

June 20, 2011

BY FACSIMILE AT 301-827-6870
BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Dr. Margaret A. Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dockets Management Branch
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

180 Day Notice of Substantive Response pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706 (2000), (pursuant to 5 U.S.C. § 553(e), and Title 21 of the Code of Federal Regulations, Sections 10.30, 10.33, and 10.35, as related to the Federal Food, Drug, and Cosmetic (FDC) Act

Dear Commissioner Hamburg:

Pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706 (2000), pursuant to 5 U.S.C. § 553(e), and Title 21 of the Code of Federal Regulations, Sections 10.30, 10.33, and 10.35, as related to the Federal Food, Drug, and Cosmetic (FDC) Act this letter provides notice of the intent of our clients, GotMercury.org, a project of the Turtle Island Restoration (TIRN), and The Center for Biological Diversity (CBD). We are filing the enclosed to Petition to initiate rulemaking to reduce human exposure, particularly for women childbearing age, pregnant and nursing women, children and the most vulnerable populations to mercury levels from commercial fish sold in the United States on their behalf.

TIRN is a California-based non-profit organization dedicated to public awareness of mercury in seafood and the conservation of sea turtles and their habitat. CBD is a national, non-profit conservation organization dedicated to the protection of endangered species and wild places.

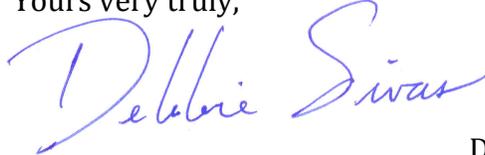
TIRN and CBD request that the Food and Drug Administration (FDA) adhere to the charge of the United States Government to enforce and regulate all matters of mercury in commercially sold seafood to prevent human exposure to mercury, particularly for women of childbearing age, pregnant and nursing women, children and the most vulnerable

populations. The Petitioners respectfully request the FDA adopt all of the suggested policy and regulatory recommendations.

The FDA is required to give prompt consideration to this petition. In keeping with the urgency of addressing mercury in seafood, Petitioners hereby request a substantive response to this petition within one hundred eighty (180) calendar days.

We would be happy to discuss these issues with you further.

Yours very truly,



DEBORAH A.

SIVAS

Luke W. Cole Professor of Environmental
Law and Director of the Stanford
Environmental Law Clinic

enc.

cc w/enc:

Buffy Martin Tarbox, Campaign Coordinator
Got Mercury, Turtle Island Restoration Network

Catherine Kilduff, Staff Attorney
Center for Biological Diversity

Michael Landa
Director of the FDA Center for Food Safety and Applied Nutrition

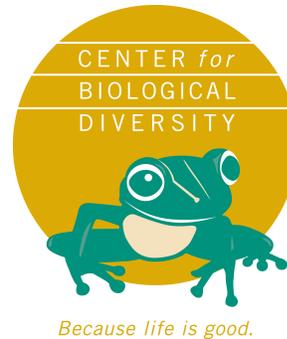
Michael A. Chappell
Action Associate Commissioner for the FDA Office of Regulatory Affairs

Lisa Jackson
Environmental Protection Agency Administrator

NOAA Seafood Inspection Program

Got Mercury?

A Project of Turtle Island Restoration Network



June 20, 2011

Dr. Margaret A. Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993
Via certified mail and facsimile at 301-827-6870

Re: Petition to initiate rulemaking to reduce human exposure, particularly for women of childbearing age, pregnant and nursing women, children and the most vulnerable populations to mercury levels from commercial fish sold in the United States

Dear Commissioner Hamburg,

GotMercury.org, a project of the Turtle Island Restoration Network and the Center for Biological Diversity (“Petitioners”) remain concerned that American seafood consumers, especially women of childbearing age and children in the United States, continue to be exposed to potentially dangerous levels of methylmercury in commercial fish without adequate protection, information or warning. While the U.S. Food and Drug Administration (FDA) issued a public health advisory in 2004 to warn women who are pregnant or who plan to become pregnant not to eat certain fish and to reduce their consumption of other fish species, the agency has not required seafood sellers to distribute or post this warning. As a result many, if not most, Americans remain inadequately informed about making healthier seafood choices.

In addition to failing to require advisory postings, the FDA has not enforced its action level of 1 part per million methylmercury for fish in the food supply,¹ has ceased testing seafood for mercury levels, has not updated mercury levels in fish for several years, and seems to be ignoring new science that clearly documents that certain fish species contain potentially unsafe levels of mercury.

On top of these failings, the FDA and other U.S. government agencies including the National Marine Fisheries Service are actually promoting increased consumption of seafood without clearly flagging the species that contain mercury to be a health hazard.

¹ Compliance Policy Guide ec. 540.600 Fish, Shellfish, Crustaceans and other Aquatic Animals - Fresh, Frozen or Processed - Methyl Mercury, available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074510.htm>.

In addition, tuna companies have recently begun advertising canned tuna products as a “wonderfish” while never mentioning the word mercury anywhere, which we believe conflicts with U.S. public health and advertising standards.²

Given these concerns and lack of FDA’s attention to mercury in fish as a public health concern, the Petitioners hereby request the FDA to initiate rulemaking to reduce human exposure, particularly for women of childbearing age, pregnant and nursing women, children and the most vulnerable to mercury levels from commercial fish sold in the United States by taking the actions listed herein.

Petitioners request this action of the Commissioner of the U.S. FDA pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706 (2000), pursuant to 5 U.S.C. § 553(e), “[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” This petition is also submitted pursuant to Title 21 of the Code of Federal Regulations, Sections 10.30, 10.33, and 10.35, as related to the Federal Food, Drug, and Cosmetic (FDC) Act, which prohibits adulterated and misbranded food, including seafood, in interstate commerce and the Public Health Service Act. The intent of this petition is to request the Commissioner of Food and Drugs to amend regulations and guidance regarding methylmercury in seafood to reduce human exposure to mercury and to limit allowable levels of mercury in commercially sold seafood in the United States through a series of actions as described in this petition.

GotMercury.org, the lead petitioner, was established in 2002 to protect consumers from mercury in seafood and to help them make healthier, safer seafood choices. GotMercury.org hosts an online calculator that uses the U. S. Environmental Protection Agency (EPA) formula for mercury exposure with the FDA published data on seafood mercury levels. GotMercury.org has been actively involved in direct testing of methylmercury in commercially sold seafood since 2002.

The Center for Biological Diversity is a national, nonprofit conservation organization with more than 320,000 members and online activists dedicated to the protection of endangered species and wild places.

The FDA is required to give prompt consideration to this petition. In keeping with the urgency of addressing mercury in seafood, Petitioners hereby request a substantive response to this petition within one hundred eighty (180) calendar days.

² www.tunathewonderfish.com

This petition is organized in the following manner:

A. ACTIONS REQUESTED

B. STATEMENT OF GROUNDS

- 1) Statutory Background
- 2) Health and Environmental Impacts of Mercury in Seafood
- 3) Origins of Mercury in Seafood
- 4) Health Effects of Mercury Exposure
- 5) High-risk Populations
- 6) Seafood Consumption and Mercury Levels in Pelagic Fish
- 7) Regulation of Mercury-in-Seafood in the U.S.
- 8) Regulatory Actions Requested

C. PROPOSED REGULATORY LANGUAGE ESTABLISHING A MAXIMUM 0.5 PPM TOLERANCE, ACTION LEVEL AND REGULATORY LIMIT FOR METHYLMERCURY

D. CONCLUSION AND CERTIFICATION STATEMENT

A. ACTIONS REQUESTED

The Petitioner requests that the Commissioner of the FDA initiate rulemaking or the relevant regulatory process to adopt the following policies and procedures to reduce human exposure, particularly for women of childbearing age, pregnant and nursing women, children and the most vulnerable populations to mercury levels in commercially sold seafood in the U.S.:

- 1) Reduce the current mercury action level from 1 part per million (ppm) to methylmercury expressed as mercury in excess of 0.5 ppm (edible portion only) to be in line with the Environmental Protection Agency (EPA) action level for recreation and sport caught fish to protect women of childbearing age, pregnant and nursing women, children and the most vulnerable populations or
- 2) Establish by regulation a tolerance level for the presence of methylmercury in seafood that shall not exceed 0.5 ppm (edible portion only) to protect women of childbearing age, pregnant and nursing women, children and the most vulnerable populations or
- 3) Establish a regulatory limit for the presence of methylmercury in seafood that shall not exceed 0.5 ppm (edible portion only) to protect women of childbearing age, pregnant and nursing women, children and the most vulnerable populations.
- 4) Develop and implement a transparent government program of regular, widespread testing of commercial seafood for methylmercury levels.
- 5) Enforce the action level, tolerance level, regulatory limit, and/or prohibit sale in the U.S. of seafood that exceeds the action level, tolerance level or regulatory limit.
- 6) Include advice on Hazard Analysis Critical Control Point (HACCP) controls for methylmercury in the Fish and Fishery Products Hazards and Controls Guidance.
- 7) Require seafood distributors, retailers, restaurants and all institutions that sell seafood to post the FDA/EPA mercury-in-fish advisory at “point-of-sale” locations and/or label fish products that are known to be high in mercury.
- 8) Update the FDA/EPA What You Need to Know About Mercury in Fish and Shellfish advisory to reflect lower action level, tolerance level or regulatory limit for mercury in fish when adopted.

- 9) Revise and update the FDA Concentrations in Fish: FDA Monitoring Program through conducting new mercury analysis of each fish species listed in the Mercury Levels in Commercial Fish and Shellfish.

To the extent that any of the petitioned actions are unavailable, the others should still be included in rulemaking or other appropriate regulatory process.

B. STATEMENT OF GROUNDS

1) Statutory Background

The FDA is one of the primary federal regulatory agencies responsible for seafood safety in the United States. Other agencies include the National Oceanic and Atmospheric Administration (NOAA), the Department of Commerce, the EPA, and the U.S. Department of Agriculture (USDA).

The FDA is responsible for administering several Acts, including the Federal Food, Drug, and Cosmetic (FDC) Act, 21 U.S.C. §§ 301-399a, that prohibits adulterated and misbranded food, including seafood, in interstate commerce, and the Public Health Service Act, 42 U.S.C. §§ 201-300jj, which authorizes measures to prevent the spread of communicable diseases.

Under the FDC Act, a food is adulterated if it contains any substance that may render it injurious to health (i.e., if it poses a human health risk), or if quality defects affect its fitness as food.³ Food can also be economically adulterated if it is made to appear to be better than it is or if its labeling is false or misleading.⁴ The FDA “shall promulgate regulations limiting the quantity therein or thereon to such extent . . . necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe,” or adulterated.⁵ In other words, the FDA must establish rules necessary to protect public health and has the discretion to do so by setting an appropriate action level.

Tolerances, Regulatory Limits and Action Levels

In order to protect public health, the FDA may establish a tolerance, a regulatory limit, or an action level for an added poisonous or deleterious substance.⁶ A tolerance and regulatory limit may be established by regulation, while the FDA may establish an action level “to define a level of contamination at which a food may be regarded as adulterated” by publishing a notice in the Federal Register inviting public comment.⁷ First, a tolerance may be established for an added poisonous or deleterious substance in any food when the criteria specified in 21 C.F.R. § 109.6(b) are met:

- (1) The substance cannot be avoided by good manufacturing practice.

³ See 21 U.S.C. § 402(a).

⁴ See 21 U.S.C. § 402(b).

⁵ 21 U.S.C. § 346 (citing 21 U.S.C. 342(a)(2)(A), which includes food with an unsafe substance in the meaning of adulterated).

⁶ 21 C.F.R. § 109.4.

⁷ 21 C.F.R. § 109.4(a) and (c).

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

A regulatory limit may be established when it meets the first criterion listed above, there is no tolerance established for the substance, and there is “insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance.”⁸ An action level may be established when the criteria in paragraph (b) are met, “except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future.”⁹ An action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established.¹⁰

The Agency's mercury action level of 1 ppm was established in 1979 as a result of a lawsuit initiated by the Anderson Seafood Company.¹¹ Prior to the lawsuit, the FDA's mercury action level was 0.5 ppm, the same as the EPA's for recreational fish.¹² The FDA has the authority to alter the mercury action level and any portion of commercial seafood and mercury regulation and enforcement under the provisions of the Federal FDC Act, the Public Health Service Act, and related regulations. This includes research, inspection, compliance, enforcement, outreach, and the development of regulations and guidance.

The HACCP System

In 1997, FDA adopted a program of preventive controls designed to identify hazards early in the seafood-production process and minimize the risk of contamination, the HACCP system.¹³ The FDA requires that every processor “shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards” and have and implement a plan when the analysis reveals a hazard.¹⁴ The Government Accountability Office (GAO) found in 2001 that FDA's compliance data showed that 40 percent of HACCP plans were inadequate, but noted that even “if the plans were complete, according to FDA requirements, they would still omit a serious

⁸ 21 C.F.R. § 109.6(c).

⁹ 21 C.F.R. § 109.6(d).

¹⁰ *Id.*

¹¹ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980).

¹² Action level for mercury in fish, shellfish, crustaceans, and other aquatic animals, 44 Fed. Reg. 3990 (Jan. 19, 1979).

¹³ 21 C.F.R. § 123.6.

¹⁴ *Id.*

hazard because methylmercury, a highly toxic substance, is not identified or covered in FDA's seafood guide as a hazard reasonably likely to occur."¹⁵ The 2001 GAO report notes specifically that contaminated fish is the major source of human exposure to methylmercury and can cause, among other things, serious neurological problems such as mental retardation in young children.

The fourth edition of the seafood guide, the Fish and Fishery Products Hazards and Control Guidance ("Guidance"), released April 28, 2011, still does not address mercury, but merely states:

As with previous editions of the "Fish and Fishery Products Hazards and Controls Guidance," this fourth edition does not contain advice on Hazard Analysis Critical Control Point (HACCP) controls for methylmercury, except where federal, state, local, or foreign authorities close certain waters to commercial harvesting as described in Chapter 9.¹⁶

This Guidance was released ten years after the GAO noted omission of methylmercury, a serious hazard, in FDA's seafood guide. The Guidance also mentions at page 10 that the FDA is receiving comments on a draft quantitative risk assessment for methylmercury but does not say whether the results of that assessment will be incorporated into the Guidance. This Guidance, dated January 15, 2009, has yet to be finalized.¹⁷

There are opportunities for the FDA and the National Marine Fisheries Service (NMFS) to coordinate monitoring and enforcement of safety measures for seafood. Specifically, a 2011 GAO report found that "FDA did not take advantage of NMFS inspection services or results to reduce its own inspection workload. In particular, from fiscal years 2005 through 2009, we found that FDA inspected 315 facilities that NMFS also inspected."¹⁸ The GAO found that the agencies have made limited progress in implementing the 2009 Memorandum of Understanding to enhance federal oversight of seafood.¹⁹

2) Health and Environmental Impacts of Mercury in Seafood

Without knowing it, mothers, children, dieters, sushi lovers and other people who regularly eat fish are consuming quantities of mercury that can be harmful to their health because the FDA has not fulfilled its mandate to promulgate regulations necessary to protect public health. A study revealed that nationwide, one of every ten women of childbearing age—nearly 7 million women—exceeded levels of mercury concentration in their blood that may pose a risk to fetuses.²⁰ Low-income women, women of color and economically disadvantaged children are

¹⁵ GAO. 2001. Federal Oversight of Seafood Does Not Sufficiently Protect Consumers, GAO-01-204.

¹⁶ FDA, 2011. Fish and Fishery Products Hazards and Controls Guidance, *available at* <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm>.

¹⁷ Draft Risk and Benefit Assessment Report, January 15, 2009, Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population, *available at* <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm088794.htm>.

¹⁸ GAO, April 2011. SEAFOOD SAFETY: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources, GAO -11-0286 at 11, *available at* <http://www.gao.gov/products/GAO-11-286>.

¹⁹ *Id.* at 23-24.

²⁰ Mahaffey KR, Clickner RP, Jeffries RA 2009. Adult Women's Blood Mercury Concentrations Vary Regionally in the United States: Association with Patterns of Fish Consumption (NHANES 1999–2004). *Environ Health Perspect* 117:47-53. doi:10.1289/ehp.11674

often at higher risk of mercury contamination due to lack of information and inclusion of high-mercury fish in national food programs, thereby triggering an environmental justice issue.

Mercury in the form of methylmercury is a toxin that can cause birth defects and harm a child's developing nervous system, leading to loss of motor skills and serious developmental delays. It can also cause kidney failure, cardiovascular collapse and genetic damage in adults. Many other less overt symptoms are also possible in children and adults, particularly those who regularly eat fish high in mercury.

Public agencies responsible for protecting people from mercury exposure are relying on obsolete 1970s policies and data despite mounting evidence that eating mercury-laden fish is harmful and toxicity levels are higher than current government averages. Testing of seafood for mercury has virtually ceased even though new scientific studies and case studies document mercury poisoning from eating commercial fish.

The 2004 FDA/EPA Advisory is not required to be posted at fish point-of-sale locations, and can only be found buried on the FDA website. This represents a very serious lapse in clear communication of the risks of mercury exposure to consumers from seafood. It would be easy for those especially vulnerable to the effects of mercury, such as women and children, to avoid eating high-mercury fish if the FDA/EPA Advisory was posted in locations where it would benefit those populations the most.

Mercury cannot be regulated out of the seafood supply, so the most practical option to prevent the health risks of mercury exposure is to provide clear information that is widely available so consumers can manage their own exposure risk. The current FDA/EPA mercury advisory is not providing maximum benefit to fish eaters. The advisory clearly states women should not eat swordfish, shark, tilefish and king mackerel and limit consumption of albacore tuna. Yet the advisory is largely absent from fish point-of-sale locations.

Furthermore the advisory needs to be updated to reflect recent scientific studies and publications to show that other species of tuna contain higher amounts of mercury than currently reflected in the FDA data.

Regulation of commercial seafood falls within the jurisdiction of the FDA, and the public relies upon accurate information and data to safeguard their health. Although the FDA has set an "action level" of 1 ppm for mercury levels in commercial seafood, many species of predatory fish such as swordfish and tuna regularly exceed the 1 ppm action level. Lack of rigorous testing and enforcement has increased the availability of high-mercury fish on the market and is being sold to consumers who are often completely unaware of toxic levels in these fish.

In 2007, a former FDA associate commissioner testified before a United States House of Representatives Committee that the FDA has neither the resources nor inspectors to stop importation of tainted food. Overall, the FDA inspects about 1 percent of the commercial fish sold on the U.S. market. A report from the *New York Times* revealed importers of swordfish, a

very high-mercury fish, use a smaller, younger sample of swordfish in order to pass the FDA mercury test. One FDA seafood expert said that over half of the imported swordfish probably contains unacceptable levels of mercury.²¹

In 2009, scientists from Harvard University and the U.S. Geological Survey published findings that the ocean's mercury levels have risen about 30 percent over the last 20 years.²²

These facts clearly point to the need for the FDA to revise its mercury-in-fish program to ensure that women of childbearing age in particular receive adequate warning and protection from mercury tainted fish in the U.S. food supply. Not only is the status quo a threat to human health, but it also has the potential to burden the overtaxed health care system with costs for illness that can easily be prevented.

3) Origins of Mercury in Seafood

According to the EPA, the primary source of mercury exposure in humans is consumption of fish. Mercury is a dangerous neurotoxin that enters the environment as a result of human activities such as burning coal and producing chlorine. Although volcanoes and other natural sources contribute to mercury's pervasive nature, two thirds of the mercury present in our environment is a result of human activities.²³ Mercury is deposited in the environment primarily from anthropogenic sources such as coal-fired power plants and industrial processes. Once released into the air, mercury is deposited back onto land and water. Bacteria then convert mercury to toxic methylmercury.²⁴ This methylmercury is absorbed or consumed by small plants and animals such as plankton, which are then eaten by larger animals, including fish. These larger animals accumulate mercury from their prey through the process of bioaccumulation in which concentrations increase through the food chain so that larger predatory fish such as tuna, sharks and swordfish have the highest mercury levels among fish. Humans and other large mammals at the top of the food chain have the highest exposure.

Recognizing this danger, FDA and the EPA issued a joint advisory to women and children about methylmercury in seafood.²⁵ The federal advisory warns women and children to limit their consumption of tuna and to eliminate four other species of fish from their diets. The joint advisory states:

1. Do not eat Shark, Swordfish, King Mackerel, or Tilefish because they contain high levels of mercury.
2. Eat up to 12 ounces (2 average meals) a week of a variety of fish and shellfish that are lower in mercury.

²¹ <http://www.nytimes.com/2007/07/18/washington/18imports.html>

²² Sunderland, E. M., D. P. Krabbenhoft, J. W. Moreau, S. A. Strode, and W. M. Landing (2009), Mercury sources, distribution, and bioavailability in the North Pacific Ocean: Insights from data and models, *Global Biogeochem. Cycles*, 23, GB2010, doi:10.1029/2008GB003425.

²³ US Environmental Protection Agency (EPA). 1999 National Emission Inventory Documentation and Data. Final Version 3.0. Research Triangle Park, NC: US Environmental Protection Agency (EPA), Office of Air Quality Planning and Standards. Available at: <http://www.epa.gov/ttn/chief/net/1999inventory.html#final3haps> Accessed January 25, 2006.

²⁴ Lehnher, I., V.L. St. Louis, H. Hintelmann, and J.L. Kirk. 2011. Methylation of inorganic mercury in polar marine waters. *Nature Geoscience* DOI: 10.1038/NGEO1134.

²⁵ <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucml15662.htm>

- 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 6 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 6 ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.

4) Health Effects of Mercury Exposure

Methylmercury can damage critical internal organs of the central nervous and cardiovascular systems. Children are particularly vulnerable to mercury's toxic effects. Infants and children exposed to high doses of mercury in the womb or after birth may have problems with attention span, language, visual-spatial skills, memory and coordination. Very high levels of mercury exposure in children can lead to brain damage, seizures, blindness, mental retardation and even death.

A 2000 National Research Council report estimates that 60,000 newborns each year are at increased risk for developmental delays due to the mother's mercury exposure.²⁶ The same report also concludes that EPA's current reference dose for methylmercury (0.1 µg/kg per day) is scientifically justifiable for the protection of public health and provides critical guidance for a broad range of public-health and regulatory initiatives aimed at reducing mercury exposures and preventing adverse health impacts.²⁷ The goal of the reference dose is to estimate a level of daily exposure without adverse public health impacts even for sensitive individuals.²⁸

Mercury's effects on adults can vary from increasing the risk of heart disease to a tingling sensation in the fingers. Recent studies have linked mercury to dementia and Alzheimer's disease.²⁹ People often do not associate their symptoms with mercury poisoning because the effects are sometimes very subtle. As a result, many people may continue to eat fish with high mercury levels, worsening the problem. Nervous system problems can include impaired coordination, tremors, irritability, memory loss, depression, blurred vision and a tingling sensation in the skin. Other symptoms include fatigue, nausea, headache, decreased concentration and muscle or joint pain.

A 2009 study conducted by the School of Medicine at the University of California, Los Angeles found that the mercury levels of women increased from 2 percent with elevated mercury levels in 1999-2000 to 30 percent with elevated mercury levels in 2005-2006.³⁰ Studies have even shown

²⁶ National Research Council, *Toxicological Effects of Methylmercury*, 2000, at 325.

²⁷ *Id.* at 329.

²⁸ *Id.* at 322.

²⁹ Joachim Mutter; Annika Curth; Johannes Naumann; Richard Deth; Harald Walach, Does Inorganic Mercury Play a Role in Alzheimer's Disease? A Systematic Review and an Integrated Molecular Mechanism. *Journal of Alzheimer's disease*, 2010 Aug

³⁰ Dan R. Laks, Assessment of chronic mercury exposure within the U.S. population, National Health and Nutrition Examination Survey, 1999-2006, *BioMetals*, ahead of print, 2009. doi: 10.1007/s10534-009-9261-0.

links between cardiovascular disease in adults and the consumption of fish high in mercury. A study published in 2010 in the *Neurotoxicology and Teratology Journal* showed that people who ate enough contaminated fish to raise mercury levels in their bodies to levels still considered "safe" had subtle changes to their heart rhythm that may affect their long-term health.³¹

5) High-risk Populations

Pregnant women, women of childbearing age and children are especially vulnerable to the detrimental health effects of mercury exposure through the consumption of seafood. Unfortunately, the current FDA/EPA advisory is not reaching these populations and is negligent in stating that canned "chunk light" tuna is a safer, lower mercury option.³²

Although mercury exposure in the womb is more dangerous, postnatal exposure to mercury should also be avoided. There is no safe exposure level of mercury and all steps should be taken to eliminate or reduce the risk of mercury exposure as much as possible.

Repeated studies have shown that mothers expose their nursing infants to methylmercury and inorganic mercury during breastfeeding.³³ Both forms of mercury are neurotoxins that are dangerous to the developing nervous system.

Researchers have advised mothers to avoid high-mercury fish during pregnancy and lactation while eating low-mercury fish in moderation to obtain the benefits of seafood consumption.

The promotion of canned "chunk light" tuna through Women, Infant and Children's (WIC) program as safe for breastfeeding mothers undermines the public health efforts to avoid canned tuna before and during pregnancy. For example, a study found that mercury in fish contributed to increased risk of premature birth.³⁴

Encouraging canned tuna consumption could put future pregnancies at risk. If the United States government hopes to promote healthier eating habits, then it should advocate canned fish options with little or no mercury exposure risks so that healthier eating habits can be encouraged.

Low-income families of color are already more exposed to high levels of mercury and other environmental contaminants than more affluent families. African-American and Mexican-American children had higher hair mercury levels than Caucasian children in studies of U.S. mercury levels in women of childbearing age and children. Mercury levels in the children corresponded to the amount of fish consumed per week.³⁵

³¹ Kozue Yaginuma-Sakuraia, Katsuyuki Muratac, Miyuki Shimadaa, Kunihiko Nakaia, Naoyuki Kurokawaa, Satomi Kameoa and Hiroshi Satoh, Intervention study on cardiac autonomic nervous effects of methylmercury from seafood, *Neurotoxicology and Teratology* Volume 32, Issue 2, March-April 2010, Pages 240-245

³² Hawkins, Monica, An Assessment of Awareness of Fish Consumption Advisories Concerning Mercury Among Women of Childbearing Age, 2009

³³ Karolin Björnberg et al., *Transport of Methylmercury and Inorganic Mercury to the Fetus and Breast-Fed Infant*, *Environmental Health Perspectives*, 113(10): 1381–1385 (October 2005). See also H. Drexler and K.H. Schaller *The Mercury Concentration in Breast Milk Resulting from Amalgam Fillings and Dietary Habits*. *Environmental Research*, 77(2):124-129(6). (May 1998).

³⁴ Fei Xue et al, *Maternal Fish Consumption, Mercury Levels and Risk of Preterm Delivery*, *Environmental Health Perspectives* (September 2006). Available at

³⁵ McDowell, M. et al, *Hair Mercury Levels in U.S. Children and Women of Childbearing Age: Reference Range Data from NHANES 1999–2000*, *Environmental Health Perspectives*

Further analysis of the national testing data showed that Asian, Pacific Islander, Native American (including Alaska Natives), or multiracial women tested had higher levels of mercury than women of other ethnicities surveyed between 1999-2000.³⁶

Promoting canned tuna and failure to update average mercury levels in canned tuna consistent with current scientific data will continue to contribute to health disparities between different ethnic and racial groups in the US. This creates an environmental justice issue when low-income ethnic and racial groups are disproportionately consuming canned tuna and encouraged to do so.

Many consumers are confused about low-mercury fish and the risks of high mercury canned tuna. The FDA estimated that between 30 and 50 percent of all women were not aware of the risks of mercury exposure from high-mercury fish like tuna.³⁷ A study in Wisconsin of pregnant mothers participating in WIC found that 74 percent of fish consumed by mothers was canned tuna (average of three meals per month), but two-thirds of the women did not know that predatory fish like tuna were high in mercury.³⁸

Furthermore, consumers are bombarded by advertising from the tuna companies touting the benefits of tuna, which further confuses consumers about the FDA and EPA mercury-in-fish advisories. A study in 2005 found that only 13 percent of people surveyed had heard about the FDA warnings about high-mercury fish in general. In the case of canned tuna, only 53 percent of those surveyed knew about the risks of canned tuna consumption.³⁹

Overall, the objectives of the FDA's seafood safety programs could be better served if participants were better educated about the benefits and risks of fish consumption that would enable mothers to make informed decisions based on both preferences and reasonable precaution against unnecessary mercury exposure.

6) Seafood Consumption and Mercury Levels in Pelagic Fish

Americans are encouraged by the FDA and other government agencies to eat up to 12 ounces of seafood per week. Shrimp is the top type of seafood consumed, but tuna is the second most popular fish. One out of every six of our seafood meals is tuna, and most of it is canned tuna. Of the two popular varieties, about three times as much canned light tuna is consumed as canned albacore (or "white") tuna. Fresh and frozen tuna steaks and tuna sushi are also popular choices, although they make up much smaller fractions of the market. Canned tuna, especially the canned light variety, is an inexpensive source of protein. Although sales have been declining as Americans have responded to a growing variety of seafood choices, canned tuna is still very

³⁶ Jane Hightower et al., *Blood Mercury Reporting in NHANES: Identifying Asian, Pacific Islander, Native American, and Multiracial Groups*, Environmental Health Perspectives

³⁷ Joanna Burger, *Fishing, fish consumption, and knowledge about advisories in college students and others in central New Jersey*, Environmental Research, 98:268-275 (June 2005).

³⁸ Gemma Gliori et al., *Fish Consumption and Advisory Awareness Among Expectant Women*, Wisconsin Medical Journal, 105(2):41-4 (March 2006).

³⁹ Joanna Burger, *Fishing, Fish Consumption and Knowledge about advisories in college students and others in Central New Jersey*, Environmental Research, 98:268-272 (June 2005)

popular. It's a favorite sandwich ingredient for families with children, and a staple of the federal school lunch program.

**Top Ten US Seafood Choices
2007-2009 (per the National Fisheries Institute)
Per Capita consumption, pounds per year**

Rank	Variety	2007	Variety	2008	Variety	2009
1	Shrimp	4.10	Shrimp	4.10	Shrimp	4.10
2	Canned Tuna	2.70	Canned Tuna	2.80	Canned Tuna	2.5
3	Salmon	2.364	Salmon	1.84	Salmon	2.04
4	Pollock	1.730	Pollock	1.34	Pollock	1.454
5	Tilapia	1.142	Tilapia	1.19	Tilapia	1.208
6	Catfish	0.876	Catfish	0.92	Catfish	0.849
7	Crabs	0.679	Crabs	0.61	Crabs	0.594
8	Cod	0.465	Cod	0.44	Cod	0.419
9	Clams	0.449	Flatfish	0.43	Clams	0.413
10	Flatfish	0.319	Clams	0.42	Pangasius	0.356
Total Pounds per year		16.3		16.0		15.8

Unfortunately, as long-lived ocean predators, tuna accumulate high amounts of mercury. Shrimp has the lowest methylmercury level among seafood items, with 0.012 ppm per the FDA average. In contrast, canned light tuna contains 10 times as much mercury, 0.118 ppm according to the FDA average.⁴⁰

The FDA mercury averages for canned albacore tuna and fresh/frozen tuna steaks contain 0.353 ppm and 0.384 ppm mercury, respectively, about three times as much as canned light has. It should be noted that numerous scientific studies have found much higher average mercury levels in all types of tuna than the FDA data show. Tuna sushi often made from large bluefin tuna, which are older and therefore have higher mercury levels, contains about 1.0 ppm mercury, putting it on a par with swordfish and shark among the highest-mercury fish.

Tuna of all types is the number one source of mercury in the American diet, contributing more than one-third of all mercury ingested from fish. Of that, about 16 percent comes from canned albacore, 16 percent from canned light tuna and about 6 percent from fresh or frozen tuna.⁴¹ The promoting of canned tuna consumption by the FDA puts women and children at significantly greater risk than the population at large, and raises the issue of environment injustice toward program participants.

⁴⁰ <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm191007.htm>

⁴¹ Edward Groth III, Ranking the contributions of commercial fish and shellfish varieties to mercury exposure in the United States: Implications for Risk Communications. Environmental Research, April 2010, pages 226-236

The FDA cannot guarantee the health safety of canned light tuna because of its failure to adequately screen canned tuna for mercury and to remove high-mercury tuna from grocery shelves and government programs. Contrary to FDA reported averages of the levels of mercury in light tuna, other studies have found higher levels and wide variability of mercury levels in light tuna. Repeated studies have shown that even chunk light or canned light tuna contain mercury levels higher than reported by the FDA and often close to the levels of mercury in albacore tuna.

Testing by GotMercury.org found that fresh tuna sampled from grocery stores averaged 0.47 ppm of mercury. One hundred and nine samples of tuna from grocery stores and restaurants across the U.S. were tested for mercury in 2010. There was a substantial difference between the lowest level of mercury in tuna sampled (0.01 ppm) and the highest mercury level of tuna tested (2.97 ppm).⁴² Further testing conducted by GotMercury.org found swordfish samples to harbor mercury levels more than 30 percent over the FDA's mercury average for the predatory fish. The testing was conducted in 2010 in California, Florida, New York, Iowa and Nevada and included 184 samples of seafood from 134 randomly selected retailers. Key findings from the sampling included:

- 47 of the 66 swordfish samples measured over 1.0 ppm mercury
- 13 of 32 swordfish samples measured over 2.0 ppm mercury, double the federal mercury action levels
- The average mercury level of the swordfish samples was 1.33 ppm, more than 30 percent over the FDA action level
- 84 percent of stores did not have mercury-in-seafood advisory signs posted to warn customers

In 2010, environmental health researchers at the University of Nevada, Las Vegas tested 300 cans of tuna including albacore, skip jack and other tuna species. More than half of canned tuna samples failed to meet the strict EPA's safety level for mercury in fish and five percent exceeded the FDA's action level.⁴³ With more than half of the canned tuna samples registering amounts of mercury much higher than the FDA's average of 0.118 ppm, it is clear that the data needs to be updated and new advisories should be issued to protect the most vulnerable populations.

Data published in 2011 by the Consumer Union found canned tuna samples to contain mercury levels well above the FDA's average. The results prompted Consumer Union to issue an advisory to pregnant and nursing women and young children to avoid all types of canned tuna due to the unpredictable levels of mercury.⁴⁴

Furthermore, because the FDA blends multiple samples of light tuna together for mercury testing, the averages of mercury in light tuna and the extremes of the cans containing yellow fin or bigeye tuna are obscured by this testing method.

Without accurate data on methylmercury levels in canned tuna, the FDA cannot rely on its own reported mercury levels claimed for chunk light tuna.

⁴² data collected from Got Mercury in 2010. Can be found at www.gotmercury.org

⁴³ Shawn L. Gerstenberger, Adam Martinson, Joanna L. Kramer. *An evaluation of mercury concentrations in three brands of canned tuna*, Environmental Toxicology and Chemistry, Volume 29 Issue 2, Pages 237 - 242

⁴⁴ <http://www.consumerreports.org/cro/magazine-archive/2011/january/food/mercury-in-tuna/overview/index.htm>

Without adequate enforcement of its own regulations, the FDA cannot guarantee that mothers and children will receive low-mercury canned tuna even when they choose only light tuna instead of albacore tuna. Therefore, the FDA must remove chunk light tuna from the low mercury option list to reduce unnecessary mercury exposure risk.

7) Regulation of Seafood in the U.S.

In the 1970s, the FDA set an “Action Level” for mercury in fish. Initially, FDA set the level at 0.5 ppm, the level adopted by most other countries that have similar limits. However, the fishing industry sued FDA, arguing that the economic impacts of the standard were likely to be too severe. A court agreed, and FDA had to revise the Action Level, raising it to its current level, 1.0 ppm. The change in policy also allowed for the regulation of mercury testing and reporting to be self-policed on behalf of the fishing industry.

An Action Level is a legal device; it allows FDA to order fish with more than 1 ppm of mercury to be taken off the market, without needing to establish that a hazard exists in each specific case, which would otherwise be required under food safety laws. However, in recent history and despite mounting evidence of high-mercury fish knowingly on the market, the FDA has not issued a recall, allowing seafood with toxic amounts of mercury contamination to continue being sold to unsuspecting consumers.

A 2004 GAO report stated that the FDA has not done enough to protect seafood safety. This included noting that the FDA fails to provide protection from mercury in seafood. Among the recommendations, the GAO suggested (and the FDA agreed) that enforcement needed more attention and that the FDA should explore equivalent foreign seafood inspection systems for improving the U.S. seafood safety net.⁴⁵

In response to criticism by the GAO, the FDA only slightly increased the number of seafood products it tested at U.S. ports of entry to about 1 percent.⁴⁶ The GAO found that the FDA did not prioritize enforcement and, on the rare occasion that the agency took enforcement action, that the FDA took an inordinate amount of time to respond.

8) Regulatory Actions Requested:

- 1) Reduce the current mercury action level from 1 part per million (ppm) to methylmercury expressed as mercury in excess of 0.5 ppm (edible portion only) to be in line with the Environmental Protection Agency (EPA) action level for recreation and sport caught fish to protect women of childbearing age, pregnant and nursing women, children and the most vulnerable populations or
- 2) Establish by regulation a tolerance level for the presence of methylmercury in seafood that shall not exceed 0.5 ppm (edible portion only) to protect women of childbearing age, pregnant and nursing women, children and the most vulnerable populations or

⁴⁵ United State General Accounting Office, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed.* (2004).

⁴⁶ Id.

- 3) Establish a regulatory limit for the presence of methylmercury in seafood that shall not exceed 0.5 ppm (edible portion only) to protect women of childbearing age, pregnant and nursing women, children and the most vulnerable populations.
- 4) Develop and implement a transparent government program of regular, widespread testing of commercial seafood for methylmercury levels.
- 5) Enforce the action level, tolerance level, regulatory limit, and/or prohibit sale in the U.S. of seafood that exceeds the action level, tolerance level or regulatory limit.
- 6) Include advice on Hazard Analysis Critical Control Point (HACCP) controls for methylmercury in the Fish and Fishery Products Hazards and Controls Guidance.
- 7) Require seafood distributors, retailers, restaurants and all institutions that sell seafood to post the FDA/EPA mercury-in-fish advisory at “point-of-sale” locations and/or label fish products that are known to be high in mercury.
- 8) Update the FDA/EPA What You Need to Know About Mercury in Fish and Shellfish advisory to reflect lower action level, tolerance level or regulatory limit for mercury in fish when adopted.
- 9) Revise and update the FDA Concentrations in Fish: FDA Monitoring Program through conducting new mercury analysis of each fish species listed in the Mercury Levels in Commercial Fish and Shellfish.

C. PROPOSED REGULATORY LANGUAGE ESTABLISHING A 0.5 PPM TOLERANCE FOR METHYLMERCURY

We propose the following regulatory language to establish a tolerance for methylmercury:

21 C.F.R. Ch. I, Subchapter B, Part 109

Subpart B - Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 109.40 – Tolerance for methylmercury

Mercury is a dangerous neurotoxin that enters the environment as a result of human activities such as burning coal and producing chlorine. Although volcanoes and other natural sources contribute to mercury’s pervasive nature, two thirds of the mercury present in our environment is a result of human activities. Mercury is deposited in the environment primarily from anthropogenic sources such as coal-fired power plants and industrial processes. Once released into the air, mercury is deposited back onto land and water. Bacteria then convert mercury to toxic methylmercury. Because methylmercury in seafood cannot be avoided and no technological or other changes are foreseeable in the near future to reduce the levels of methylmercury in seafood, a tolerance level that shall not exceed 0.5 parts per million is set in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

D. CONCLUSION AND CERTIFICATION STATEMENT

Based on the foregoing, Petitioners respectfully request that FDA:

Adhere to the charge of the United States Government to enforce and regulate all matters of mercury in commercially sold seafood to prevent human exposure to mercury, particularly for women of childbearing age, pregnant and nursing women, children and the most vulnerable populations. The Petitioners respectfully request the FDA adopt all of the suggested policy and regulatory recommendations.

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners that are unfavorable to the petition.

Sincerely,

Buffy Martin Tarbox, Campaign Coordinator
Got Mercury, Turtle Island Restoration Network
P.O. Box 370
Forest Knolls, CA 94933
415-663-8590

Catherine Kilduff, Staff Attorney
Center for Biological Diversity
351 California Street, Ste. 600
San Francisco, CA
415-644-8580

cc:
Dockets Management Branch
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Michael Landa
Director of the FDA Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740

Michael A. Chappell
Acting Associate Commissioner for the FDA Office of Regulatory Affairs
5600 Fishers Lane, Room 14-10, HFC 1
Rockville, MD 20857

Lisa Jackson
EPA Administrator
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 1101A
Washington, DC 20460

NOAA Seafood Inspection Program
U.S. Department of Commerce/NOAA Fisheries
1315 East West Highway
Silver Spring, MD 20910
NMFS.Seafood.Services@noaa.gov