CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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Dr. Jane Henney
Commissioner
Food and Drug Administration
5600 Fischer Lane
Rockville, MD 20857

Re: Petition to Set A Regulatory Limit for Methylmercury In Seafood That Reflects the Risk to Pregnant Women and Children From the Intake of Seafood Containing Methylmercury

Dear Commissioner Henney:

More than 60,000 children are born each year at risk for neurological problems due to low-level methylmercury contamination from seafood eaten by pregnant women, according to a National Academy of Sciences (NAS) report released last week.[1] This warning is not new. Concerns about the effects of this toxic metal on pregnant women and their fetuses were raised nearly a decade ago, in a 1991 NAS report and in a citizen petition I submitted to the Food and Drug Administration (FDA) in 1992. Both the report and the petition were highly critical of the FDA's weak standard on methylmercury in seafood[2] and offered the agency specific guidance on performing a more rigorous risk assessment on the substance. Unfortunately, the FDA has never revised its methylmercury action level or responded to the petition. It is imperative that the agency act without further delay. On behalf of the Center for Science in the Public Interest (CSPI), I am resubmitting the attached petition urging the agency to set a regulatory limit for methylmercury in fish and shellfish that protects pregnant women and children from mercury contamination.

As in the earlier NAS report, several of the panel's recommendations, when applied to the FDA's guidelines on methylmercury, reveal fatal flaws in the agency's standard-setting process. Most importantly, the 2000 NAS panel validated the EPA's stringent regulatory limit for

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[1] National Academy of Sciences, Toxicological Effects of Methylmercury, 276 (not yet published), found at *http://www.nap.edu/openbook/0309071402/html/276.html* [hereinafter cited as 2000 NAS report].

[2] The FDA's action level for methylmercury is 1 part per million (ppm).

1875 Connecticut Avenue, N.W. / Suite 300 / Washington, DC 20009-5728 / (202) 332-9110 / FAX (202) 265-4954
On the Internet at *www.cspinet.org* • Executive Director: Michael F. Jacobson, Ph.D.

methylmercury,[3] but when the data used in FDA's risk assessment are plugged into the model, **the FDA's biomarker and exposure levels for methylmercury are four times higher than the NAS endorses.**[4] Specifically, the 2000 NAS panel found the following:

1. There is a "strong data base" of human and animal studies showing neurotoxic effects from in utero exposure to methylmercury and particularly the 1997 Faroe Islands study[5] on the effects of low-level chronic exposure.[6] *The FDA action level is based upon a 1971 study of two high-exposure poisoning episodes occurring in the 1960's. Although the FDA conceded in 1994 that long-term exposure to methylmercury in fetuses and infants might have adverse harm,[7] the agency did not reevaluate its action level when the Faroe Islands, Seychelles (1998) or New Zealand (1986, 1989) studies on developmental neurotoxicity were released.*[8]

2. Developmental neurotoxicity should be the end point used in calculating the appropriate regulatory level of methylmercury.[9] *The FDA used overt neurological symptoms in adults as the end point; therefore its action level is set to protect adult men weighing 154 pounds and over.*

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[3] Id. at 277, found at *http://www.nap.edu/openbook/0309071402/html/277.html.* The 2000 NAS report was issued following an 18-month review of the toxicological effects of methylmercury and the validity of the EPA's risk assessment on the substance. As part of its work, the panel of scientists analyzed the data and assumptions used by FDA, EPA and other agencies. Id. at 257, found at *http://www.nap.edu/openbook/0309071402/html/277.html.*

[4] Id. at 17, 277, found at *http://www.nap.edu/openbook/0309071402/html/17.html, http://www.nap.edu/openbook/0309071402/html/277.html.* The FDA's action level for methylmercury is based upon a biomarker in adult blood of 0.2 ppm (or a concentration of 0.02 μg/g of blood, including a safety factor of ten, which equates to 20μg/L of blood). Removing the safety factor leaves a blood concentration of 200 μg/L of blood, and applying the 250:1 blood/hair ratio results in 50 ppm in hair.

[5] See, 2000 NAS report at Chapter 6: Comparison of Studies for Use in Risk Assessment at 209-226, found at *http://www.nap.edu/openbook/0309071402/html/209.html - http://www.nap.edu/openbook/0309071402/html/226.html* for a discussion of the Faroe Islands study as well as the Seychelles and New Zealand studies on exposure to methylmercury and developmental neurotoxicity.

[6] 2000 NAS report at 275, found at *http://www.nap.edu/openbook/0309071402/html/275.html.*

[7] FDA, Mercury in Fish: Cause for Concern?, FDA Consumer (Sept. 1994, rev'd. May 1995).

[8] See, *supra*, note 5.

[9] 2000 NAS report at 275, found at *http://www.nap.edu/openbook/0309071402/html/275.html.*

3. The risk assessment should be based upon a benchmark dose limit (BMDL)[10] corresponding to 12 ppm in hair.[11] *The FDA action level corresponds to a biomarker of 50 ppm in hair, which is more than 4 times the NAS recommendation.*

4. A regulatory limit for methylmercury of 0.1 μg/kg/day–the EPA standard–is "scientifically justifiable for the protection of public health."[12] *The FDA's action level is equivalent to 0.4 μg/kg/day.*

The NAS report adds to the large body of science showing the adverse effects of low-level methylmercury exposure on developing fetuses and documents that 60,000 children are born each year at risk of developing neurological problems from mercury exposure linked to seafood. It is imperative that FDA act now to protect women of child-bearing age and their children from this hazard. First, FDA should immediately adopt EPA's standard for methylmercury as an "action level." Second, FDA should monitor methylmercury levels in shark, swordfish and tuna and remove seafood from the market that violates FDA's standard. Third, FDA should act on the attached 1992 petition by initiating rulemaking to adopt a tolerance for methylmercury that fully protects the children of women who are or may become pregnant. Further delay by the agency would be unconscionable.

Sincerely,

Caroline Smith DeWaal
Food Safety Director

Encl.

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[10] "Benchmark dose" (BMD) refers to the estimated dose that corresponds to a specified risk above the background risk. BMDL denotes the corresponding lower limit. Id. at 228, found at *http://www.nap.edu/openbook/0309071402/html/228.html.* For example, the benchmark dose of 11 ppm of mercury in hair was calculated as the 95% lower confidence limit on the maternal-hair concentration corresponding to a 10% extra risk level. The lower confidence limit is the BMDL. Id. at 258, found at *http://www.nap.edu/openbook/0309071402/html/258.html.*

[11] Id. at 277, found at *http://www.nap.edu/openbook/0309071402/html/277.html.* The NAS determined that the BMDL used by EPA (11 ppm) is "nearly identical" to the panel's recommendation of 12 ppm in hair. Id.

[12] Id. at 277, found at *http://www.nap.edu/openbook/0309071402/html/277.html.* The 2000 NAS report was issued following an 18-month review of the toxicological effects of methylmercury and the validity of the EPA's risk assessment on the substance. As part of its work, the panel of scientists analyzed the data and assumptions used by FDA, EPA and other agencies. Id. at 257, found at *http://www.nap.edu/openbook/0309071402/html/277.html.* The panel's findings reveal serious defects in the methods and data that FDA used in determining its action level for methylmercury.