



EARTHJUSTICE

ALASKA CALIFORNIA FLORIDA MID-PACIFIC NORTHEAST NORTHERN ROCKIES
NORTHWEST ROCKY MOUNTAIN WASHINGTON, DC INTERNATIONAL

July 5, 2011

2011 JUL 18 P 2:59

Dockets Management Branch
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Enclosed please find four copies of "Citizen Petition Seeking FDA Rulemaking for Labeling and Point of Sale Advisories Concerning Mercury in Seafood to Minimize Methylmercury Exposure to Women of Childbearing Age and Children" along with attachments containing information referred to and relied on pursuant to 21 C.F.R. § 10.20.

FDA-2011-P-0537

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**CITIZEN PETITION SEEKING FDA RULEMAKING FOR LABELING AND
POINT OF SALE ADVISORIES CONCERNING MERCURY IN SEAFOOD TO
MINIMIZE METHYLMERCURY EXPOSURE TO WOMEN OF
CHILDBEARING AGE AND CHILDREN**

Pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301–399, including §§ 321, 331, 342, 343, 371, the Administrative Procedure Act, 5 U.S.C. § 553(e), and 21 C.F.R. §§ 10.25, 10.30, Petitioners submit this Petition to the U.S. Food and Drug Administration (FDA) to request that the Commissioner initiate formal rulemaking with respect to labeling and point of sale consumer advisories for seafood containing elevated levels of methylmercury. The purpose of this rulemaking would be to clarify and better communicate federal seafood advice to women of childbearing age and parents of children. The grounds for this Petition are set forth as follows, as well as in the below-referenced studies and documents. Per 21 C.F.R. § 10.20(c), documents referred to or relied upon in the Petition are attached.

I. INTRODUCTION

Each year hundreds of thousands of children in the U.S. are born with elevated blood mercury levels due to maternal consumption of fish and shellfish contaminated with mercury. Approximately 200,000 children in the U.S. between the ages of two and five have mercury levels almost 50% higher than the base mercury level recommended by the EPA.¹ Indeed, large segments of the population—children, pregnant women and

¹ One percent of the U.S. population of children ages 2-5 has blood mercury levels of 8.8 µg/L. There are 19,175,798 children under the age of five in the U.S., according to 2000 Census data, so this equates to at least 191,758 children in this age group with elevated mercury levels. These mercury levels are 52% higher than the EPA Reference Level of 5.8 µg of methylmercury per liter of blood. Additionally, the above figure likely underestimates the number of children with elevated exposures because the Census data do not include children who are age five, but rather include only children *under* the age of five. See FDA, Draft Risk-Benefit and Assessment Report: Section II, Exposure to Methylmercury in the U.S. (January 15, 2009), available at: <http://www.fda.gov/food/foodsafety/product-specificinformation/seafood/foodborne pathogenscontaminants/methylmercury/ucm173271.htm>

women of childbearing age, in particular—have elevated mercury levels above the levels recommended for fetal and child health.² These figures are even higher in coastal regions, and among groups such as African-Americans and Asians,³ the affluent, and those in the fishing industry or who rely on subsistence or recreational fishing.⁴ Most of these individuals do not know of the risks inherent in exposing themselves and their families to this potent neurotoxin, which in sufficient amounts can lead to developmental delays or more serious health consequences in children. Moreover, most individuals in the U.S. do not know how to best minimize the risk to their families and unborn children.

These risks are preventable. Most seafood is healthy, and through better communication to at-risk consumers—i.e., women of childbearing age and parents of young children—people can minimize this potential harm to their children while maximizing the benefits of consuming healthy, low-mercury seafood.⁵ Due to the health benefits of fish, the FDA currently recommends that women of childbearing age, pregnant women, and children (the “TARGET GROUP”) try to eat two servings, up to 12 oz., of *lower-mercury* fish and shellfish.⁶ Exposure to elevated mercury levels may be significantly reduced simply by giving these women and families better information as to which seafood contains elevated mercury and should be limited, as well as which seafood is healthiest and should be consumed more regularly. While many seafood products emphasize the benefits of omega-3 fatty acids, at-risk consumers also need to know the federal consumption guidelines that apply to these foods. The rules proposed in this

(Table II-1, National Health and Nutrition Examination Study (“NHANES”) data 1999-2004 showing that children ages 2-5 at the 99th percentile have blood levels of 8.8 µg of Hg/L). Compare with U.S. Census Bureau, Census 2000 Brief—Age 4 (2000), available at: <http://www.census.gov/prod/2001pubs/c2kbr01-12.pdf>.

² Data from 1999-2002 show that an estimated 3.8 million women of childbearing age in the U.S. exceed the EPA’s Reference Level for methylmercury. Elsie M. Sunderland, Mercury Exposure from Domestic and Imported Estuarine and Marine Fish in the U.S. Seafood Market, 115 *Env’tl Health Persp.* 235, 241 (2007), available at: <http://www.ehponline.org/members/2006/9377/9377.html>. See also R.L. Jones et al., Blood Mercury Levels in Young Children and Childbearing-Aged Women—United States, 1999-2002, 53 *Morbidity and Mortality Wkly. Rep.* 1018–1020 (2004), available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5343a5.htm>.

³ Kathryn R. Mahaffey et al., Adult Women’s Blood Mercury Concentrations Vary Regionally in the United States: Association with Patterns of Fish Consumption (1999–2004), 117 *Env’tl Health Persp.* 47 (2009); Kathryn R. Mahaffey et al., Mercury Exposure: Medical and Public Health Issues, 116 *Transactions of the Am. Clinical and Climatological Ass’n* 127, 137 table 5 (2005); Kathleen L. Caldwell et al., Total Blood Mercury Concentrations in the U.S. Population: 1999-2006, 212 *J. of Hygiene and Env’tl Health* 588 (2009) (finding that blood mercury levels in African-American women of childbearing age in the U.S. are “significantly higher” than in non-Hispanic, Caucasian women); Sunderland, *supra* note 2 (finding that geographic variability of mercury levels in fish consumption affects blood mercury levels); Jane M. Hightower et al., Mercury Levels in High-End Consumers of Fish, 111 *Env’tl Health Persp.* 604, 606 (2003) (finding that women in the study had blood mercury levels at 10 times the national average, while some children in the study had blood mercury levels over 40 times greater than the national average).

⁴ See FDA, *supra* note 1.

⁵ In this Petition the term “seafood” refers to fish and shellfish, both from ocean and freshwater sources, which are sold commercially in interstate commerce and thus are subject to FDA oversight.

⁶ FDA, What You Need to Know About Mercury in Fish and Shellfish, EPA-823-R-04-005 (March 2004), at: <http://www.fda.gov/food/foodsafety/product-specificinformation/seafood/foodbornecontaminants/methylmercury/ucm115662.htm> (“Online Advisory”).

Petition will enable these consumers to maximize healthy intake of seafood by allowing them to identify and select fish and shellfish that contain both high omega-3s *and* low mercury.

The FDA and EPA recognize the importance of conveying this information to women of childbearing age and children, and for this reason the agencies have, since 2004, jointly published advice to this risk group through an online fish advisory.⁷ Despite these efforts, however, the TARGET GROUP by and large has not received this information and remains in the dark and at risk to this potent yet avoidable neurotoxin.⁸ The proposed rules in this Petition seek to close this information gap by providing information about eating seafood to consumers where they can readily access it while making purchasing decisions: in grocery stores through product labeling and point of sale advisories.

As discussed below, providing access to this information will not only enable parents to better protect their children, but will also promote healthy seafood consumption as a whole, enhancing market efficiency via the efficient flow of information concerning seafood risks and benefits. This will improve consumer decision-making, and help restore consumer confidence in the seafood supply by eliminating uncertainty as to which seafood is healthiest. Although most varieties of seafood are relatively low in mercury, as consumers have become increasingly aware of the fact that seafood can contain mercury, some have avoided seafood unnecessarily due to lack of reliable information about which seafood species are safest to eat.⁹ The proposed rules

⁷ *Id.* However, notably, a 2008 study of state-issued seafood advisories in the U.S. found that only 13 state advisories referenced the FDA-EPA federal “Online Advisory” or reiterated the federal guidance. Alison Scherer et al., Comparative Analysis of State Fish Consumption Advisories Targeting Sensitive Populations, 116 *Env’tl Health Persp.* 1598, 1603 (2008). This supports the necessity for labeling on packaged seafood and point of sale advisories at grocery stores to better illustrate and convey the federal guidance to the general population.

⁸ Jay P. Shimshack et al., Mercury Advisories: Information, Education, and Fish Consumption, 53 *J. of Env’tl Econ. and Mgmt.* 158, 177 (2007) (finding that a large group of at-risk consumers required seafood methylmercury outreach methods in addition to the 2004 Online Advisory, including “in-store advisory signs, and mandatory product labeling.”); Edward Groth III, Ranking the Contributions of Commercial Fish and Shellfish Varieties to Mercury Exposure in the United States: Implications for Risk Communication, 110 *Env’tl Res.* 226, 228, 232 (2009); Joanna Burger and Michael Gochfeld, Perceptions of the Risks and Benefits of Fish Consumption: Individual Choices to Reduce Risk and Increase Health Benefits, 109 *Env’tl Res.* 343, 345–46 (2009); Joanna Burger and Michael Gochfeld, Knowledge About Fish Consumption Advisories: A Risk Communication Failure Within a University Population, 390 *Sci. of the Total Env’t* 346, 351-52 (2007) (the authors of the study acknowledged that because their study was conducted in a university setting and those surveyed tended to be more highly educated with greater access to technological resources, their results may have overestimated the knowledge base regarding fish consumption advisories in the general public); Doris Hicks et al., Consumer Perceptions About Seafood—An Internet Survey, 19 *J. of Foodservice* 213, 221, 224–25 (2008) (finding that although people surveyed ranked the media number 1 and the internet number 2 as their most common sources for obtaining seafood information, “[b]oth knowledge about and attitudes toward seafood and seafood consumption were low.”). *Id.*

⁹ Emily Oken et al., Decline in Fish Consumption Among Pregnant Women After a National Mercury Advisory, 102 *Obstetrics & Gynecology* 346 (2003); Hicks, *supra* note 8, at 221 (finding that 79% of seafood consumers surveyed were unsure or did not agree that pregnant women should eat seafood and

are designed to communicate to the TARGET GROUP the large variety of lower-mercury seafood choices and the specific consumption limits for those fish species that contain elevated mercury. Families need this health information readily available to them in grocery stores. They need to know both that most seafood is beneficial and, for women of childbearing age and children, how to maximize their healthy intake of seafood through selecting lower-mercury seafood.

concluding that “most Americans do not fully understand the government’s advice on eating seafood and its implications for pregnant women.”). Id.

II. ACTION REQUESTED

This Petition requests that the FDA initiate rulemaking to better communicate and clarify its current recommendations for seafood consumption directed towards women of childbearing age and parents of children through labeling disclosures on packaging of certain seafood products and through point of sale advisories in grocery stores. Specifically, the proposed rules would:

A. **Provide for informational labeling on packaged seafood to generally reflect the FDA-EPA Online Advisory recommendations, which state:**

1. Most seafood is healthy, so women of childbearing age should ideally eat up to two servings per week of low-mercury seafood. Women and children who weigh less than 154 lbs. should eat less than 12 oz. total per week.
2. Seafood products with very high mercury (which the Online Advisory lists in the “do not eat” category) should not be eaten by women of childbearing age and children. These species include shark, swordfish, tilefish, and king mackerel.
3. While the current FDA-EPA Online Advisory recommends limiting albacore and fresh/frozen tuna to 6 oz. per week, canned albacore tuna should preferably be consumed only twice a month by the TARGET GROUP in keeping with the EPA Reference Level.¹⁰
4. Canned light tuna contains lower amounts of mercury and may be consumed up to two servings (or 12 oz. total) per week by women of childbearing age and children.

Chart 1 on page 7 provides a clarification of the current online advisory that includes more information about eating lower-mercury fish, and pages 24-25 of the Petition provide some examples of proposed packaged seafood labeling that contains information about the presence of mercury and the relevant consumption information for the TARGET GROUP.

B. **Require grocery stores to post the seafood consumption recommendations that the FDA currently publishes in the FDA-EPA Fish Consumption Online Advisory at the point of sale of unpackaged, fresh seafood, simplified into a user-friendly chart that is aimed at the TARGET GROUP.** This chart is designed to:

¹⁰ As discussed below, the Petition proposes that the FDA adjust its “6 oz. per week” albacore recommendation to comply with the EPA consumption guidelines that fish containing over 0.310 ppm of methylmercury be consumed only up to two 6 oz. servings per month (i.e., two servings per month rather than four servings per month as the Online Advisory states). Chart 1 on page 7 reflects this adjustment to the two servings per month recommendation for canned albacore. However, in the alternative, the Petition asks the FDA to better communicate its existing 6 oz. per week consumption limit for albacore tuna through point of sale advisories and product labeling on canned tuna, using labels like the examples on page 25 of the Petition.

1. Convey both the benefits of seafood consumption and the FDA advice that the TARGET GROUP eat up to 12 oz. of low-mercury seafood to optimize fetal and child health.
 2. Group commercial seafood by existing federal consumption recommendations, or by mercury ppm content level, in order to communicate to the TARGET GROUP the broad range of low-mercury seafood choices for these women and children to maximize optimal fetal and child development.
- C. Provide informational mercury level and consumption limit labeling, on packaging and/or at the point of sale, for seafood species with moderate and high mercury content¹¹ that are not otherwise listed in the Online Advisory, to specify the level of mercury content and/or the recommended consumption limit for the TARGET GROUP, including:
1. Moderate-mercury seafood, defined by federal EPA guidelines as containing above 0.12 ppm and up to 0.31 ppm of methylmercury, may be consumed up to once per week (6 oz.) by the TARGET GROUP of women of childbearing age and children.¹²
 2. Higher-mercury seafood, defined by federal EPA guidelines as fish that contains above 0.31 ppm and up to 0.47 ppm of methylmercury, may be consumed only once or twice a month by the TARGET GROUP, with no other fish consumed that month. This would include canned albacore, as well as fresh albacore.
 3. Should the FDA reject the Petition request (A-3, above) to align the canned albacore tuna and fresh/frozen tuna advice with the EPA consumption recommendation, these rules under Section C would not alter the 6 oz. weekly limit for canned albacore and fresh/frozen tuna.

There are proposed examples of notice labeling on page 25, and point of sale information in Chart 2 on page 27.

¹¹ See FDA, Mercury Levels in Commercial Fish and Shellfish, at: <http://www.fda.gov/food/foodsafety/product-specificinformation/seafood/foodbornecontaminants/methylmercury/ucm115644.htm> (last modified Nov. 19, 2009) (“FDA Fish Monitoring Data”).

¹² See EPA, Nat’l Fish and Wildlife Contamination Program, Technical Memorandum: Origin of 1 Meal/Week Noncommercial Fish Consumption Rate in National Advisory for Mercury, table 4-3, available at: <http://www.epa.gov/fishadvisories/advice/1-meal-per-week.pdf> (March 11, 2004).

Chart 1

SEAFOOD ADVICE FOR WOMEN UNDER 45 AND CHILDREN

EAT UP TO TWO WEEKLY SERVINGS (12 OZ.) OF LOW-MERCURY SEAFOOD

- Seafood is healthy, so eat up to two servings of low-mercury seafood per week (12 oz./week) and eat no other fish that week, BUT
- Children and women weighing under 154 lbs. should eat smaller portions that add up to <12 oz./week of low-mercury fish.
- Low-mercury seafood includes shrimp, salmon, catfish, pollock and light canned tuna. (See "Relative Mercury Content of Seafood" chart at the bottom of the page for more low-mercury seafood).

ADVICE FOR EATING MODERATE-MERCURY SEAFOOD

- Moderate-mercury content seafood: Limit total seafood intake to one serving per week (6 oz./week); eat no other fish that week.
- Note that light canned tuna is a LOW-MERCURY FISH and 12 oz./week can be eaten.

DO NOT EAT

Swordfish Shark Tilefish King Mackerel

RELATIVE MERCURY CONTENT OF SEAFOOD

LOW (2 servings, or 12 oz. per week)			MODERATE (1 serving, or 6 oz. per week)	HIGH (maximum 1-2 servings per month)
shrimp sardines tilapia clams oysters scallops mussels salmon freshw. Trout	ocean perch pollock Atl. mackerel anchovy flounder/sole crab pike butterfish catfish	squid Atl. croaker whitefish Pac.mackerel chub smelt cod light tuna (canned) spiny lobster	snapper skate freshwater perch monkfish skipjack tuna halibut sea trout sablefish rockfish Am. lobster	bluefish yellowfin tuna albacore tuna (canned and fresh) Chilean sea bass Span. mackerel grouper marlin orange roughy bigeye tuna eat no other seafood that month

(Chart lists fish from lowest to highest mercury content.)

III. STATEMENT OF GROUNDS FOR PETITION

A. Factual Grounds

1. Methylmercury as a Public Health Issue

Methylmercury is a neurotoxin present in most seafood in varying amounts, and when consumed at certain levels may impair fetal and child development. As the FDA-EPA Online Advisory warns, “some fish and seafood contain higher levels of mercury that may harm an unborn baby or young child’s developing nervous system.”¹³ The EPA further explains that methylmercury “accumulates in both fish and human tissues,” and long-term exposure of women to mercury can become a risk to fetal health in subsequent pregnancies because methylmercury can be transferred to the fetus through pregnancy and nursing.

Mercury is present in the food supply both from natural sources and from human activity, and for purposes of FDA food law it is considered an “added substance.”¹⁴ In United States v. Anderson Seafoods, Inc., the Fifth Circuit found that the presence of mercury in the oceans, the food chain, and ultimately in commercial seafood, is due at least in part to human activity and thus is an “added” substance.¹⁵ Coal-fired power plants, for example, are major human sources of mercury entering the oceans.¹⁶ Through a process called methylation, industrial, inorganic mercury in the oceans is converted into methylmercury, marine animals are exposed to the methylmercury and it becomes incorporated into their body tissue, and it then enters the human food supply through seafood.¹⁷ In turn, consumption of contaminated seafood is the primary source of methylmercury in humans,¹⁸ and indeed the FDA has found that “[t]he connection between fish consumption and exposure to methylmercury in the United States is well established.”¹⁹

Consuming methylmercury from seafood is a particular concern for fetal and child health. Fetuses and children are at a greater risk for health effects from mercury because the developing brain has a less developed blood-brain barrier and moreover, is particularly susceptible to mercury exposure.²⁰ As a result, the EPA has reported that studies in other countries have shown that even “mothers with no symptoms of nervous system damage [have given] birth to infants with severe disabilities, [from which] it

¹³ FDA, supra note 6.

¹⁴ United States v. Anderson Seafoods, Inc., 622 F.2d 157, 161 (5th Cir. 1980).

¹⁵ Id.

¹⁶ See FDA, supra note 1, at (b).

¹⁷ Id.

¹⁸ Id.

¹⁹ Id.

²⁰ Transande et al., Public Health and Economic Consequences of Methyl Mercury Toxicity to the Developing Brain, 113 Env't'l Health Persp. 590, 593 (2005).

became clear that the developing nervous system of the fetus may be more vulnerable to methylmercury than is the adult nervous system.”²¹

The Center for Disease Control (“CDC”) has been studying the levels of mercury in U.S. women of childbearing age and children through its National Health and Nutrition Examination Survey (“NHANES”). NHANES data reveal that although most people in the U.S., including children, do not have elevated mercury levels, a segment of the population is at risk. According to CDC data from 1999-2002, “approximately 6% of childbearing-age women have mercury levels at or above [the EPA’s] Reference dose...($\geq 5.8 \mu\text{g/L}$).”²² Though these figures have dropped somewhat in the more recent 2002-2004 data, the CDC and the National Center for Health Statistics has stated that the averaged, longer term results from 1999-2004 should be used.²³ These combined 1999-2004 data suggest that of the almost 6% of women of childbearing age who have elevated mercury levels,²⁴ at least 230,000 infants are born each year with elevated mercury levels.²⁵ This is consistent with studies based on the initial 1999-2001 NHANES data, in which it was estimated that 300,000 infants were born each year with mercury levels at or above the EPA Reference Level.²⁶ While these children do not necessarily exhibit clinical signs of disabilities, they may suffer from subtle, sub-clinical neurological deficits that can lower their IQ and potential for educational attainment.²⁷

The estimated number of children at risk is significantly higher if more recent studies on the higher ratio of fetal cord blood to maternal blood are taken into account. The initial estimates of this ratio, on which the EPA’s Reference Level is based, assumed that the level of methylmercury that reaches the fetus does so in a 1:1 ratio of fetal cord to maternal blood.²⁸ Newer research on cord blood suggests, however, that the proper ratio may instead be 1.7:1, which means that the fetus receives more methylmercury through the cord blood than is reflected in the mother’s blood.²⁹ Based on this, some studies suggest that the proper Reference Level should be lowered to $3.5 \mu\text{g/L}$ rather than the

²¹ EPA, Mercury: Health Effects, available at: <http://www.epa.gov/mercury/effects.htm>. These women, however, were exposed to greater mercury levels than those to which most women in the U.S. are exposed.

²² Jones et al., *supra* note 2, at 1018.

²³ *Id.*

²⁴ *Id.*

²⁵ The CDC reports that 5.5% of women of childbearing age have mercury levels above the EPA Reference Level, which, at birth rates in 2004 of 4,112,052, equates to at least 226,163 infants born every year with blood levels of elevated mercury over the EPA Reference Level ($5.5\% \times 4,112,052 = 226,163$ infants). See CDC, *supra* note 22 (5.5% elevated figure). See also National Vital Statistics Reports, 55 Births: Final Data for 2004 1 (2006), available at: http://www.cdc.gov/nchs/data/nvsr/nvsr55/nvsr55_01.pdf.

²⁶ Mahaffey et al., *Mercury Exposure: Medical and Public Health Issues*, *supra* note 3, at 136; Trasande et al., *supra* note 20, at 593.

²⁷ Trasande et al., *supra* note 20, at 593.

²⁸ Mahaffey et al., *Mercury Exposure: Medical and Public Health Issues*, *supra* note 3, at 145.

²⁹ *Id.* at 146; Mahaffey et al., *Adult Women’s Blood Mercury Concentrations Vary Regionally in the United States*, *supra* note 3, at 47.

current level of 5.8 µg/L.³⁰ Applying a revised cord blood ratio to the 1999-2001 NHANES data, 15.7% of women of childbearing age and 10.4% of women in the 1999-2004 study would have elevated blood mercury levels.³¹ Although the rules proposed here do not seek to change the EPA Reference Level, “nonetheless...several hundred thousand infants are born each year with in utero exposures to methylmercury exceeding those considered to be free of risk from adverse neurodevelopmental effects.”³²

Moreover, these figures are conservative. It is well documented, and the FDA recognizes, that the NHANES data underestimates mercury exposure in many subgroups of the population, including noted differentials in geographic and regional exposures, as well as elevated levels—likewise not reflected in the CDC data—among high-end consumers and ethnic populations that consume greater amounts of seafood.³³ As the FDA has acknowledged, NHANES “does not lend itself to regional analysis, i.e., it does not reveal whether there are regional exposures to methylmercury that are notably different from the national picture. As a consequence, NHANES is likely to miss subgroups of high fish consumers such as sport and subsistence fishers.”³⁴ Studies have shown, for example, that affluent consumers in coastal areas may have elevated mercury levels beyond the NHANES averages.³⁵ African-American women of childbearing age in the U.S. have “significantly higher” blood mercury levels than Caucasian women,³⁶ and the NHANES data also under-represents Asian-American populations in the U.S. that have higher rates of fish consumption.³⁷

This Petition seeks to obtain better dissemination and clarification of the current federal online advice and does not seek to strengthen the EPA Reference Level. Nevertheless, it is important to point out that the number of infants and children exposed to elevated mercury each year may be higher than previously estimated, and in any event, add up to hundreds of thousands of infants born each year with elevated mercury levels.³⁸ This potential burden on the population can have long-range health and economic implications for states and the nation as a whole. Most importantly, this risk can be substantially avoided simply through better risk communication to women of childbearing age and parents with young children.

³⁰ Mahaffey et al., Mercury Exposure: Medical and Public Health Issues, *supra* note 3, at 145; Alan H. Stern & Andrew E. Smith, An Assessment of the Cord Blood: Maternal Blood Methylmercury Ratio: Implications for Risk Assessment, 111 *Env'tl Health Persp.* 1465, 1468–69 (2003).

³¹ Kathryn R. Mahaffey et al., Blood Organic Mercury and Dietary Mercury Intake: National Health and Nutrition Examination Survey, 1999 and 2000, 112 *Env'tl Health Persp.* 562, 565, 569 (2004); Mahaffey et al., Mercury Exposure: Medical and Public Health Issues, *supra* note 3, at 134, 146–7; Trasande, *supra* note 20, at 591, 593.

³² Mahaffey et al., Mercury Exposure: Medical and Public Health Issues, *supra* note 3, at 147.

³³ See *supra* note 3.

³⁴ FDA, *supra* note 1.

³⁵ Hightower et al., *supra* note 3.

³⁶ Caldwell et al., *supra* note 3.

³⁷ Mahaffey et al., Mercury Exposure: Medical and Public Health Issues, *supra* note 3, at 127, 141; Mahaffey et al., Adult Women's Blood Mercury Concentrations Vary Regionally in the United States, *supra* note 3, at 47, 50–52.

³⁸ See *supra* notes 25-37.

Seafood has noted health benefits, so the FDA also advises that the TARGET GROUP eat more seafood. Studies have shown that fish with high omega-3 fatty acids can enhance cognitive function in children,³⁹ and for this reason the FDA's Online Advisory recommends that pregnant women and women of childbearing age eat fish twice per week (up to 12 oz. total) from lower-mercury species.⁴⁰ The research suggests that the neurological benefits of seafood to fetal and child health are maximized when low-mercury species of seafood are consumed.⁴¹ By emphasizing *lower-mercury* seafood, the FDA can pursue its dual goals of maximizing the benefits of seafood while minimizing the fetal/developmental risks associated with elevated mercury. The proposed rules go beyond the Online Advisory in promoting seafood consumption by communicating the nutritional advantages of eating seafood while also eliminating uncertainty about which types of seafood are high or low in mercury. Women of childbearing age and parents need this information readily available to them at grocery stores, both at the fresh fish counter and on packaged seafood products.

2. Existing FDA Online Advice on Mercury in Seafood

Since 2004, the FDA has sought to communicate dual risk-benefit information to the TARGET GROUP through its Online Advisory, which it publishes jointly with the EPA.⁴² This Advisory gives women of childbearing age and children recommended consumption limits for various types of seafood, and it advises this group to eat up to 12 oz. per week (two servings) of lower-mercury seafood. If the individual eats higher-mercury seafood, the total fish intake from all sources should be reduced to 6 oz. or less, as outlined below.

³⁹ Comm. on Nutrient Relationship in Seafood, Nat'l Academy of Sciences, *Seafood Choices: Balancing Benefits and Risks* 73–82 (2007), available at: http://www.nap.edu/catalog.php?record_id=11762.

⁴⁰ Comm. on the Toxicological Effects of Methylmercury, Nat'l Academy of Sciences, *Toxicological Effects of Methylmercury* 8 (2000), available at: http://books.nap.edu/openbook.php?record_id=9899&page=R1. By contrast, the 2000 National Academy of Sciences ("NAS") report, concluded that "reasonable intake" for women of childbearing age, children, and non-target consumers was 6 oz. per week (two servings of 3 oz. per week), however it also stated that they "can safely consume 12 ounces." *Id.* at 8, Box S-1.

⁴¹ *Id.* The 2007 NAS report, *supra* note 39, discussed studies which found that the mercury benefits of fish intake to fetal health decrease as mercury intake increases. The NAS report cited a study by Oken et al., which noted the contradiction that "higher mercury levels lead to worse cognition but, on the other hand, higher fish consumption is associated with better cognition." *Id.* at 82; Emily Oken et al., *Maternal Fish Consumption, Hair Mercury, and Infant Cognition in a U.S. Cohort*, 113 *Env'tl Health Persp.* 1376, 1379 (2005). The 2007 NAS study also found "decline in [developmental] scores as mercury burden increases," and noted the "remarkably concordant" findings between studies from the Seychelles, the Faroe Islands, and New Zealand regarding human methylmercury levels. The latter two of these studies "appear[ed] discrepant" with the Seychelles study, which on its face found little connection between cognition and mercury intake. *Id.* at 130. The modeling used in the FDA Draft Risk and Benefit Report included the Seychelles study but did not include the Faroe Islands or the New Zealand studies, and in so doing may have minimized the perceived developmental risk of increased mercury intake. See FDA, *supra* note 1. Additionally, in a re-analysis of the Seychelles data two years after the study's publication, the authors found that when they concluded that there was little connection between cognition and mercury intake, they had not considered the confounding factor of seafood's cognitive benefits to the children in the study. Once they corrected for that factor, their results were more consistent with the Faroe Islands and New Zealand studies. Groth III, *supra* note 7, at 227.

⁴² FDA, *supra* note 6.

The FDA-EPA Online Advisory currently issues three specific recommendations for the TARGET GROUP:

1. Do not eat certain very high-mercury species (shark, swordfish, tilefish, and king mackerel);
2. Limit albacore and fresh/frozen tuna to 6 oz. per week; and
3. Eat up to 12 oz. per week of lower-mercury seafood, which includes shrimp, salmon, pollock, catfish and canned light tuna.

The FDA-EPA Online Advisory is designed to reduce methylmercury exposure among the TARGET GROUP, and to keep levels generally at or below the EPA's Reference Level of 5.8 µg/L of mercury, which corresponds to a Reference Dose of 0.1 µg Hg/kg-body weight/day (the "RfD"). The EPA established this RfD for methylmercury in 1999, based on the best evidence then available, using data from a long-term epidemiological study in the Faroe Islands carried out by researchers at Harvard University and elsewhere.⁴³ In 2000, the National Academy of Sciences ("NAS") analyzed the EPA Reference Dose and validated the EPA's standard as consistent with its findings.⁴⁴ In turn, the CDC uses the EPA Reference Dose and Reference Level to analyze mercury levels in the population through its NHANES, which, as discussed, are based on this EPA Reference Level of ≤5.8 µg/L of methylmercury.⁴⁵ The FDA then uses this data to assess mercury exposure among women of childbearing age and children.⁴⁶

The FDA's Online Advisory does not specifically mention the EPA Reference Level, but its recommendation that average-weight women of childbearing age consume

⁴³ EPA Integrated Risk Information System, Methylmercury (MeHg), at: <http://www.epa.gov/iris/subst/0073.htm>; Philippe Grandjean et al., Methylmercury Exposure Biomarkers as Indicators of Neurotoxicity in Children Aged 7 Years, 150 Am. J. of Epidemiology 301 (1999).

⁴⁴ Comm. on the Toxicological Effects of Methylmercury, supra note 40, at 12.

⁴⁵ The NAS extensively studied the EPA standard for methylmercury and found it to be justifiable. See supra note 40, at 32. In setting the RfD, the EPA included an uncertainty factor. It is routine for such standards to include uncertainty factors that reduce the "safe" level of a particular substance for human consumption. Id. at 318. This factor in part accounts for expected differences in consumer weights, ages, health status, ability to detoxify heavy metals, and the wide variances in "typical" mercury levels per species of seafood. In the case of methylmercury, the level at which harm was observed based on the Faroe Islands study is 58 µg/L and the EPA used an "uncertainty factor" of 10 to determine its Reference Level standard of 5.8 µg/L. Id. at 328–29; Jones, supra note 23, at 1019; EPA, Integrated Risk Information System, Methylmercury (MeHg), at: <http://www.epa.gov/iris/subst/0073.htm>. However, even with this factor in place, studies have shown that adverse effects are observed when blood mercury levels are below the EPA Reference Level. Trasande, supra note 20, at 591; Groth, supra note 8, at 227.

Further, as previously discussed, supra notes 28–30, new research suggests that the umbilical cord blood ratio used by the EPA to compute the Reference Dose level should be 1.7:1 (cord blood:maternal), rather than the less protective 1:1 ratio that the EPA used when it determined the current Reference Dose. EPA Integrated Risk Information System, Methylmercury (MeHg), at: <http://www.epa.gov/iris/subst/0073.htm>. While this Petition is not asking the FDA to strengthen the Reference Level, this new research nevertheless demonstrates the necessity of the FDA setting consumption limits that are aimed at keeping blood levels of women of childbearing age and children at or below the EPA's limit.

⁴⁶ FDA, supra note 1.

up to 12 oz. of lower-mercury fish corresponds to the EPA's guidelines for consuming seafood containing 0.12 ppm or less of methylmercury.⁴⁷ Light canned tuna, with an average of 0.118 ppm of methylmercury according to FDA monitoring data,⁴⁸ represents the cutoff point for fish that can be consumed by the TARGET GROUP under EPA guidelines up to twice per week while keeping blood levels at or below the EPA Reference Level for mercury exposure.⁴⁹

While the EPA cutoffs are used by the EPA for its consumption recommendations for *noncommercial* fish, they are based on the Reference Level for mercury blood limits and thus apply equally to commercial seafood. The EPA has six consumption categories, several of which the Online Advisory combines for ease of understanding.⁵⁰ For example, the EPA's detailed breakdown includes two categories of fish with very low mercury (below 0.078 ppm) that can be eaten 3-4 times a week, and another category for lower mercury fish (between 0.078 and 0.12 ppm) that can be consumed up to twice per week.⁵¹ The FDA-EPA Online Advisory lists only three categories.⁵² First, the Online Advisory lists four very high mercury fish in the "do not eat" category—shark, swordfish, tilefish, and king mackerel—the lowest of which contains an average of 0.730 ppm of mercury. Second, the Online Advisory combines the EPA's two lowest-mercury categories into a single "lower mercury" category of seafood that should be eaten up to twice per week; this includes shrimp, salmon, pollock, catfish and light canned tuna (which range from "very low mercury" to "low mercury" on the more detailed EPA consumption breakdown). Third, the Online Advisory includes a 6 oz. weekly limit for canned albacore and fresh tuna.

The 6 oz. limit for canned albacore and fresh/frozen tuna has been criticized for exceeding the EPA Reference Dose guidelines.⁵³ Under the EPA's consumption guidelines, for example, fish exceeding 0.310 ppm of mercury should not be eaten weekly, but only twice per month. Canned albacore averages 0.353 ppm of methylmercury according to FDA monitoring data,⁵⁴ so it falls within this more stringent EPA twice-per-month category for fish containing between 0.310 ppm and 0.470 ppm of

⁴⁷ EPA, *supra* note 12.

⁴⁸ FDA, Fish Monitoring Data, *supra* note 11.

⁴⁹ EPA, *supra* note 12, at table 4-3.

⁵⁰ *Id.* The other low-mercury fish listed in the Online Advisory such as shrimp, salmon, pollock, and catfish, have even less mercury and even fall below the 0.086 ppm weighted average methylmercury content of U.S. commercial seafood consumed. See FDA, *supra* note 19, at 2.

⁵¹ *Id.*

⁵² FDA, *supra* note 11.

⁵³ Environmental Working Group (EWG), Information Quality Appeal—EWG Appeal Requesting Correction of FDA Seafood Advisory Entitled "What You Need to Know About Mercury In Fish and Shellfish: 2004 FDA and EPA Advice for Women Who Might Decide to Become Pregnant, Women Who Are Pregnant, Nursing Mothers, Young Children", (March 15, 2005), *available at*: <http://aspe.hhs.gov/infoquality/request&response/11c.pdf>. In 2005, the Environmental Working Group (EWG) objected to the FDA's 2004 decision to recommend 6 oz. of canned albacore tuna per week in the Online Advisory. The EWG asserted that the FDA's 6 oz. recommendation conflicted with EPA guidelines, lacked final approval from the expert panel of the Food Advisory Committee that had been reviewing the advisory language, and would not reduce mercury exposure.

⁵⁴ FDA, Fish Monitoring Data, *supra* note 11.

mercury,⁵⁵ rather than the four-times-per-month guideline (6 oz. per week) stated in the Online Advisory. As a result, a 140-pound woman who eats the 6 oz. amount of canned albacore tuna per week, as recommended by the Online Advisory, would exceed the monthly EPA Reference Dose (0.1 µg/kg/body weight/day) by 30%.⁵⁶ The proposed rules in part seek to correct this discrepancy.

It is important to note that the federal Online Advisory also advises children to eat proportionally smaller-sized portions.⁵⁷ This reflects the fact that the EPA's Reference Dose is based on weight, which for purposes of the consumption recommendations has been converted to serving sizes based on an assumed adult body weight of 70 kg, or 154 lbs.⁵⁸ Lighter-weight individuals in the TARGET GROUP, such as children, need to adjust the FDA-EPA consumption recommendations downward. Moreover, the recommended consumption limits are *totals*, so someone in the TARGET GROUP who eats one serving of higher-mercury fish should not eat any other fish that month. Likewise, a person in the TARGET GROUP who eats 12 oz. of lower-mercury light canned tuna in a week should not eat any other fish that week, which is why the Online Advisory states that consuming "up to" 12 oz. is allowable. Similarly, a pregnant woman who eats 6 oz. of canned albacore should not have any other fish that week, regardless of whether that other fish has a high or low mercury content. Any other reading would push the consumer over the EPA's Reference Dose.

3. Proposed Labeling Rules

The proposed rules are designed to better communicate to the TARGET GROUP (a) the FDA's existing Online Advisory information on the benefits and risks of seafood consumption for women of childbearing age and for children, and (b) the corresponding seafood consumption recommendations for this group. The proposed changes retain most of the existing federal standards on mercury in seafood and, except as discussed below regarding albacore tuna, they do not generally impose stricter consumption standards or differing mercury data than those currently published through the joint FDA-EPA Online Advisory and/or the additional related online information published by each agency. These proposed changes are designed to protect the TARGET GROUP while promoting increased consumption of healthy seafood, in part by dispelling current consumer uncertainty that surrounds the issue of mercury in seafood.

While the FDA-EPA advice is currently available online through the joint Online Advisory and on other FDA and/or EPA websites, the current online system under-serves women and families who do not, or cannot, readily access online information. Further, for those people that do access the Online Advisory, this small subset of the TARGET GROUP who know enough to seek this information online are not only *already aware* of the issue of mercury in seafood (enough to go online to research the issue), but also have

⁵⁵ EPA, supra note 12, at table 4-3.

⁵⁶ EWG, supra note 53.

⁵⁷ FDA, supra note 6.

⁵⁸ EPA, supra note 12, at table 4-3.

the time, educational expertise and Internet access to be able to do so. Unfortunately, many women do not fall into this category.

Moreover, even for these consumers who do access the FDA website, it can take considerable time and expertise to sift through the FDA and EPA online data to find out which seafood species fall into which low-, moderate-, and high-mercury categories, beyond the few species listed on the Online Advisory.⁵⁹ While the Online Advisory advises women in the TARGET GROUP to consume two servings of seafood from lower-mercury varieties and to limit albacore and fresh tuna to one serving a week, it does not list other fish with elevated mercury, apart from the four “do not eat” fish. Thus, even women who access the Online Advisory can be left confused as to which seafood species to eat, even when they want to maximize their seafood consumption to reap its health benefits.⁶⁰

Surveys confirm this, revealing that many women and parents who know about the issue of mercury in fish are confused about which types of seafood they should choose to maximize their weekly seafood consumption while minimizing their or their children’s exposure to mercury.⁶¹ The studies further show that a segment of these women limit their seafood intake due to this confusion, and moreover that they would increase their seafood intake if they had ready access to the species-specific information of the type that the proposed rules would provide.⁶²

⁵⁹ Studies published after the issuance of the 2004 Online Advisory have found that even those that are aware that there is an FDA-EPA Online Advisory regarding mercury are not able to identify high- or low-mercury seafood species. Groth III, *supra* note 8, at 232–33; Burger and Gochfeld, *supra* note 8, at 345.

⁶⁰ Several recent studies regarding consumer behavior in purchasing and eating commercial seafood have concluded that there is inadequate information and confusion among those surveyed about seafood low in mercury that should be consumed by the TARGET GROUP, which affects individual ability to determine what types of seafood to eat. Doris Hicks et al., *supra* note 8, at 224–25; Joanna Burger and Michael Gochfeld, Perceptions of the Risks and Benefits of Fish Consumption: Individual Choices to Reduce Risk and Increase Health Benefits, *supra* note 8, at 345–46; Joanna Burger and Michael Gochfeld, Knowledge About Fish Consumption Advisories: A Risk Communication Failure Within a University Population, *supra* note 8, at 351–52; Pamela Imm et al., Fish Consumption and Advisory Awareness in the Great Lakes Basin, 113 *Env’tl Health Persp.* 1325, 1329 (2005); Joanna Burger et al., Mercury in Commercial Fish: Optimizing Individual Choices to Reduce Risk, 113 *Env’tl Health Persp.* 1, 5 (2005); Joanna Burger, Fishing, Fish Consumption, and Knowledge About Advisories in College Students and Others in Central New Jersey, 98 *Env’tl Res.* 268, 271 (2004).

⁶¹ *Supra* notes 59–60. This confusion is further amplified by inconsistent federal government publications like the USDA’s Dietary Guidelines for Americans—2010, which discusses American seafood consumption, but advises women who are pregnant or breastfeeding to, “[c]onsume 8 to 12 ounces of seafood per week from a variety of seafood types. Due to their methyl mercury content, limit white (albacore) tuna to 6 ounces per week and do not eat the following four types of fish: tilefish, shark, swordfish, and king mackerel.” U.S. Dept. of Agric. & U.S. Dept. of Health and Human Services, Dietary Guidelines for Americans—2010, 34 (2011), available at: <http://www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf>. Additionally, the guidelines do not provide any specific advice on children’s seafood consumption, but discuss seafood generally, broadly advising readers to, “[i]ncrease the amount and variety of seafood consumed by choosing seafood in the place of some meat and poultry.” *Id.*

⁶² Oken et al., *supra* note 9, at 346–351 (It should be noted that the Oken study was conducted directly after the 2001 FDA-EPA joint advisory which recommended that pregnant women avoid eating the four highest mercury fish but did not contain information about low-mercury fish choices); Shimshack et al., *supra* note

The proposed rules effectively communicate this information to the TARGET GROUP through two components: notice labeling and point of sale advisories. In addition to labeling containing a notice regarding elevated levels of mercury and consumption limits for packaged seafood products with elevated mercury, the posted advisories are also key because at stores the TARGET GROUP needs to know not only the relative mercury content of the food they are buying, but also the mercury burden of the other seafood they have eaten earlier that week or month.

Another key component of the proposed labeling changes is communicating the FDA's current consumption advice to the TARGET GROUP through mercury level and consumption limit notices on labels of canned tuna. Proposed examples of such labels can be found at page 25 of the Petition. Tuna is not only an important source of low-cost protein for consumers, but with its large market share and mercury variability among species it also represents the largest single source of mercury intake by consumers, accounting for almost 40% of the nation's exposure to methylmercury from seafood.⁶³ Differences between the relative mercury content of the two main types of canned tuna (albacore tuna and light canned tuna) further make it important for the TARGET GROUP to have this information readily available at their fingertips—on the can label—when deciding which type of tuna is appropriate for themselves and/or their families, and in what amounts.⁶⁴ Recognizing this, in 2004 the American Medical Association approved a policy resolution stating, “[g]iven the limitations of national consumer fish consumption advisories, the [FDA] should consider the advisability of requiring that fish consumption advisories and results related to mercury testing be posted where fish, including canned tuna, are sold.”⁶⁵

Labels are necessary for both canned albacore and canned light chunk tuna to minimize confusion between the two types of tuna by informing the TARGET GROUP of the varying mercury levels and consumption recommendations for each. Specifically, it is important to label light canned tuna so that lower-mercury tuna is not confused with the consumption limits applicable to albacore. Also, TARGET GROUP consumers need to know that light canned tuna should be consumed only *up to* two servings per week, as the FDA-EPA Online Advisory states, since over that amount would expose this group to mercury levels above the EPA Reference Dose.⁶⁶

8, at 168-177; Barbara A. Knuth et al., Weighing Health Benefits and Health Risk Information When Consuming Sport-Caught Fish, 23 Risk Analysis 1185, 1194-95 (2003); Burger and Gochfeld, Knowledge About Fish Consumption Advisories: A Risk Communication Failure Within a University Population, supra note 59, at 348; Shimshack et al., supra note 8, at 177.

⁶³ See Groth III, supra note 8, at 230-31.

⁶⁴ Id.

⁶⁵ AM. MED. ASS'N, H-150.947 Mercury and Fish Consumption: Medical and Public Health Issues, available at, <https://ssl3.ama-assn.org/apps/ecom/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-150.947.HTM>. The resolution additionally states, “[t]esting of the mercury content of fish should be continued by appropriate agencies; results should be publicly accessible and reported in a consumer-friendly format.”

⁶⁶ Light canned tuna is listed on the Online Advisory as a “lower mercury” fish choice, but it nevertheless contains more mercury than the weighted average content in the commercial seafood market (i.e., 0.118 ppm compared to the weighted average of 0.086 ppm for all commercial seafood). See FDA, supra note 1.

The proposed rules also would revise the canned albacore consumption recommendations to adhere to the EPA consumption limits and Reference Dose standard (e.g., that seafood containing over 0.310 ppm of mercury, such as canned albacore tuna, should be consumed only twice per month, and no other seafood consumed that month). In the alternative, even if the FDA does not revise this albacore consumption limit, the Petition asks the FDA to, at a minimum, disclose the levels of mercury in canned albacore and fresh/frozen tuna and to better communicate the FDA's existing recommendation that women of childbearing age and children consume no more than one, 6 oz. serving per week. Both versions of the proposed rule would communicate this information through package labeling and/or through posted advisories at the point of sale.

In conjunction with this, the proposed rules also would require product labeling and/or point of sale advisories for other seafood that similarly does not fall within the Online Advisory's general recommendation that the TARGET GROUP eat two servings of lower-mercury fish per week. Apart from the issue of albacore and fresh/frozen tuna, these rules would apply to (1) moderate-mercury seafood that exceeds the 0.120 ppm mercury content level (and thus should be eaten only once per week by the TARGET GROUP) as well as (2) higher-mercury seafood that contains above 0.310 ppm of mercury (which should be consumed by the TARGET GROUP only once or twice per month). The labeling itself would include information about the moderate or high level of mercury in the seafood as well as consumption recommendations, like the examples listed on page 25 of the Petition.

In particular, these rules would first include seafood that the FDA describes as containing "mid-range" mercury content.⁶⁷ According to the EPA consumption guidelines (based on the EPA Reference Dose), women of childbearing age and children should only eat those species that contain between >0.12 - 0.31 ppm of methylmercury approximately once a week (three or four times a month).⁶⁸ This category includes, for example, seafood such as snapper (0.189 ppm), halibut (0.252 ppm), saltwater bass (0.219 ppm, excluding higher-mercury Chilean bass (at 0.386 ppm), and American lobster (0.310), as well as various other species for which FDA monitoring data indicates average between >0.12 - 0.31 ppm of mercury content.⁶⁹ The species in this category comprise a relatively small market share—approximately 2.8% of the national commercial seafood market—but nevertheless account for close to 10% of the nation's exposure to methylmercury in seafood.⁷⁰ Second, the proposed rules would also communicate mercury level and recommended consumption limits for higher-mercury

⁶⁷ FDA, *supra* note 1.

⁶⁸ EPA, *supra* note 12, at table 4-3.

⁶⁹ FDA, Fish Monitoring Data, *supra* note 11.

⁷⁰ Groth III, *supra* note 8, at 231 table 6. While this analysis groups a few fish differently than the FDA, it generally uses the same ppm figures as the FDA monitoring data or figures consistent with it. The article's use of market share information is important given the weighted average contribution to the nation's overall mercury burden from each category of commercial seafood.

seafood that the EPA classifies under its “twice a month” category of fish and shellfish that contain between >0.31 - 0.47 ppm of methylmercury.⁷¹

These proposed rules for moderate and high-mercury seafood would extend to five fish in the current top 20 list of most consumed raw fish in the U.S.: halibut (0.252 ppm), American lobster (0.310-ppm⁷²), tuna (skipjack: .205 ppm, yellowfin: .325 ppm, albacore: .357 ppm, bigeye: .639 ppm), orange roughy (0.554 ppm), and swordfish (.976 ppm, “do not eat”).⁷³ Since most seafood is low in mercury, the rules would not affect most commercial seafood that the Advisory does not already address. The rules nevertheless would help prevent unnecessary exposure through better risk communication since higher-mercury fish account for a sizable portion of the nation’s mercury burden from commercial seafood.⁷⁴ These two proposed categories of seafood that do not fall within the current Online Advisory’s general recommendation that the TARGET GROUP eat two servings of lower-mercury fish a week (>0.12 ppm and >0.31 ppm, respectively) alone account for almost half (45%) of the nation’s mercury exposure from seafood. Even if tuna’s large share of the market is excluded from this figure, these proposed categories remain responsible for almost a quarter (23%) of the nation’s overall mercury burden from commercial seafood.⁷⁵

Further, while the impact on national blood mercury levels is substantial, the impact on overall market share of the seafood market is small: the mid-range elevated mercury category (>0.12 ppm -0.31 ppm) accounts for approximately 9% of overall seafood consumed and the higher-mercury category (>.31 ppm) accounts for only 0.54% of market share, excluding albacore and fresh tuna.⁷⁶ Although not all women of childbearing age and children eat these higher-mercury fish, those women and children who do should be informed that these species contain elevated mercury.

This disclosure is significant for women of childbearing age and children. Eating a 6 oz. serving of orange roughy per week, for example, would expose a 70-kg (154 lb.) pregnant woman to almost double the EPA’s recommended Reference Level for mercury. Moreover, it would deprive her of the beneficial impact of eating another serving of fish each week for the rest of the month, since TARGET CONSUMERS who exceed their consumption limits *should not eat any other fish for that entire weekly or monthly consumption period*. This would be far from the recommended twice-weekly servings of lower-mercury fish for beneficial omega-3 fatty acid intake during pregnancy and child brain development.⁷⁷ Thus, for example, the decision to eat orange roughy not only

⁷¹ EPA, *supra* note 12, at table 4-3.

⁷² FDA, Fish Monitoring Data, *supra* note 11. American lobster, which contains .310-ppm of methylmercury on average, technically falls into the EPA consumption limit of three times per month, but for ease of consumer understanding the proposal would collapse this into a more workable four times a month, or “once a week”, rule.

⁷³ Compare 21 C.F.R. § 101.44(c) (“What are the 20 most frequently consumed raw fruits, vegetables, and fish in the United States?”), with FDA, Fish Monitoring Data, *supra* note 11.

⁷⁴ Groth III, *supra* note 8, at 231 table 6.

⁷⁵ Groth III, *supra* note 8, at 231 table 6.

⁷⁶ *Id.*

⁷⁷ FDA, *supra* note 6.

effects the amount of that particular fish she should eat, but more importantly also determines the amount (if any) of other fish that she should consume for the rest of that month.

This is why members of the TARGET GROUP needs to know not only the mercury content of the particular fish they are buying, but also that of the other fish they have eaten earlier that week or month at the point of sale. This also explains why it is not sufficient to require only labeling of seafood products with large market share, such as tuna. In this way, disseminating current FDA-EPA advice and improving on it as discussed above, will enable the TARGET GROUP to better select from the many healthy, low-mercury seafood choices available in grocery stores. Doing so will also dispel existing confusion and concern about the types of seafood that are best for children and fetal health, and thus will in turn foster healthy seafood consumption. More importantly, by encouraging increased consumption of low-mercury seafood by children and pregnant women, the proposed rules will promote the cognitive development and the educational potential of America's youth.

B. Legal Grounds

The FDA has broad general authority to require notice labels regarding mercury level and consumption limits and point of sale advisories to promote healthy fetal and child development through better communication of the federal consumption guidelines for seafood to the TARGET GROUP. The FDA also has authority for the proposed rules under section 701(a), and sections 402 and 403 of the FFDCA.⁷⁸ Use of this authority to promulgate the proposed rules would enable women of childbearing age and children to minimize their consumption of methylmercury in seafood while maximizing seafood's beneficial effects.

As a threshold matter it is critical to note that the FFDCA applies not only to food processors and manufacturers, but also to anyone who is in "receipt in interstate commerce of any food...that is adulterated or misbranded..." such as grocers who sell food.⁷⁹ Moreover the FDA's ability to require labeling, which is discussed in more detail below, extends to point of sale advisories, since the Act defines the term "labeling" to include "all labels and other written, printed, or graphic matter...accompanying such article."⁸⁰

⁷⁸ 21 U.S.C. § 371 (efficient enforcement of the Act); 21 U.S.C. § 343(q) (nutrition labeling); 21 U.S.C. § 342 (adulterated foods); 21 U.S.C. § 343(a) (misbranded foods); 21 U.S.C. § 321(n) (misbranding).

⁷⁹ 21 U.S.C. § 331(c).

⁸⁰ 21 U.S.C. § 321 states in relevant part:

"(k) The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(m) The term "labeling" means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

1. THE FDA HAS THE GENERAL AUTHORITY TO PROTECT PUBLIC HEALTH

a. The Public Health Purpose of the FDA

The proposed rules fall within the FDA's broad authority to protect public health. As the FDA describes its history, "[t]he Food and Drug Administration is the oldest comprehensive consumer protection agency in the U.S. federal government," which dates back to its origins in 1848 and the subsequent adoption of the 1906 Pure Food and Drugs Act.⁸¹ Section 903 of the FFDCFA states as to the mission of the FDA:

"The Administration shall--(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action in the marketing of regulated products...[and] (2) with respect to such products, protect the public health by ensuring that--(A) foods are safe, wholesome, sanitary, and properly labeled..."⁸²

The U.S. Supreme Court has stated that "we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with *the Act's overriding purpose to protect the public health...*"⁸³ The Court further stated that in light of the fact that "people, which in the circumstances of modern industrialism, are largely beyond self protection," the FDA's statutory authority has been "successively strengthened [and]... Congress [has] exerted its power to keep impure and adulterated foods and drugs out of the channels of commerce.... Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government..."⁸⁴

The FDA's statutory power to protect the public health has been increasingly broadened as the modern food supply has expanded across state lines and even across the nation's borders. Although at different points in time the FDA has chosen to wield its power to varying degrees, and likewise has varied in the way in which it has enforced or acted on this mandate to protect public health, it nevertheless retains its authority to do so. The current Administration, under Commissioner Margaret Hamburg, views this public health role seriously. Dr. Hamburg signaled this position in the *New England Journal of Medicine*, in which they emphasized that the one "constant is the agency's 'overriding purpose', in the words of the Supreme Court, of protecting the public health."⁸⁵ Noting the importance of such a role and the importance of keeping with its Congressional mandate as elucidated by the Supreme Court, Commissioner Hamburg

⁸¹ See FDA History, at: <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>.

⁸² 21 U.S.C. § 393(b).

⁸³ *United States v. Article of Drug...Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (emphasis added).

⁸⁴ *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951) (quoting *United States v. Dotterweich*, 320 U.S. 277, 280 (1943)).

⁸⁵ Margaret A. Hamburg and Joshua M. Sharfstein, *The FDA as a Public Health Agency*, 360 *New Eng. J. of Med.* 2493 (2009), available at: <http://www.nejm.org/doi/full/10.1056/NEJMp0903764>.

explained that the FDA is not merely a regulatory agency but, more importantly, a public health agency.⁸⁶

The FDA has long taken regulatory action to promote public health as to food. In 1996, for example, the FDA took the novel step of promoting child development by requiring that certain enriched grain products contain folic acid.⁸⁷ It did this by mandating that the “standard of identity” for enriched grain products include folic acid in order to reduce the number of neural-tube related birth defects.⁸⁸ Similarly, in the 1980s the FDA began to propose broader nutritional labeling to help consumers make healthy food choices in the marketplace. This process culminated with Congress passing the Nutrition Labeling and Education Act of 1990 (“NLEA”), which expanded the FDA’s reach regarding mandatory disclosures to give consumers more information about the foods they eat.⁸⁹ Subsequently, Congress went further to allow the FDA to require mandatory labeling of common allergens in foods (such as wheat, dairy, and nuts),⁹⁰ and in 2003 the FDA promulgated regulations under NLEA to require mandatory labeling of trans-fats.⁹¹

b. Requiring Labeling for the Methylmercury Content of Seafood Comports with FDA’s Purpose to Promote Public Health

The proposed rules comport with the public health mandate of the FDA in that the rules protect fetal and child development by giving women of childbearing age and families more information about recommended seafood consumption. Better communication of the federal methylmercury consumption standards for seafood is key to complying with the FDA’s primary role to protect and promote the public health. As FDA Commissioner Hamburg explained upon taking office, “[t]he CDC and the FDA should [] work closely to identify areas of potential progress in nutrition. Working with industry and others, the FDA can support efforts to educate the public about nutrition and promote more healthful foods.”⁹²

In the past, the FDA has focused on the benefits of seafood to the population as a whole, but this does not negate the need to supply vulnerable subpopulations (here, the TARGET GROUP) with access to the health information they need in order to make informed health decisions about the amount and type of seafood to consume. Specifically, although the FDA previously took informal steps to block state efforts to

⁸⁶ *Id.*

⁸⁷ Food Standards: Amendment of Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, 61 Fed. Reg. 8,781 (March 5, 1996).

⁸⁸ *Id.* at 8,790–92.

⁸⁹ Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

⁹⁰ Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905, 906–08 (codified at 21 U.S.C. §§ 343(m), 321(qq)).

⁹¹ Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434 (July 11, 2003) (codified at 21 C.F.R. § 101).

⁹² Hamburg and Sharfstein, *supra* note 85.

provide this information to the TARGET GROUP,⁹³ under the current Administration, the FDA takes the view that consumers should take greater roles in their health and should not be deprived of access to vital health information about the products they eat.⁹⁴ This is particularly true here, given the potential harm to fetal brain development that could result from over-consumption of certain seafood with elevated mercury levels.

Moreover, the information at issue here would give these consumers the ability to both maximize the benefits of eating seafood while minimizing these risks. In situations such as this, the FDA Commissioner has directed that “the agency must communicate frequently and clearly about risks and benefits” rather than assuming that consumers cannot be trusted with this information to weigh these pros and cons for themselves.⁹⁵ Specifically, the FDA should not simply predetermine that risks should not be communicated where there are corresponding benefits associated with that food, but instead it should communicate “about what organizations and individuals can do to minimize risk.”⁹⁶ As applied to the proposed rules, the FDA has the authority and the discretion to act in the interest of fetal and child health to require the disclosures of relative mercury levels in certain seafood. Again, this will allow women of childbearing age and parents of young children to maximize the benefits of healthy seafood by enabling them to select low-mercury seafood for their families.

Even in situations in which the risks are uncertain, the FDA takes the position that “in the absence of perfect information, the FDA cannot delay in providing reasonable guidance—guidance that informs rather than causes unnecessary anxiety.”⁹⁷ Thus despite the ever-expanding volume of information regarding risk-versus-benefit and the pending nature of FDA’s Draft Risk and Benefit Assessment Report, there is no reason to delay communicating the potential risks to the TARGET GROUP.⁹⁸ Indeed, putting aside the question of the status of the Draft Report,⁹⁹ the Draft should be consistent with

⁹³ Letter from former FDA Commissioner Crawford to Bill Lockyer, Attorney General of the State of California, RE: a suit filed on June 21, 2004 in San Francisco Superior Court, The People of the State of California v. Tri-Union Seafoods, LLC, et al., Case no: CGC-04-432394 (August 12, 2005) (in which the California sought mercury disclosures under California’s “Proposition 65” law) (on file with author).

⁹⁴ See supra note 85.

⁹⁵ Id.

⁹⁶ Id.

⁹⁷ Id.

⁹⁸ See FDA, Draft Risk and Benefit Assessment Report: Exposure to Methylmercury in the United States-- 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 (January 15, 2009) at: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm173271.htm>. Despite the emphasis on the overall benefits of seafood in the Draft Report, the proposed rules propose a distinct approach to enable the TARGET GROUP to get the benefits of low-mercury seafood while minimizing the risk from higher-mercury species.

⁹⁹ This Petition does not address the merits of the modeling used in the FDA Draft Risk and Benefit Assessment Report but supports the comments to the Report made by the EPA and by the Environmental Working Group. See US EPA, Letter to Dr. Sundlof Re: Comments on the Draft FDA Report Assessing Risks and Benefits From Fish Consumption (April 17, 2009), available at: www.epa.gov/fishadvisories/files/epa-comments-fda.pdf.

the FDA's recommendations in the Online Advisory that women of childbearing age and children eat 12-ounces of lower-mercury seafood per week.

To withhold this information from the public can cause anxiety and erode public confidence in the safety of FDA seafood rules and thus in the seafood supply as a whole. As previously discussed, the public is already aware of mercury risks but is confused about what seafood is low in mercury.¹⁰⁰ Thus, in absence of clear information from the FDA on this issue, some consumers have avoided and will likely continue to avoid even healthful seafood due to confusion surrounding FDA advisories.¹⁰¹

The necessity for this labeling falls squarely within the wide range of other warning labels that the FDA currently requires for other foods. FDA-mandated labeling, for example, gives people with Celiac disease (gluten intolerance) or with dairy allergies information about the presence of wheat and milk in food,¹⁰² just as other FDA-required labeling notifies people with phenylketonuria (PKU) which foods with aspartame contain phenylalanine.¹⁰³ So, too, should seafood products have labeling that provides information about elevated mercury so parents can identify which products would be harmful to their developing fetuses or young children if consumed in amounts over the recommended limits.

As discussed above, the proposed labeling rules are supported by scientific studies on the harm to fetal health from ingesting elevated mercury from certain types of seafood, as well as by the NHANES, which estimates that between 200,000-400,000 infants are exposed to elevated mercury levels *every year* through mercury content in seafood.¹⁰⁴ This remains true in light of the facts discussed above that the general public is either unaware of, or confused by FDA's Online Advisory.¹⁰⁵ Concern for food safety means that women of childbearing age and parents should receive this vital information to protect the health of their children.

2. THE FDA HAS AUTHORITY UNDER THE NUTRITIONAL LABELING AND EDUCATION ACT TO REQUIRE INFORMATIONAL LABELING FOR MERCURY CONTENT

In addition to its general authority, the FDA also has specific authority to require informational labeling of elevated mercury levels and consumption limits under the NLEA. The NLEA requires uniform food product labeling to list common nutritional information such as the content of protein, fat, calorie, and sugar on the nutrient label.¹⁰⁶ These changes were instituted to enable consumers to make meaningful comparisons between food products so that they can make healthier food choices. As discussed below, the NLEA gives the FDA specific authority to require labeling of mercury levels and

¹⁰⁰ See *supra* notes 60 and 62.

¹⁰¹ Oken et al., *supra* note 9.

¹⁰² 21 U.S.C. §§ 321(qq), 343(m).

¹⁰³ 21 C.F.R. § 172.804(d)(2).

¹⁰⁴ See *supra* notes 1-3.

¹⁰⁵ See *supra* notes 60 and 62.

¹⁰⁶ 21 U.S.C. § 343(q).

consumption limits in packaged seafood, such as canned tuna and packaged high-mercury fish. It also gives it authority to issue voluntary guidelines for grocery stores to post the recommended consumption limits for the 20 most common raw, unpackaged fish at the point of sale.¹⁰⁷

Most important to the instant Petition, the NLEA further gives the FDA broad discretion to require other health information to be included on the food label, beyond the categories enumerated in the statute. In particular, section 403(q) of the Act provides that the FDA may, by regulation, require labeling of additional nutrients “for purposes of providing information regarding the nutritional value of such food *that will assist consumers in maintaining healthy dietary practices.*”¹⁰⁸

a. Packaged Seafood

Alerting consumers to the elevated mercury level and consumption advisory limits on the labels of packaged seafood products that contain moderate or high levels of mercury would “assist consumers in maintaining healthy dietary practices,” per the statute.¹⁰⁹ It would allow women of childbearing age to track their mercury intake, as well as give parents the ability to regulate the mercury content of the fish their children consume. Specifically, the rules proposed here would list mercury on the package label denoting the level of mercury content. These groupings by mercury content would be based on the FDA’s fish testing and monitoring data for each species.

The label could highlight that the information pertains to women of childbearing age and children, and/or can incorporate the recommended consumption limits. Various alternatives include:

WOMEN OF CHILDBEARING AGE AND CHILDREN: In general, for fetal health eat 12 oz. of low-mercury fish a week. **Albacore tuna contains ELEVATED mercury--limit total fish intake to twice a month.***

[* Or in the alternative, one 6 oz. serving per week if the FDA does not use the EPA limit for canned albacore.]

Women Under 45 and Children: Elevated mercury; limit to no more than 2 servings/month.

¹⁰⁷ 21 U.S.C. § 343 (q)(4)(D)(ii–iii).

¹⁰⁸ 21 U.S.C. § 343(q)(2)(A)(emphasis added). This provision states in full: “If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to paragraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.”

¹⁰⁹ 21 U.S.C. § 343(q)(2)(A).

Warning for children and pregnant women:
Contains **elevated** mercury.

Fetal risk advisory: Mercury content—children and pregnant women should eat this product no more than 2 times/month.

Women of childbearing age and children: elevated mercury; limit total fish intake to twice per month if you eat albacore tuna.

WOMEN OF CHILDBEARING AGE AND CHILDREN: In general, for fetal health eat 12 oz. of low-mercury fish a week. **Light canned tuna contains low mercury**, so eat up to two servings (6 oz.) per week.

b. Raw, Unpackaged Seafood Sold at Grocery Stores

For raw seafood, the same rules apply under NLEA but on a voluntary basis. Thus, if the FDA asserts authority under NLEA for raw seafood, under Section 403(q)(4) of the Act it can only provide *voluntary* guidelines for information grocery stores should post or make available to consumers as to the 20 most commonly eaten species of raw seafood.¹¹⁰

In the Code of Federal Regulations, the FDA publishes the current listing of the top 20 most commonly consumed raw fish, which includes five fish with elevated mercury.¹¹¹ The list includes swordfish, which is in the FDA's "do not eat" category for women of childbearing age and children, as well as Atlantic/Pacific mackerel, and king mackerel is also in FDA's "do not eat" category.¹¹² High-mercury fish such as orange roughy (0.554 ppm, which EPA guidelines recommend the TARGET GROUP eat only once a month) and fresh tuna (0.383-0.639 ppm, which depending on the species should be consumed either one or two times a month) are also on the list.¹¹³ Additionally, it includes moderate-mercury species such as halibut (0.252 ppm) and American lobster (0.310 ppm), which under EPA guidelines should be eaten by the TARGET GROUP once a week (three or four times a month).¹¹⁴

¹¹⁰ 21 U.S.C. § 343(q)(4)(A).

¹¹¹ 21 C.F.R. § 101.44(c)(20) states, "[t]he 20 most frequently consumed raw fish are: Blue crab, catfish, clams, cod, flounder/sole, haddock, halibut, lobster, ocean perch, orange roughy, oysters, pollock, rainbow trout, rockfish, salmon (Atlantic/coho/Chinook/sockeye, chum/pink), scallops, shrimp, swordfish, tilapia, and tuna." See 71 Fed. Reg. 42,044 (July 25, 2006).

¹¹² *Id.*

¹¹³ Compare EPA, *supra* note 12, at table 4-3 (ppm cut-offs for noncommercial fish) with FDA, Fish Monitoring Data, *supra* note 11. The FDA Monitoring Data for fresh tuna includes several different tuna subspecies with varying mercury levels. Combined, the mercury content of fresh/frozen tuna averages out to 0.383 ppm, but the averages for each subspecies vary from 0.205 ppm for skipjack tuna to 0.639 ppm for bigeye tuna. "Species unknown" fresh/frozen tuna averages at 0.414 ppm, or 2 servings a month.

¹¹⁴ 21 C.F.R. § 100, App. D.

Under the rules proposed here, the FDA would establish voluntary guidelines for information that grocery stores and other fresh fish retailers would post for consumers to see at the fresh fish counter. As discussed above, this information would include an easy-to-read chart that conveys the information in the FDA-EPA Online Advisory and lists the relative mercury content of the top 20 species of raw seafood. The FDA could adopt one of several potential formats for this point of sale information.

In the first but less preferable option, the FDA would simply add to the existing chart of nutritional information for these top-20 species of raw seafood.¹¹⁵ Under this approach, a column could be added to list the mercury content as the ppm of mercury for each species or the maximum number of servings per month for the TARGET GROUP. The FDA could also add a corresponding column for omega-3 fatty acid content so that consumers can directly compare the omega-3 values with the mercury content of each species.

A second and more preferable version of the chart could follow the format of Chart 2, on the following page. This format would not only list the relative mercury content for each species, but also would communicate the Online Advisory recommendations and clearly identify the range of high and low mercury fish in a visual format. This would enable members of the TARGET GROUP to maintain healthy dietary practices because this information would:

- (a) inform them of the benefits of eating lower-mercury seafood twice a week to maximize intake of beneficial omega-3 fatty acids;
- (b) inform them of the five, top 20 species of seafood which contain elevated mercury and the recommended consumption limits for these species;
- (c) group the seafood by low, moderate, and high-mercury content and corresponding consumption recommendations, which will enable them to identify:
 - (i) that most of the seafood on the top 20 list is low in mercury and thus should be consumed more often, ideally up to 12 oz. per week, and
 - (ii) which types of seafood should be eaten once per week (such as halibut and American lobster), versus those that should be eaten only once or twice per month (such as orange roughy) or should be avoided (such as swordfish).

¹¹⁵ See FDA, Cooked Seafood Poster: Nutrition Information for Cooked Seafood (Purchased Raw), available at: <http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/InformationforRestaurantsRetailEstablishments/ucm114223.htm>.

Chart 2

SEAFOOD ADVICE FOR WOMEN UNDER 45 and CHILDREN:

Top 20 Species of Raw Seafood Consumed in the U.S.		Relative Mercury Content (ppm)	
Lower Mercury	shrimp	.012	For fetal/child health, eat lower mercury seafood twice per week, up to 12 oz. per week
	tilapia	.02	
	clams	.023	
	oysters	.013	
	scallops	.023	
	salmon	.028	
	rainbow trout	.037	
	ocean perch	.04	
	pollock	.041	
	flounder/sole	.045	
	Blue crab	.05	
	catfish	.068	
	spiny lobster	.09	
Moderate mercury	cod	.115	Limit to one, 6 oz. serving per week
	haddock	.17	
	skipjack tuna (see below for mercury content of other types of tuna)	.205	
	halibut	.252	
	rockfish	.301	
American lobster	.310		
High mercury	tuna yellowfin	.325	Max. 1-2, 6 oz. servings/month; eat no other fish that month *DO NOT EAT*
	albacore	.357	
	orange roughy	.554	
	bigeye tuna	.639	
	swordfish	.976	

The relative mercury content data for Chart 2 was taken from FDA, Draft Risk Benefit and Assessment Report, Appendix A, Technical Description of the Risk and Benefit Methodology, available at: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm173113.htm> and Groth, *supra* note 8, at 226-36.

Regarding the issue of consumption recommendations for fresh tuna, this Petition asks the FDA to modify its advice in the Online Advisory in order to classify tuna to be consistent with the EPA's consumption limits—fresh tuna should be consumed by the TARGET GROUP only twice per month rather than once per week (i.e., 6 oz. every two weeks rather than every week). This approach is reflected in the alternative language on pages 5 and 16-17 of this Petition. If it chooses not to modify its Online Advisory advice, the FDA could either: (1) simply list the ppm mercury content for fresh tuna without directly discussing the consumption limit, or (2) retain its existing 6-oz.-per-week recommendation without revising it to adhere to the EPA's Reference Dose standard.

For any of these approaches, however, the mercury values for fresh tuna should be separated out by subspecies whenever possible, since FDA Monitoring Data shows considerable differences between the mercury content of different types of fresh tuna. Bigeye tuna, for example, contains an average of 0.639 ppm of mercury and thus should be avoided or only eaten once a month, whereas fresh skipjack tuna averages at 0.205 ppm. When the species of fresh tuna is unknown, the methylmercury content averages 0.414 ppm.¹¹⁶

Under the foregoing NLEA authority, the FDA can require labeling alerting consumers to elevated mercury content and consumption limits for packaged seafood and can issue voluntary mercury content guidelines for the top 20 raw, unpackaged seafood species that grocery stores and other retailers can post or provide at fresh fish counters.

3. FDA HAS THE AUTHORITY UNDER THE FFDCA TO PREVENT ADULTERATED AND MISBRANDED FOODS

Authority for the proposed labeling and point of sale advisories also comes from sections 701, 402, and 403 of the FFDCA. Along with the FDA's overarching responsibility to protect public health, discussed above, it has an obligation to prevent the adulteration and misbranding of foods. Specifically, the Act prohibits "[t]he receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise."¹¹⁷ Further, section 701(a) of the Act gives the FDA "[t]he authority to promulgate regulations for the efficient enforcement of th[e] Act," which includes taking steps to ensure that foods are not adulterated or misbranded.¹¹⁸

a. Preventing Adulterated Foods

The adulterated foods provision of the FFDCA states that "[a] food shall be deemed to be adulterated...[i]f it bears or contains any poisonous or deleterious substance

¹¹⁶ FDA, Fish Monitoring Data, *supra* note 11.

¹¹⁷ 21 U.S.C. § 331(c).

¹¹⁸ 21 U.S.C. § 371.

which may render it injurious to health.”¹¹⁹ This provision applies specifically to “added substances,” which federal courts have held applies to methylmercury in seafood.¹²⁰

Given this designation of “added” under section 402(a)(1) of the FFDCFA, methylmercury in seafood is subject to the “may render injurious” standard for adulteration, as compared with the stricter “does not ordinarily render it injurious to health” standard for non-added substances.¹²¹ The key distinction here is that, under the applicable standard for “added” substances, the question is not whether the substance “ordinarily renders” the food injurious (*i.e.*, to most people), but rather whether there is a reasonable possibility of injuring the health of subgroups of consumers. It is therefore no defense to adulteration to claim that the added substance is potentially harmful only to a segment of the population—“such as the old, the young, and pregnant women.”¹²²

The FDA’s labeling rules for a variety of other substances further clarify that the harm need not apply to *all* consumers. Indeed, the FDA has used warning labels for products such as non-pasteurized juice to protect subsets of consumers, “particularly those at greatest risk” such as children, the elderly, or those who have compromised immune systems.¹²³ Likewise, the FDA has used label warnings on foods to protect children from iron supplements,¹²⁴ to protect teens from the dangers of sniffing pressurized containers,¹²⁵ to protect people on low-calorie diets from using protein

¹¹⁹ 21 U.S.C. § 342(a)(1) (emphasis added).

¹²⁰ United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980) (addressing the sole issue of mercury as an “added substance” on appeal). While the Fifth Circuit in the Anderson case affirmed the district court’s finding that swordfish would only be considered “adulterated” if it contained 1.0 ppm of mercury or higher (rejecting the previous .5 ppm level above which FDA could take legal enforcement action regarding adulterated seafood), they noted that the district court’s decision to apply that standard was “based only on the scientific and empirical data accepted into evidence in these cases. It may be that further studies will reveal the decisions [] made [by the district court] were based on erroneous or insufficient data.” *Id.* at 162. Additionally, in a later case discussing the 1.0 ppm standard for FDA legal enforcement action, the Third Circuit clarified that the 1.0 ppm level applied in Anderson was not a standard for food quality or a tolerance level for poisonous foods and made the point of stating that FDA had yet to set any such guidelines for seafood under the FFDCFA. Fellner v. Tri-Union Seafoods, LLC, 539 F.3d 237, 252 (3rd Cir. 2008). The court specifically rejected the appellant’s argument that FDA had “determined that there is no hazard associated with methylmercury concentrations of less than 1 ppm,” and went on to hold that “[o]n its face the [FDA] guideline does not state that tuna with mercury levels below 1 ppm poses no risk nor that a manufacturer has met any particular standard of care if its tuna does not exceed 1 ppm; it merely suggests that the FDA *recommend enforcement action* if mercury levels exceed 1 ppm.” *Id.* at 252–53 (emphasis added).

¹²¹ 21 U.S.C. § 342(a)(1). In Anderson, the Fifth Circuit stated “[t]he ‘may render injurious’ standard has been interpreted to mean that there is a reasonable possibility of injury to the consumer” rather than “that the substance would ‘ordinarily render’ (the food) injurious to health.” Anderson, 622 F.2d at 157.

¹²² United States v. Blue Ribbon Smoked Fish, Inc., 179 F.Supp.2d 30, 48 (E.D.N.Y. 2001).

¹²³ See Final Rule, Food Labeling: Warning and Notice Statement; Labeling of Juice Product, 63 Fed. Reg. 37,029, 37,030 (July 8, 1998), *available at*: <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/JuiceHACCP/ucm082009.htm> (“untreated juice products [must] bear a warning statement informing at-risk consumers of the hazard posed by untreated juices to allow them to make informed decisions on whether to purchase and consume such products.”).

¹²⁴ 62 Fed. Reg. 2,218 (January 15, 1997); 21 C.F.R. § 101.17(e).

¹²⁵ 21 C.F.R. § 101.17(a–b).

products,¹²⁶ and to protect people with phenylketonuria (PKU) disease from products with aspartame that contain phenylalanine.¹²⁷

It is key to note that although the FDA has set a methylmercury action level for seafood at 1.0ppm,¹²⁸ this level is a nonbinding policy statement and does not dictate the level at which the FDA may find that a food is adulterated.¹²⁹ Therefore, the fact that the FDA has a more lenient action level for mercury enforcement actions does not bar the agency from issuing stricter labeling requirements.

The FDA's non-binding treatment of action levels began in 1987, after Community Nutrition Institute v. Young, in which the D.C. Circuit struck down the FDA's action levels, holding that they constituted substantive rules that were invalid since they had been promulgated without the requisite notice and comment procedures.¹³⁰ Rather than initiate notice and comment for the action levels, the FDA instead clarified in its Final Rule for Action Levels for Added and Poisonous or Deleterious Substances in Food that "action levels constitute prosecutorial guidance rather than substantive rules."¹³¹ There the FDA reiterated its statement from an earlier notice in the Federal Register following Community Nutrition Institute v. Young, that the "current action levels are not binding on the courts, the public (including food and feed producers), or the agency... and that action levels do not have the 'force of law' of substantive rules."¹³² Most important for purposes of the proposed rules here, the FDA emphasized:

"[I]f a food bears or contains an unavoidable added poisonous or deleterious substance in an amount below the action level for that substance, [the] FDA is not precluded from recommending to the Department of Justice that court enforcement action be instituted against the food or the persons responsible for its shipment, and the Government is not barred from bringing such action... Action levels do not create a legal immunity from prosecution for food or feed producers, nor do action levels grant to food or feed producers a legal privilege to ship in interstate commerce food or feed with added contaminants up to the applicable action levels."¹³³

Applied here, the unique nature of methylmercury in seafood makes informational labeling preferable to the action level process at this juncture. First, although mercury

¹²⁶ 21 C.F.R. § 101.17(d).

¹²⁷ 21 C.F.R. § 172.804(d)(2).

¹²⁸ FDA Compliance Policy Guide § 540.600, *available at*:

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074510.htm>.

¹²⁹ See *supra* note 120.

¹³⁰ Community Nutrition Inst. v. Young, 818 F.2d 943 (D.C. Cir. 1987) (on remand from the Supreme Court, 474 U.S. 974 (1986)).

¹³¹ 55 Fed. Reg. 20,782-01 (May 21, 1990).

¹³² *Id.*

¹³³ *Id.*

enters seafood in significant part through human activity, it cannot be effectively removed through processing. Second, it also has varying impacts on different groups of consumers. The action level guideline does not address the unique problem that the risk is a function of not only the level of mercury in the fish, but also a combination of the amount of fish consumed and the weight and developmental stage of the person eating it.¹³⁴ It is prudent for the FDA to address the problem of elevated mercury exposure to infants and children through informational labeling on the product and through point of sale advisories to communicate the optimal type and amount of seafood to consume to the TARGET GROUP.

Applied here, the current levels of methylmercury in some species of seafood render this food injurious, since such levels should not be ingested by women of childbearing age, infants, and young children. In the canned tuna context, an unknowing pregnant woman weighing 140 pounds who eats one 6 oz. can of albacore tuna per week could exceed the EPA RfD by 30%.¹³⁵

This situation can be averted by (1) informational labeling on canned tuna and on packages of other seafood with elevated mercury describing consumption limits, and (2) point of sale advisories in the fresh fish section of supermarkets. The point of sale advisories would alert women of childbearing age and parents of young children to the presence of mercury in unpackaged, fresh seafood, and would moreover convey to this group the relative mercury content of other fish in order for them to calculate their overall weekly or monthly mercury intake. This would allow non-target consumers to maintain their current access to seafood and at the same time would allow members of the TARGET GROUP to minimize their exposure to high-mercury fish while maximizing their consumption of lower-mercury seafood.

While the FDA can exercise discretion as to whether to set or enforce an action level, tolerance, or regulatory limit for mercury in seafood, it also has the power and discretion to minimize harm to this large segment of consumers through these proposed rules. Under section 701(a) of the FFDCA, the FDA may thus require labels and posted advisories that disclose the presence of mercury and disclose what constitutes safe consumption limits for high- and moderate-mercury seafood species. Further, as discussed above, this authority extends to regulating not only seafood companies but also food retailers such as supermarkets under section 301 of the FFDCA.¹³⁶

¹³⁴ See *supra* note 128.

¹³⁵ EWG, *supra* note 53, at 6. While the current average weight of a woman in the U.S. is larger than 140 pounds, women who weigh more than 140 pounds are also at risk. Cynthia L. Ogden et al., Mean Body Weight, Height, and Body Mass Index, United States 1960-2002, 347 National Center for Health Statistics Advance Data from Vital and Health Statistics 8, table 6 (2004). A women weighing 154 pounds (70 kg.), the adult body weight used to calculate the EPA Reference dose, should only eat 4.8 oz. of albacore per week according to FDA guidelines as calculated using EWG's tuna calculator, at <http://www.ewg.org/tunacalculator>.

¹³⁶ Section 301 of the FFDCA states, "The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded[; and] (b) [t]he adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce[;] and (c) [t]he receipt in interstate commerce of any food, drug,

b. Preventing Misbranded Foods

The FDA is also authorized to require mercury labeling of certain seafood under the FFDCA's prohibitions against misbranded foods.¹³⁷ Under Section 403 of the FFDCA, food products must bear labels that are not misleading. As it states, "[a] food shall be deemed to be misbranded...[i]f its labeling is false or misleading in any particular."¹³⁸

1. Omissions

It is important to emphasize that the FDA may regulate not only affirmative statements on labels that may be misleading, but also omissions. Misbranding applies where "the labeling or advertising fails to reveal facts...material *with respect to consequences which may result from the use of the article*... [under] such conditions of use are customary or usual."¹³⁹

2. Materiality

Applied to this Petition, the presence of high and moderate levels of mercury in seafood products is a "material fact" that the TARGET GROUP needs to know. Seafood that lacks a label disclosing this toxin may be considered misbranded by omission under sections 403(a) and 201(n) of the FFDCA. This omission should be regarded as material in light of the fact that the mercury is a latent toxin in these foods that can affect the neurological development of fetuses and children.

Second, seafood companies' failure to disclose the presence of elevated mercury is particularly material since seafood is generally regarded as a healthful food. The seafood industry represents seafood as healthful, as many brands post American Heart

device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery for pay or otherwise." 21 U.S.C. § 331 (emphasis added).

¹³⁷ The Third Circuit has reinforced this authority specifically in regards to the mercury concentrations in tuna. In discussing mercury in tuna, the court in Fellner referenced the misbranding provisions of the FFDCA, and stated, "In the above-listed [misbranding] provisions, Congress provided a broad spectrum of ways in which the FDA may act in order to enforce the statutory prohibition on misbranded food-'a suitable written notice or warning;' an administrative proceeding of the type required to precede a criminal prosecution; a federal court action seeking an injunction or criminal penalties, and *affirmative regulation*."Fellner, 539 F.3d at 255 (emphasis added).

¹³⁸ 21 U.S.C. § 343(a).

¹³⁹ 21 U.S.C. § 321(n) (emphasis added). This provision states:

"(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations *or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use* prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual." (Emphasis added).

Association “heart healthy” symbols on their products and others tout the omega-3 benefits of seafood.¹⁴⁰ Indeed, seafood *is* generally healthful, and the FDA seeks to promote healthy fish consumption, even among children and pregnant women. However, for the TARGET GROUP to derive the most benefit from fish, it needs information about which species and in what amounts to consume to minimize the mercury risks from seafood. The representations made by the seafood industry do not reveal that the FDA recommends that the TARGET GROUP only eat up to 12 oz. of lower-mercury fish per week and up to 6 oz. of moderate-mercury fish per week.

Seafood packaging for high- and moderate-mercury seafood should disclose the presence of mercury and the federal consumption recommendations that pertain to that particular type of seafood. Even for “lower-mercury” seafood, such as light canned tuna, the FDA recommends that pregnant women (and the TARGET GROUP as a whole) consume *up to* 12 oz. a week rather than unlimited amounts, so labeling is warranted on light tuna even though it does not have as much mercury as canned albacore tuna. Including labeling on canned light tuna that discloses the presence of mercury and provides consumption limits is also important for informing the TARGET GROUP that it represents a lower-mercury alternative to canned albacore.

In the absence of specific information regarding the mercury content in seafood, the TARGET GROUP is missing information necessary to tailor their consumption and may instead intentionally eat larger quantities of fish under the (inaccurate) presumption that more fish (over 12 oz./week) means better health for fetal development and children. Although more salmon, or canned light tuna—up to 12 oz. per week—is considered beneficial, this potentially-harmful notion is particularly untrue for excessive consumption of higher-mercury fish. Further, even if the TARGET GROUP knows of the benefits of low-mercury seafood, these consumers cannot effectively make these informed choices if they do not have the information in stores so they can determine the

¹⁴⁰ See FDA Notice of Proposed Rulemaking, Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids, 72 Fed. Reg. 66,103 (November 27, 2007), *available at*: <http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/RegulationsFederalRegisterDocuments/ucm073457.htm> (discussing nutrient content claims for foods that contain omega-3 fatty acids; also listing tables of Docosahexaenoic Acid and Eicosapentaenoic Acid levels in seafood); FDA, Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease, September 8, 2004, *available at*: <http://www.fda.gov/food/labelingnutrition/labelclaims/qualifiedhealthclaims/ucm072932.htm>. In its Notice of Proposed Rulemaking, 72 Fed. Reg. 66,103, the FDA explained that “because the agency did not issue a regulation prohibiting [the above petitions for health claims],” the Martek and Ocean Nutrition claims regarding Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acid content in food “became permissible 120 days after the FDA received the respective notifications.” 72 Fed. Reg. at 66,109. In the Proposed Rule the FDA stated that this “result in no change to the current situation...is not a viable option,” but the rule was not finalized. See also regarding other nutrient claims made on packaging without explicit FDA approval, FDA, Guidance for Industry: Letter Regarding Point of Purchase Food Labeling, October 2009, *available at*: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm>. (discussing FDA concern regarding nutritional accuracy and impact of symbols and other front-of-package designations not specifically approved by the agency to convey nutrient status, such as ‘heart healthy’ symbols).

relative mercury content when they are deciding which fish to purchase. For this reason, the FDA should view this seafood as misbranded if it does not contain these disclosures. In turn, it should use its authority under section 701 to require supermarkets and seafood packaging to disclose this material information about elevated mercury content.

Third, this omission is material because harm may result from eating seafood “under such conditions of use as are customary or usual.”¹⁴¹ A child or a nursing mother would not need to eat a great deal of canned tuna to exceed the EPA’s recommended Reference Dose.¹⁴²

Last, the omission to disclose moderate- and high-mercury content in seafood is also material because mercury exposure is not readily apparent when it occurs. In most food products, harm from the product is evident shortly after the product is ingested, such as stomach cramps from eating too much sorbitol in sweetened candies, jitters from eating a beverage with caffeine, or an allergic reaction that a person with Celiac disease would experience after ingesting a product that contains gluten. Yet notably, even in such discernable situations the FDA requires warnings and/or disclosure for each of these products.¹⁴³ In contrast, mercury in seafood does not typically produce immediate, clinical signs of mercury poisoning. Thus, absent disclosure on a the seafood product or advisories posted at the point of sale, the TARGET GROUP would otherwise have no reason to curb their exposure to mercury by choosing lower-mercury seafood.

As detailed above, the FDA has authority to require the proposed regulations that certain seafood products with elevated mercury be labeled to disclose the presence and risk of mercury, both on the product packaging and at the point of sale, and should exercise it.

For the reasons stated above, the Petition asks the FDA to initiate formal rulemaking to require seafood labeling and point of sale advisories to communicate to women of childbearing age, and to parents of young children, both: (a) the presence of elevated mercury in certain seafood species, and (b) the recommended consumption limits associated with relative mercury content, including the importance of eating 12 oz. of lower-mercury seafood a week.

This issue represents a public health matter of the highest order: protecting children’s developing brains and enhancing their cognitive health. Americans should eat more fish but, especially women of childbearing age and for children, should also minimize the amount of mercury that they ingest through seafood. The FDA has the responsibility as steward of the public health to ensure that this sizable group has the

¹⁴¹ 21 U.S.C. § 321(n).

¹⁴² See *supra* note 135 and accompanying text.

¹⁴³ See 21 C.F.R. § 101.17 for various types of food warnings that the FDA currently requires.

consumption information and species-specific nutrient information regarding relative mercury content that they need to make informed decisions. The proposed rules promote healthy seafood consumption for this target group by minimizing potential exposure to mercury contaminants while maximizing the benefits of seafood.

IV. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exclusion under 21 C.F.R. § 25.32(a) and (m) and therefore does not require the preparation of an environmental assessment.

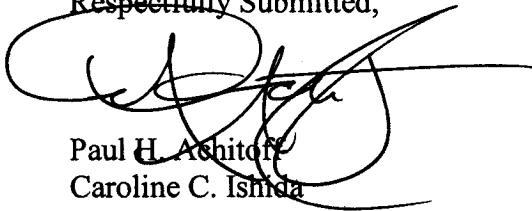
V. ECONOMIC IMPACT

No statement of the economic impact of the requested action is presented because none has been required by the Commissioner.

VI. CERTIFICATION

The undersigned certify that, to the best knowledge and behalf of the undersigned, this Petition includes all information and views on which the Petition relies, and it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Respectfully Submitted,



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ATTACHMENT LIST FOR DOCUMENTS ATTACHED PURSUANT TO 21 C.F.R. § 10.20(c) FOR “CITIZEN PETITION SEEKING FDA RULEMAKING FOR LABELING AND POINT OF SALE ADVISORIES CONCERNING MERCURY IN SEAFOOD TO MINIMIZE METHYLMERCURY EXPOSURE TO WOMEN OF CHILDBEARING AGE AND CHILDREN”

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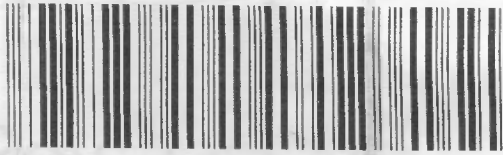
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