on the advisory for those who might want further information; and
- Design the advisory in such a way that it is understood by more than just the original target audience, to avoid the need to issue multiple advisories.

[2] These recommendations are available at http://www.fda.gov/ohrms/dockets/ac/03/briefing/4010b1_Ltr%20of%20recommendation-Dr%20Miller.pdf .

FDA and EPA considered these recommendations, along with other public comments, including those of EWG, as they refined the 2003 Draft Advisory into the 2004 Advisory.

The 2004 Advisory

On March 19, 2004, the FDA and EPA jointly released the 2004 Advisory, "What You Need to Know About Mercury in Fish and Shellfish." The purpose of the 2004 Advisory, as described in the Backgrounder document released simultaneously, is to inform women who may become pregnant, pregnant women, nursing mothers, and parents of young children how to get the health benefits from eating fish and shellfish, while reducing their mercury exposure. The Backgrounder document is available at www.fda.gov/oc/opacom/hottopics/mercury/backgrounder.html.

The 2004 Advisory provides the following three principal consumption recommendations for women (www.cfsan.fda.gov/~dms/admehg3.html).

1. Do not eat Shark, Swordfish, King Mackerel, or Tilefish because they contain high levels of mercury.
2. Eat up to 12 ounces (two average meals) a week of a variety of fish and shellfish that are lower in mercury.
   - Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, Pollock, and catfish.
   - Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to six ounces (one average meal) of albacore tuna per week.
3. Check local advisories about the safety of fish caught by family and friends in your local lakes, rivers and coastal areas. If no advice is available, eat up to six ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.

With respect to young children, the consumption recommendation is to follow the recommendations for adult women (listed above) when feeding fish and shellfish to young children, but serve them smaller portions.

RESPONSE TO EWG RECOMMENDATIONS FOR CORRECTING THE INFORMATION

Below are responses to the six specific recommendations made in your letter.

1. EWG recommends that FDA conduct an updated, comprehensive sampling program for seafood.

FDA Response: FDA agrees with EWG that it would be desirable to have additional data on mercury levels in fish and that additional monitoring data should be collected.

The available mercury testing database includes 2,406 samples of fish analyzed for mercury or methylmercury over a 13 year period (1990-2003). This dataset includes analysis of 38 species of finfish and 7 species of shellfish. The data set is available on the web at (http://www.cfsan.fda.gov/~frf/seamehg2.html). In FY04, FDA had an assignment to collect and analyze 17 species of fish for total mercury (280 samples of canned and fresh tuna and 355

samples of imported and domestic fish). FDA will update its web page with the new FY04 data once analysis is complete. In FY05, FDA plans to collect additional data on shrimp, tilapia, clams and tilefish.

FDA would also welcome the submission of high quality data from other sources. We are willing to work with the industry and other stakeholders on the format of the data and to assure compliance with FDA's quality standards, and are making arrangements with the University of Maryland and the Joint Institute of Food Safety and Nutrition (JIFSAN) to make any stakeholder-collected data that is shared with us widely available through the JIFSAN Food Safety Risk Analysis Clearinghouse (www.foodriskclearinghouse.umd.edu). A public announcement will be made indicating that mercury fish data can be submitted to the Clearinghouse as soon as a standard operating procedure for data handling is developed.

FDA believes that the desire for additional data should not stop FDA from issuing advice based on current data, with the understanding that as new or different data become available, the advice to consumers may need to be revised accordingly.

2. EWG recommends that FDA provide consumption advice that consumers can follow without appreciable risk to their health.

FDA Response. FDA recognizes that a well-balanced diet that includes a variety of fish and shellfish can contribute to a healthy heart and a child's proper growth and development. FDA and EPA revised the 2003 Draft Advisory to provide information on how to get the health benefits from eating fish and shellfish while reducing exposure to mercury. The 2004 Advisory provides specific information concerning the consumption of fish (including canned tuna) and shellfish and lists the types of fish that are lower in mercury as well as those that are higher in mercury. It also provides specific advice on the amount and number of meals per week to eat in order to receive the benefits of eating fish and shellfish and reduce one's exposure to mercury. In the Question and Answer section of the 2004 Advisory there is a link to data on mercury levels in other fish (http://www.cfsan.fda.gov/~frf/sea-mehg.html). By following the 2004 Advisory, women who might become pregnant, pregnant women, nursing mothers and young children can maintain a healthy diet and gain the positive health benefits from eating fish and shellfish while reducing their exposure to mercury.

The consumption advice in the 2003 Draft Advisory was based in part on an analysis of the mercury levels in different types of fish. FDA developed that advice by comparing the reference dose (RfD) to the predicted exposure from the consumption of different fish species. While an RfD is determined to be an exposure that a person can experience every day for a lifetime without appreciable risk of harm, an RfD is not a bright line just above which there is a likelihood, much less certainty of an adverse effect. Furthermore, most RfDs have a degree of uncertainty (of conservatism) built into them. For the methylmercury RfD, this a 10 fold factor. FDA's approach is to provide consumers with advice to help them to reduce exposure to methylmercury, while enabling them to continue to achieve the health benefits from eating fish and shellfish.

3. EWG recommends that FDA provide specific advice on canned tuna.

FDA Response. The 2004 Advisory provides specific advice on canned tuna. FDA has revised the consumer message regarding canned tuna consumption in the 2004 Advisory in order to provide specific information concerning the different types of canned tuna, together with their relative amounts of mercury. The 2004 Advisory provides specific advice on the amount and number of tuna meals per week to eat. Thus, it now states:

> "Eat up to 12 ounces (two average meals) a week of a variety of fish and shellfish that are lower in mercury.
>
> - Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, Pollock, and catfish.
> - Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to six ounces (one average meal) of albacore tuna per week."

In addition, the Frequently Asked Questions section of the 2004 Advisory recommends that adults may eat up to 6 ounces (one average meal) of tuna steak per week as a part of the two average meals of fish and shellfish per week.

4. EWG recommends that FDA provide specific advice on how much seafood young children can safely consume.

FDA Response. For both adults and children, the 2004 Advisory has been reframed to promote smart dietary choices that reduce risk while maintaining the benefits of fish and shellfish. The 2004 Advisory indicates that women can eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury, and adds that the same recommendations should be followed when feeding fish and shellfish to young children, but by serving smaller portions.

FDA and EPA have gone to considerable effort to use focus groups and communication experts to establish the utility of consumer messages, such as for the 2003 Draft Advisory and the 2004 Advisory. For instance, the focus groups indicated that most of the respondents found the content of the 2004 Advisory to be understandable and that, when asked, were able to accurately state the important take-away messages. Therefore, we believe the respondents understood that they should serve their children less than the recommended amounts for adults. There were no instances when a focus group respondent interpreted the 2004 Advisory as stating that children should eat 12 ounces of seafood per week if it is eaten in smaller, more frequent servings. On the contrary, the respondents seemed to easily comprehend that the recommendation is that children eat less overall fish and shellfish than adults.

5. EWG recommends that calculations of risk on "exceedences" of the reference dose for the last half of the third trimester of pregnancy be consistent with interpretations of the National Academy of Sciences (NAS) 2000 report.

FDA Response. FDA took the NAS committee's recommendations into consideration, including those which deal with high exposures (NAS/NRC Methylmercury Report) when it conducted its

exposure assessment (Carrington, Montwill and Bolger, Reg. Tox. Pharm. 40:272-280, 2004). FDA assessed ranges of methylmercury exposure and the impact of consumption of different types of commercial fish on the distribution of methylmercury exposure in women of child-bearing age. FDA's exposure assessment did evaluate "exceedences" of several expressions of dose that included the RfD. The EPA RfD is consistent with the NAS (2000) report.

6. EWG recommends that FDA develop and make public documentation of a scientific assessment conducted in correcting the 2003 Draft Advisory.

FDA Response. Information used to revise the 2003 Draft Advisory is documented and publicly available. The document titled, "Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish" (www.fda.gov/oc/opacom/hottopics/mercury/backgrounder.html) provides a summary of the changes made to the 2003 Draft Advisory for the 2004 Advisory. The transcripts for the FAC meetings, which detail the scientific information considered and the discussion of those data relative to the development of the advisories are also available (http://www.fda.gov/ohrms/dockets/ac/03/briefing/4010b1.htm).

Because FDA strives to use the best science and information available in support of information it disseminates, it obtained a peer review for the FDA Exposure Assessment. FDA carefully considered the comments, responded to those comments, and has made both the peer review comments and our responses available to public view (see FDA's Food Safety website at www.cfsan.fda.gov/seafood1.html or http://www.fda.gov/ohrms/dockets/ac/03/briefing/4010b1-12-%20EPA.pdf).

FDA sought advice from experts concerning the content and language in the 2003 Draft Advisory. FDA's review process is extensive and is appropriate to the particular information to be disseminated. Prior to issuing the 2003 Draft Advisory FDA diligently sought the advice and opinion of experts, including the FAC, involved the public in stakeholder meetings, and performed focus group testing.[3]

The underlying scientific data and assessments presented at the December 2003 FAC meeting are available on the web for those who are interested in additional details (http://www.fda.gov/ohrms/dockets/ac/03/briefing/4010b1.htm). FDA has made available to the public the citations to the data sources and, where possible, the sampling and analysis plans. The mercury testing data used in the exposure assessments come from three sources: the FDA Food and Cosmetics Compliance Program/ Toxic Elements in Food Survey and Special Assignments (1990-2003), Gulf of Mexico Report (2000), and National Marine Fisheries Service Report (1978).

General information about the FDA Compliance Program is available in the Compliance Program Testing Manual: www.fda.gov/ora/cpgm/default.htm

- The Food and Compliance Testing Programs: www.cfsan.fda.gov/~comm/cp-toc.html

[3] While neither the summary of the focus groups nor the transcripts are currently available on the Internet, FDA will make them available to anyone interested in seeing them.

- Toxic Elements in Food and Foodware, and Radionuclides in Foods-Import and Domestic: http://www.cfsan.fda.gov/~comm/cp04019.html

NEXT STEPS

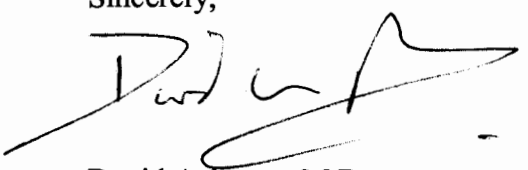
FDA and EPA have initiated an educational campaign to reach women who may become pregnant, pregnant women, nursing mothers, and parents of young children. The agencies are working with state, local, and tribal health departments to disseminate information into their communities. The 2004 Advisory is an important part of a comprehensive food safety education program to be used by educators of pregnant women. EPA and FDA also have an extensive outreach campaign to the U.S. medical community.

CONCLUSION

Because the 2004 Advisory has superceded the 2003 Draft Advisory, which has been significantly refined since you submitted your letter, FDA determined it was not necessary to respond in detail to each of the comments made in your letter. FDA appreciates your comments, which were helpful in refining the 2004 Advisory. FDA continues to collect additional data and will make further improvements to the Advisory as new information emerges. We hope that the information provided above helps to clarify the state of our work in developing a consumer advisory and our efforts to communicate it to the public.

We would like you to know that you may appeal the decision of the FDA either in writing or electronically within 30 days of receipt of this response. Your request for reconsideration should state the reasons why you believe the response is inadequate. It should include a copy of your original request together with this response, and should be marked clearly with the words "Information Quality Appeal."

Sincerely,



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