

September 9, 2019

Dockets Management Staff (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

# Re: Docket No. FDA-2014-N-0595, Educational Materials to Accompany the Joint EPA/FDA Advisory on "Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children"

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments to the Food and Drug Administration (FDA) on the revised fish advice entitled "Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children" (hereafter referred to as "the Advisory") and in particular the development of educational materials based on that advice.

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate grants and is supported primarily by the more than half million subscribers to its Nutrition Action Healthletter. CSPI provides nutrition and food safety information directly to consumers and has long advocated for clear information to help consumers choose nutritious, low-mercury fish and avoid high-mercury fish.

# Summary: FDA and EPA Must Address Serious Flaws in the Advisory

Two counterpoised problems arise with respect to fish consumption by Americans. First, most women of childbearing age do not eat enough fish to gain optimal nutritional benefits. Second, far too many people who eat fish frequently are exposed to methylmercury doses at or above levels that science now associates with a significant risk of adverse effects. Both problems are exacerbated by consumers' limited specific knowledge of which fish are best nutritionally, and which are lowest in mercury.

The current <u>Advisory</u> fails to address these problems. It presents information in an overly complicated format that obscures, rather than highlights, important differences among seafood varieties that should drive consumer choices. Critically, FDA offers no information on how fish differ in levels of omega-3 fatty acids, one of the criteria the current (2015-2020) *Dietary Guidelines for Americans* use to recommend seafood choices.

Instead, the Advisory's "seafood choice chart" sorts items based only on their mercury content and promotes 59 varieties as "best" or "good" choices, including such high-mercury items as albacore tuna, grouper, and bluefish. These, and many other higher-mercury fish, do not belong on any "best" or "good" choices list. The chart thus offers consumers little useful guidance for either obtaining omega-3s or avoiding mercury. Many people who follow its advice will be overexposed to mercury.

Educational materials to be used in conjunction with the Advisory present an opportunity to improve communication of essential messages. CSPI believes educational materials should clearly and simply advise consumers which fish to eat and which ones to avoid. Specific low-mercury seafood varieties should be recommended, also chosen where applicable based on their omega-3 content. Educational materials should continue to warn against eating highest-mercury species and need to include moderately-high-mercury species on the "avoid" list.

The 2015-2020 *Dietary Guidelines for Americans* present one such list, with nine recommended seafood varieties, but no list of items to avoid. CSPI has, using clearly explained criteria for omega-3 and mercury content, compiled our own list of 18 recommended choices and listed a similar number of items to avoid. Our recommendations are shown on the chart on page 4.

As a criterion for identifying "low-mercury" seafoods, CSPI defined a maximum tolerable daily mercury intake as half of the Reference Dose (RfD), the federal guideline FDA and EPA used when identifying "best choices" and "good choices" in the current Advisory. As we explain in these comments, the RfD is almost 20 years old and is obsolete. Compelling evidence shows that it no longer protects health. Taking into account more recent scientific evidence, one-half the current RfD is the highest level of mercury exposure that should be tolerated until the EPA's new risk assessment and ongoing review of the RfD is completed.

CSPI's list of 18 choices represents about two-thirds of the total US seafood market. In other words, with proper guidance, consumers can meet omega-3 needs and minimize mercury exposure, while still enjoying familiar and affordable seafood.

Educational materials should be broadly distributed to many more audiences than the targets of the Advisory. Everyone who eats fish frequently—which we define as at or above the widely recommended intake of 8 ounces per week—needs clear advice on omega-3-rich, low-mercury seafood choices.

We present evidence in these comments that some sub-populations with high-fish diets are often exposed to mercury doses far above acceptable levels, and identify other specific audiences in need of advice that FDA's educational materials and outreach might provide. We urge the FDA to take specific and culturally appropriate steps to inform impacted communities of the risks.

# **Recommendations**

CSPI recommends that FDA should:

• Using its Toxic Elements Working Group, work closely with EPA to update the Advisory to reflect current science, as well as to finalize and update its draft assessment of the risks that mercury poses for coronary heart disease and fatal stroke;

- Update its action level for methylmercury to better reflect current science and conduct regular marketplace testing and surveillance to recall products above the current and adjusted action levels;
- Provide educational materials for everyone who eats fish frequently, expanding the audience far beyond the target groups of the current Advisory;
- Focus the educational materials primarily on better identifying and recommending truly lowmercury seafood choices;
- Include comparative data on the omega-3 content of listed seafoods, as an additional factor for consumers to consider;
- Use a more protective definition of "low mercury" than one based on the 2001 RfD, which extensive recent research shows is no longer adequate to safeguard health;
- Use this protective definition of tolerable mercury exposure as a starting point to expand the list of fish that people following the Advisory should avoid eating; and
- Transparently provide the relative mercury content of different seafood items.

# CSPI's RECOMMENDED SEAFOOD CHOICES for Women Who Are or Might Become Pregnant, Breast-feeding Mothers and Young Children

# CHOOSE THESE

(Eat 2 or more 4-oz servings per week) Lowest mercury choices Other low-mercury choices

\* GOOD or \*\* EXCELLENT source of omega-3s

Seafood listed from *less* to *more* mercury

Scallops Shrimp \* Tilapia Oysters Mussels \* Catfish Sardines \*\* Clams \* Salmon \*\* Freshwater Trout Crayfish Pollock \*\* Atlantic Mackerel Anchovies \*\* Herring \*\* Shad **Butterfish** Crabs

# DON'T CHOOSE THESE

(Do not eat at all)

Highest-Mercury Moderately High Mercury

#### Seafood listed from *more* to *less* mercury

Gulf of Mexico Tilefish Swordfish Shark **King Mackerel** Marlin **Orange Roughy Bigeye** Tuna Grouper Fresh/Frozen Tuna Spanish Mackerel Sablefish Bluefish Canned Albacore (White) Tuna Pacific Croaker Lingcod & Scorpionfish Saltwater Trout Sea Bass Halibut

# WHAT IF A FISH IS NOT ON EITHER LIST?

Fish not listed here (such as canned light tuna, cod, flounder, haddock, squid, perch or lobster) have **too much mercury to be recommended**, but not so much that you should never eat them. We suggest you eat those fish no more often than once a month.

Source of mercury and omega-3 data: FDA (2014), table V-8. See text for full reference.



# **Introduction and Background**

The FDA/EPA Advisory that was issued in 2017 was the product of a lengthy interagency process to update the first such Advisory issued in 2004. The final 2017 Advisory was modified from a draft version proposed in 2014, partly in response to critical public comments. The agencies eventually fell back on the approach used in 2004. The resulting Advisory was substantially flawed, as we discuss below, and the flaws remain despite the 2019 revisions. The Advisory puts consumers at risk for overexposure to mercury, and urgently should be updated to align it with current science.

In the interim, educational materials that help consumers interpret and use the Advisory could help to mitigate the harm. Our comments here will suggest ways to do that, but first, we explain the flaws in the Advisory.

Both the 2004 and 2017 Advisory recognized that consuming fish has many health benefits but focused primarily on managing the risks from methylmercury exposure. They were based on a definition of tolerable daily intake, called the Reference Dose (RfD), which the EPA had established in 2001, and included fish consumption advice generally intended to help women avoid exceeding the RfD. Both advisories suggested consuming amounts of albacore tuna that would exceed the RfD for most women.

#### (1) The Advisory is Based on a Scientifically Indefensible Definition of Tolerable Exposure, That Puts Consumers at Risk

From 2004 to 2017, more than 20 new epidemiological studies were published, examining associations between fish consumption during pregnancy and cognitive performance in children. Some looked for (and found) only beneficial effects on neurodevelopment. Some looked for (and found) adverse effects of methylmercury exposure. The best-designed studies carefully measured both beneficial and harmful outcomes.

Overall, that literature supported two conclusions. First, maternal fish consumption during pregnancy is associated with improved cognitive performance in children. Second, exposure to mercury from fish consumption during pregnancy has adverse effects on many of the same functions that show beneficial effects from nutrients, and these adverse effects are about the same magnitude—as large and affecting as many people—as the beneficial effects.<sup>1</sup>

The most crucial data from studies published after 2004 concern the *dose* of methylmercury associated with observed adverse effects. Many studies used the US RfD as a reference point to sort subjects into higher-exposed and lower-exposed groups for comparison of outcomes. At

<sup>&</sup>lt;sup>1</sup> Groth, E. (2017) Scientific foundations of fish-consumption advice for pregnant women: Epidemiological evidence, benefit-risk modeling, and an integrated approach. *Environmental Research* 152:386-406.

least a dozen recent studies associated adverse effects with doses right around, slightly above, or even below the RfD.<sup>2</sup>

As a practical matter for policymakers, that new evidence renders the RfD obsolete as a guideline for tolerable daily intake. When it was first established, the RfD was believed to provide a ten-fold margin between the exposure limit it set and the lowest mercury dose associated with detectable harm to the developing brain. However, after 20 years of research, we now know that dose levels once thought to be "safe" are harmful. Recent evidence shows convincingly that the RfD, rather than defining a tolerable level of exposure, is close to, or even higher than the dose level at which adverse effects have now been observed.

In updating the Advisory from 2009-2017, FDA and EPA failed to provide a critical review of the recent literature, nor did they ask the National Research Council to provide one, as EPA had done when it first set the RfD in 2001. Nor did the Dietary Guidelines Advisory Committee review this literature when proposing seafood consumption advice for the 2015-2020 *Dietary Guidelines for Americans*. Thus, neither of the two primary sources of federal advice on this topic rests on an analysis of current science.

Recognizing that science on this subject has advanced markedly in 20 years, the EPA recently began to review and update the RfD, as FDA acknowledges in its July 2, 2019, *Federal Register* Notice. That review will likely take years to complete, though we urge all due speed.

In the interim, in the light of the scientific evidence indicating that the 2001 RfD is too high, it is essential to develop a more scientifically defensible definition of maximum tolerable exposure to methylmercury that can be used as a basis for advice in the educational materials.

Philippe Grandjean, lead author of the 1997 study on which the 2001 RfD is based, and a world-renowned authority on mercury toxicity, has observed that, "[b]iologically, there does not appear to be a safe level of methylmercury exposure for humans."<sup>3</sup> That is, while risk clearly diminishes with dose, some adverse effects are likely even at very low doses.

Many recent epidemiological studies found that methylmercury and seafood nutrients exert opposing effects on the same neurocognitive endpoints. In individuals with higher mercury exposure, the adverse effects can predominate. Even in people where the net effect is beneficial, the adverse impact of mercury can partially offset the beneficial effects of fish consumption. Thus, to optimize beneficial effects of eating fish during pregnancy and childhood, mercury exposure should be minimized.

Mercury exposure can be reduced substantially by eating little or no fish, but a sounder approach is to help consumers choose lower-mercury fish, so they can benefit nutritionally and keep their mercury exposure within tolerable limits. Groth (2017) addressed that risk-benefit tradeoff and

<sup>&</sup>lt;sup>2</sup> Groth (2017), note 1 above.

<sup>&</sup>lt;sup>3</sup> Comments on IRIS Assessment Plan for Methylmercury on behalf of Philippe Grandjean et al, May 6, 2019. <u>http://clinics.law.harvard.edu/environment/files/2019/05/EELPC-Mercury-IPA-Comments.pdf</u>

<sup>&</sup>lt;sup>4</sup> Groth (2017), note 1 above.

proposed using one-half of the 2001 RfD as the target upper exposure limit.<sup>4</sup> His analysis showed that, if consumers could easily choose lower-mercury fish, it is feasible to increase most people's fish consumption and nutritional benefits, while simultaneously keeping their mercury exposure within half the RfD.

# Recommendation: Educational materials should aim to keep mercury exposure below onehalf of the current Reference Dose.

Given current understanding of mercury risks, CSPI agrees that one-half of the 2001 RfD is a prudent target upper limit for exposure among women of childbearing age and young children. This judgment will be revised as better scientific data and new risk assessments, such as the EPA review of the RfD, become available. If those target audiences were able consistently to choose low-mercury seafood items, fish consumption would likely increase, substantially increasing nutritional benefits, while mercury exposure would not increase and might well decrease.<sup>5</sup>

An RfD is, by definition, a statement of maximum tolerable risk; benefits are not considered in the calculation. In the standard approach, either the highest dose at which no adverse effect was observed or the lowest dose associated with an observed adverse effect is determined, and then an "uncertainty factor" is applied, to allow for inter-individual variability in sensitivity to toxic effects and other known and unknown factors.

The best recent data on mercury effects on neurocognitive functions comes from a large Norwegian study, which associated mercury exposure at half the US RfD with delayed language development.<sup>6</sup> That is arguably the best current evidence on the lowest observable adverse effect level of methylmercury. If the revised US RfD were based on that study, and the conventional 10X uncertainty factor were applied (as was done when the 2001 RfD was set), the new RfD would be *one-twentieth* of the current one.

To keep mercury exposure that low could require telling pregnant women (and others at risk) to eat almost no fish at all, which would require them to obtain crucial nutrients from other sources, or lead to lost nutritional benefits. Taking into account more recent scientific evidence, one-half the current RfD is the highest level of mercury exposure that should be tolerated until the EPA's new risk assessment and ongoing review of the RfD is completed.

<sup>&</sup>lt;sup>4</sup> Groth (2017), note 1 above.

<sup>&</sup>lt;sup>5</sup> Oken, E. et al., 2013, A pilot randomized controlled trial to promote healthful fish consumption during pregnancy: The Food for Thought Study. *Nutrition Journal* 12:33; Lando, A.M. and Lo, S.C., 2014, Consumer understanding of the benefits and risks of fish consumption during pregnancy, *American Journal of Lifestyle Medicine* 8(2):88-92,

doi.org/10.1177/1559827613514704; also, Lando, A., 2014, Consumer understanding of the benefits and risks of fish consumption during pregnancy. Presentation at the 2014 National Forum on Contaminants in Fish, pages 266-272, Conference Proceedings, US Environmental Protection Agency, Office of Water, Washington, DC, Report No. EPA-820-R14-106 <sup>6</sup> Vejrup, K., Schjølberg, S., Knutsen, H.K., Kvalem, H.E., Brantsæter, A.L., Meltzer, H.M., et al., 2016. Prenatal methylmercury exposure and language delay at three years of age in the Norwegian Mother and Child Cohort Study. Environ.Int. 92–93, 63–69.

#### (2) <u>The Advisory Provides Little Useful Guidance for Choosing Low-Mercury Seafoods, and No</u> <u>Guidance on Higher Omega-3 Choices</u>

Because there is no real "safety margin" even at half the RfD, it is essential that dietary advice and seafood-choice guidelines help consumers identify and buy truly low-mercury fish. Consumers need seafood consumption advice that says clearly and simply, "Choose these lowmercury varieties. Don't choose these higher-mercury varieties." The Advisory does not provide that advice.

FDA's research,<sup>7</sup> and studies by others, show that target audiences for the Advisory are generally aware that fish offers important nutritional benefits. People also understand that all fish contain some mercury, and that mercury can pose health risks. But they lack specific knowledge of which fish to choose, and which not to choose. This lack of clear understanding leads directly to the two main problems associated with fish consumption: because of uncertainty about which varieties are safest, many pregnant women simply do not eat fish very often, missing out on nutritional benefits.<sup>8</sup>

On the other hand, among people who do eat fish frequently, a lack of knowledge about relative mercury content causes millions of individuals to incur mercury exposure far above safe limits (see examples and discussion below). There is some evidence that giving consumers clear seafood-choice advice increases seafood consumption and nutritional benefits *and* helps to limit their mercury intake.<sup>9</sup> An example of such an approach is on page 4 of these comments. Numerous state health officials and academic researchers have extensive experience with communicating these messages to consumers. We urge FDA to consult widely with such experts as it develops educational materials.

# Recommendation: Educational materials should focus on identifying and recommending seafood choices that are genuinely low in mercury. Recommendations should also indicate the comparative omega-3 fatty acid content of listed choices.

The current *Dietary Guidelines* represent a modest step toward this objective, recommending nine seafood items that are good sources of omega-3 fatty acids and very low in mercury. The 2017 FDA/EPA Advisory, however, goes in a much different direction.

For many years, FDA has published on its CFSAN website a database of mercury levels in seafood. The data there cover more than 60 varieties of fish and shellfish, listed in order of mercury content, from least to most. For people who find and interpret that information, the FDA database offers a comprehensive, helpful guide to low-mercury seafood choices, as well as data on higher-mercury fish to avoid.

<sup>&</sup>lt;sup>7</sup> Lando, 2014, see note 5.

<sup>&</sup>lt;sup>8</sup> Lando, 2014, Ibid.

<sup>&</sup>lt;sup>9</sup> Teisl, M., et al., 2017, Informing pregnant women about the benefits and risks of eating fish, Presentation at the 13<sup>th</sup> International Conference on Mercury as a Global Pollutant, Providence, RI. Also, Connelly, N., et. al, 2017, Reducing toxic exposure from fish consumption in women of childbearing age and urban anglers. Results of a 2-year diary study. Human Dimensions Research Unit Publication Series, Cornell University, HDRU Series No. 16-3. Also, Oken, 2013, see note 5.

The 2017 Advisory attempts to condense and simplify that information, for use by all consumers. The centerpiece of the Advisory is a "seafood choice chart," which sorts 66 seafood types into three categories, called "Best Choices," "Good Choices" and "Choices to Avoid." The sorting is based only on mercury levels; the Advisory provides no information on the relative omega-3 content of different seafood items.

The Advisory's primary purpose is to help keep women's and children's methylmercury exposure within the 2001 RfD. FDA recommends that users eat 2-3 servings (up to 12 ounces, 340 grams) per week of the "Best Choices," which should contain no more than the RfD for a 60-kg "standard pregnant woman" (42  $\mu$ g Hg/week). It recommends eating "Good Choices" up to once (4 ounces, 114 g) per week; one serving of these items also should contain no more than 42  $\mu$ g Hg. The "Choices to Avoid" list was expanded from the 2004 Advisory to include three very high-mercury species, marlin, bigeye tuna and orange roughy, each of which contains more than 42  $\mu$ g Hg in a single serving.

Since the RfD is not an acceptable upper exposure limit, people who follow the Advisory are at significant risk of potentially harmful over-exposure to methylmercury. When an upper limit of half of the RfD is applied to the Advisory's seafood choice chart, only half of the 38 "Best Choices" and one third of the 21 "Good Choices" meet that limit.

Another major flaw in the seafood choice chart is that "Best" and "Good" choices are listed alphabetically. (This is not so for the "Choices to Avoid," where items are listed from highest to lowest mercury content.) The alphabetical listing suggests strongly that all items in either category are roughly equivalent in benefits and risks, and that all "best" choices would be equally worth choosing.

In fact, the 38 items called "Best Choices" vary widely in omega-3 content and vary enormously (by more than 15-fold) in mercury content. The "best of the best" choices, those with the lowest mercury levels (scallops, shrimp and tilapia), contain 3  $\mu$ g or less of mercury in 12 ounces. The worst, canned light tuna, has 40  $\mu$ g in that same weekly amount.

An example illustrates the importance of these differences. Canned light tuna, cod, salmon, and shrimp are all called "best choices" in the Advisory. Yet a woman who switches from eating 4 oz/week each of cod and canned light tuna to eating 4 oz/week each of salmon and shrimp would more than triple her weekly intake of omega-3 fatty acids, from 490 to 1,750 mg, while reducing her methylmercury exposure 8-fold, from 25 to 3  $\mu$ g/week, thus markedly increasing the benefitrisk ratio of her seafood meals.<sup>10</sup>

The FDA's alphabetical listing in the seafood choice chart obscures critical differences among seafood varieties that, were they highlighted, could very likely determine what fish people choose to eat. The implied equivalency of all "Best Choices" and "Good Choices" in the Advisory's chart, and the fact that more than half of those items contain more than half the RfD in the recommended portions, make it very likely that people following the Advisory will be exposed to methylmercury at levels associated with adverse effects. The lack of transparency

<sup>&</sup>lt;sup>10</sup> Adapted from Groth (2017), note 1 above, using FDA data on omega-3 and mercury content.

about relative omega-3 and mercury contents also deprives consumers of the chance to weigh their choices in terms of the known risks and benefits of consumption.

In summary, to balance benefits and risks of eating seafood, consumers must be informed that different varieties vary widely in key nutrients and average mercury content. They need specific information that highlights those differences, and they need clear, focused advice that says, "Choose these fish," and "Don't choose those fish."

FDA's chart meets almost none of those needs. It offers no advice at all on good sources of omega-3s, it fails to disclose wide differences in mercury content among items it calls "best" or "good" choices and fails to help consumers differentiate those fish which are truly low in mercury. Instead, it calls almost every listed seafood--59 of 66 total items—a "good" or "best" choice. CSPI's model chart would remedy these clear deficiencies and drive consumer interest to choices that are known to be both less risky and offer comparatively higher nutritional benefits.

# Comments on Topics on Which the FDA Seeks Input

# (1) Other Target Audiences

# Recommendation: Educational materials should be designed for use by, distributed to and aggressively promoted to, every American who eats seafood frequently, not just target populations of the current Advisory.

The current advisory leaves out large numbers of people at risk for elevated mercury exposure. While pregnant and breast-feeding women, women who are likely to become pregnant, and young children are both appropriate and essential targets, the advice should be disseminated to all people who frequently eat fish.

People who follow the 2015-2020 *Dietary Guidelines* and eat eight or more ounces of seafood a week should be understood to be "frequent" consumers of fish.

In theory, if all consumers followed the *Dietary Guidelines*, the EPA/FDA Advisory and similar seafood consumption advice, every American would need to know how to eat enough fish and simultaneously avoid excessive exposure to methylmercury. But, as a practical matter, most Americans still do not eat enough fish to meet nutritional targets. An analysis by the US EPA found that median consumption (among people who eat fish—some people eat none at all) is one seafood serving per week.<sup>11</sup> The same analysis (of NHANES data from 2003-2010) found the 90<sup>th</sup> percentile intake was about 3 servings/week, and the 99<sup>th</sup> percentile intake was about 6 servings/week.

A 2014 analysis of US seafood consumption by the FDA came to similar conclusions and shed more light on high-end (i.e., those at the high end of the distribution curve for seafood intake) consumers. FDA estimated that for the US population as a whole, roughly 12 percent of women

<sup>&</sup>lt;sup>11</sup> U.S. Environmental Protection Agency, 2014. Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010) Final Report (EPA-820-R-14-002), April 2014. <u>https://www.epa.gov/sites/production/files/2015-01/documents/fish-consumption-rates-2014.pdf</u>

and 20 percent of men eat 8 or more ounces of seafood per week, so that fraction of adults is currently eating amounts recommended to obtain optimal nutritional benefits.<sup>12</sup> The EPA analysis cited above found median intake of 20.6 g/day (5 oz/week) for men, and 15.3 g/day (4 oz/week) for women, with 99<sup>th</sup> percentile intakes of 118.1 g/day (29 oz/week) for men and 87.2 g/day (21.5 oz/week) for women.

High-end consumers also are most likely to have excessive methylmercury exposure. National figures can mask important regional and cultural differences in amounts and types of seafood consumed. Recent research has examined multiple subpopulations of frequent fish consumers, and documented widespread, unacceptably high methylmercury intake in these groups (see below). Such subpopulations clearly need improved and culturally appropriate seafood-choice advice.

In assessing the mercury exposure of high-end fish eaters in the US, CSPI generally followed the lead of researchers who have used the 2001 RfD as a demarcation point. Exposure above the RfD is defined as a blood mercury level greater than 5.8  $\mu$ g/L, or a hair mercury level greater than 1.0  $\mu$ g/g (usually expressed as 1 part per million, or 1 ppm). Obviously, if a given fraction of a studied population has exposure above the RfD, a much larger fraction will exceed the more prudent limit of half the RfD.

(a) **Women of childbearing age**. Oken et al.<sup>13</sup> have studied fish intake by pregnant women and cognitive performance in their children at an ob-gyn practice affiliated with Harvard University. Their subjects are generally well educated, upper middle class urban or suburban women, with seafood intake somewhat higher than the national average for such women. The study compared cognitive outcomes for the 10 percent of subjects with the highest mercury exposure to the other 90 percent, using maternal hair mercury as the exposure biomarker. The 90<sup>th</sup> percentile hair Hg level in their cohort was 1.2 parts per million; i.e., more than 10 percent of these women exceeded the RfD from their routine fish consumption, which, while it was somewhat higher than the national average, was still far below recommended intakes.

The Environmental Working Group (Lunder 2016)<sup>14</sup> recruited 254 women of childbearing age from its membership, seeking women who ate fish often, and a control group of less frequent fish consumers. Among women who ate seafood 2-3 or more times a week, 29 percent had hair mercury levels of  $\geq$ 1.0 ppm. That is, more than one-fourth of women in the target population

http://www.fda.gov/Food/FoodborneIIInessContaminants/Metals/ucm393211.htm.

<sup>&</sup>lt;sup>12</sup> US Food and Drug Administration, 2014. A quantitative assessment of the net effects on fetal neurodevelopment from eating commercial fish (as measured by IQ and also by early age verbal development in children). May 2014. Available at

<sup>&</sup>lt;sup>13</sup> Oken, E., Wright, R.O., Kleinman, K.P., Bellinger, D., Amarasiriwardena, C.J., Hu,H., 2005. Maternal fish consumption, hair mercury and infant cognition in a U.S. cohort. *Environmental Health Perspectives* 113:1376–1380. Also, Oken, E., Radesky, J.S., Wright, R.O., Bellinger, D.C., Amarasiriwardena, C.J., Kleinman, K.P., 2008. Maternal fish intake during pregnancy, blood mercury levels, and child cognition at age 3 years in a US cohort. *American Journal of Epidemiology* 167:1171–1181.

<sup>&</sup>lt;sup>14</sup> Lunder, S. (2016) U.S. Fish Advice May Expose Babies to Too Much Mercury. Environmental Working Group, Washington, DC.

who consume the number of fish meals recommended by the current *Dietary Guidelines* exceeded the RfD.

Most of EWG's members are well educated, middle-to-upper income and white; this was not a nationally representative sample, and the women self-selected. But the study offers evidence that eating fish at recommended levels, without more careful attention to mercury content of different choices, can lead to widespread mercury exposure well above current (outdated) guidelines.

(b) **Regional and ethnic minorities with high-fish diets**. NHANES data consistently show that populations in coastal areas of the US (Atlantic, Pacific and Gulf) have modestly higher seafood consumption and higher blood mercury levels than do residents of inland areas.<sup>15</sup> This geographic variation may reflect both greater access to fresh seafood near the oceans and a higher fraction of immigrant and other subpopulations with high-fish diets in major coastal cities.

Culturally specific sub-populations with a high seafood diet are diverse, both in their cultures and in their seafood preferences.<sup>16</sup> Data are not available on every sub-population with such a diet, but there is clear evidence that many of these groups are over-exposed to mercury from the fish they eat, and need targeted advice to raise their awareness of mercury exposure and help them to minimize it.

- A study by the New York City (NYC) Department of Health<sup>17</sup> found a median blood mercury level in Asian adults of 5 µg/L, which is above the 95<sup>th</sup> percentile for Americans as a whole, according to FDA's 2014 analysis.<sup>18</sup> Of all NYC adults sampled, 25 percent had blood mercury above 5 µg/L, and 24 percent of women of childbearing age did so. Among foreign-born Asians in the study, 19 percent had mercury levels above 15 µg/L, nearly triple the RfD.
- A study of mercury exposure and child development at Columbia University in NYC included 102 Asian-American mother-child pairs (most were of Chinese ancestry). Exposure was strongly correlated with fish consumption. The average cord-blood mercury level in Asian-American babies was 14.95 µg/L, compared with 3.73 µg/L in all other babies.<sup>19</sup>
- An analysis of NHANES data from 1999-2002 found that 17 percent of women whose ethnicity was classified as "other" (a group that includes Asian, Pacific Islander, Native

<sup>&</sup>lt;sup>15</sup> Mahaffey, K.R., et al., 2009. Adult women's blood mercury concentrations vary regionally in the United States. Associations with patterns of fish consumption. NHANES (1999-2004). *Environmental Health Perspectives* 117(1): 47- 53. Also see, U.S. EPA, 2014, note 11 above <sup>16</sup> U.S. EPA, 2014, note 11 above

<sup>&</sup>lt;sup>17</sup> McKelvey, W., et al., (2007), A biomonitoring study of lead, cadmium and mercury in the blood of New York City adults. *Environmental Health Perspectives* 115(10):1435-1441. <sup>18</sup> FDA Benefit-Risk Modeling Study, note 12 above.

<sup>&</sup>lt;sup>19</sup> Lederman, S.A., Jones, R.L., Caldwell, K.L., Rauh, V., Sheets, S.E., Tang, D., et al., 2008. Relation between cord blood mercury levels and early child development in a World Trade Center cohort. *Environmental Health Perspectives* 116(8):1085–1091.

American, and multiracial) had blood mercury levels above 3.5  $\mu$ g/L, compared with only 5 percent of white, Hispanic and African-American women in the sample.<sup>20</sup>

- In the EPA analysis cited earlier, the median usual fish consumption rate for "Other Races" was approximately twice that of Mexican Americans, Other Hispanics, and Non-Hispanic Whites (32.3 g/day vs. 16.7, 16,6, and 16.7, respectively).<sup>21</sup> The same data showed that Non-Hispanic Blacks had a median fish consumption rate of 19.6 g/day.
- An analysis of more recent NHANES data that examined women with blood mercury levels above the 90<sup>th</sup> percentile as a highest-risk population found that Asian-American women of childbearing age had the highest mean blood mercury levels; 23 percent of that subgroup exceeded the RfD. Among women (of all races) who ate fish twice a week or more often, 25 percent exceeded the RfD.<sup>22</sup>

Two studies did not measure mercury exposure per se but show the importance of distinguishing sub-populations within broad cultural groups:

- A study by the Washington State Department of Ecology<sup>23</sup> examined fish consumption and the potential for exposure to toxic fish contaminants in four Native American tribes and in multi-ethnic Asian-American populations. It found that types and amounts of fish eaten varied widely among different tribes, and different Asian-American populations, and also within these sub-populations, but all groups were well above the national average in fish consumption.
- Similarly, an earlier study in King County, Washington<sup>24</sup> surveyed Asian and Pacific Islander populations with regard to fish consumption, and identified 10 different cultural subgroups in their overall sample which varied in the types and amounts of seafood eaten; overall these groups consumed seafood at a very high rate.

Studies on mercury levels in people from other countries can provide useful insights into populations that have recently migrated to the U.S. from those countries, and also provide further evidence of the relationship between high fish consumption and elevated mercury levels.

• A study of 3,972 Korean adults (living in Korea) found mean blood mercury levels of 5.1  $\mu$ g/L in men and 3.7  $\mu$ g/L in women. Mercury levels were strongly correlated with fish

910/R-99-003. May 1999. Available at

<sup>&</sup>lt;sup>20</sup> Hightower, J.M., O'Hare, A. and Hernandez, G., 2006. Blood mercury reporting in NHANES. Identifying Asian, Pacific Islander, Native American and multiracial groups. *Environmental Health Perspectives* 114:173-175.

<sup>&</sup>lt;sup>21</sup> U.S. EPA, 2014, note 11 above

<sup>&</sup>lt;sup>22</sup> Buchanan, S., Anglen, J. and Turyk, M. (2015). Methylmercury exposure in populations at risk: Analysis of NHANES 2011-2012. *Environmental Research* 140:56-64.

<sup>&</sup>lt;sup>23</sup> Washington State Department of Ecology (2011). A review of data and Information about fish consumption in Washington. Technical Support document. Publication No. 11-09-050.

<sup>&</sup>lt;sup>24</sup> Sechena, R., C. Nakano, S. Liao, N. Polissar, R. Lorenzana, S. Truong, and R. Fenske. 1999. Asian and Pacific Islander Seafood Consumption Study in King County, Washington. EPA

https://depts.washington.edu/ceeh/downloads/API\_Seafood\_Study.pdf

consumption.<sup>25</sup> The mean levels in that Korean cohort are about five times as high as corresponding means for US adults.<sup>26</sup>

• A study in New Zealand of Pacific Island populations measured hair mercury levels in mothers and 6-year-old children and found that 41 percent had exposure above the US RfD of 1 ppm.<sup>27</sup> Most subjects ate fish 3 or more times per week, and children's diets closely matched their mothers' diets.

(c) Men, women who are not pregnant or breastfeeding or likely to become pregnant, and others who eat fish frequently. Many consumers have "gotten the message" that eating seafood is good for their health, and correspondingly increased their numbers of weekly fish meals. As data cited above indicate, men eat more fish than women do, on average, and have greater methylmercury intake (see FDA data on pages 11 above). And some people—also more likely to be men—may eat far more fish than is recommended, overexposing themselves to mercury in the process, sometimes severely.

A study from Stony Brook University recruited 285 "avid" seafood consumers in their Long Island, NY, community. Their subjects' mean blood mercury level was four times the national average; 42 percent overall, and 27 percent of women of childbearing age in this cohort, exceeded the US RfD level of  $5.8 \mu g/L$ .<sup>28</sup> All those who ate seafood often, even at the recommended intake of two meals per week, had elevated blood mercury levels. Among men, 5 percent had blood mercury greater than 26 ug/L; in women, 5 percent exceeded 21 ug/L. Research on possible health consequences of this elevated exposure is still under way.

Further evidence that people who eat seafood often lack sufficient information about mercury risks comes from medical case reports on individuals who ate far more than average amounts of fish and were exposed to correspondingly extremely high doses of mercury. About a dozen such cases have been reported in the US;<sup>29,30</sup> patients had hair mercury as high as 42 ppm, blood mercury levels of 50 to 100  $\mu$ g/L or more, and severe neurotoxic symptoms that were diagnosed as methylmercury poisoning, or "Minamata Disease," as it was initially known.

<sup>28</sup> Karimi, R., Silbernagel, S., Fisher, N.S. and Meliker, J.R., 2014. Elevated blood Hg at recommended seafood consumption rates in adult seafood consumers. *International Journal of Hygiene and Environmental Health* 217(7):758-764. doi: 10.1016/j.ijheh.2014.03.007

<sup>&</sup>lt;sup>25</sup> Cho, S., Jacobs, D.R. and Park, K. (2014). Population correlates of circulating mercury levels in Korean adults: The Korean National Health and Nutrition Examination Survey, IV. *BMC Public Health* 14:527-536.

<sup>&</sup>lt;sup>26</sup> FDA Benefit-Risk Modeling Study, note 12 above.

<sup>&</sup>lt;sup>27</sup> Karatela, S., Ward, N. and Paterson, J., 2019. Mercury exposure in mother-children pairs in a seafood-eating population. Body burden and related factors. *International Journal of Environmental Research and Public Health* 16:2238-2250, doi:10.3390/ijerph16122238.

<sup>&</sup>lt;sup>29</sup> Knobeloch, L., Steenport, D., Schrank, C. and Anderson, H., 2006. Methylmercury exposure in Wisconsin: A case study series. *Environmental Research* 101:113-122.

<sup>&</sup>lt;sup>30</sup> Saint-Phard D, Gonzalez PG, Sherman P. 2004. Poster 88, Unsuspected mercury toxicity linked to neurologic symptoms: A case series. *Arch Phys Med Rehabil* 85: E25, doi:10.1016/j.apmr.2004.07.155.

Some people, who eat fish frequently for health or other reasons eat a great deal more than two servings per week. People who develop clinical symptoms of methylmercury poisoning, may be above the 99.9<sup>th</sup> percentile in both fish intake and mercury exposure.

As there are about 280 million American seafood eaters (adults and children), 280,000 would be above the 99.9<sup>th</sup> percentile.<sup>31</sup> As noted earlier, the 99<sup>th</sup> percentile fish intake in the US is 6 meals a week. This top 1 percent of fish eaters amounts to 2.8 million people, who are at significantly increased risk for very high mercury exposure.

The concordance between results of the Stony Brook study (i.e., 27 percent of women of childbearing age who eat fish twice or more weekly have blood mercury levels above the RfD) with previously cited findings by Lunder (29 percent of the same group above the RfD), Buchanan et al. (25 percent), and McKelvey et al. (24 percent above 5 ug/L), is persuasive evidence that the EPA/FDA Advisory, the *Dietary Guidelines* and other fish consumption recommendations have largely failed to help people who eat nutritionally desirable amounts of fish keep their mercury exposure within acceptable limits. Even when the target maximum mercury intake is the 2001 RfD, which is too high to be acceptable, this failure is undeniable.

All people who eat fish frequently clearly need educational materials that can help them understand mercury risks and choose low-mercury fish. CSPI believes materials targeted to subsets of the population identified here are urgently needed and long overdue.

(d) **Children between 6 and 18 years**. In general, children beyond the period of rapid brain growth are not as sensitive to the adverse effects of mercury as younger children. However, there is a small subset of "kids who love fish," and particularly kids who love canned tuna, that are at risk from overexposure to mercury. Three cases of clinical methylmercury poisoning collected by Groth (2008)<sup>32</sup> were children who ate tuna fish salad or sandwiches almost daily.

Educational materials for parents and schools must emphasize the risks of excessive tuna consumption by children. Advice should stress both the need to limit the frequency of children's tuna meals, and to choose light tuna on those (infrequent) occasions instead of albacore ("white" tuna), which has triple the mercury content of light tuna.

(e) **Physicians and other health professionals**. Many people get dietary advice from their doctors. Most doctors have virtually no knowledge of signs and symptoms of methylmercury toxicity, and lack even basic awareness that fish consumption poses risks associated with toxic contaminants like methylmercury. On average physicians are poorly prepared to help patients choose seafood varieties based on lower mercury content. A research group at Stony Brook University published a peer-reviewed article designed to inform physicians on this topic.<sup>33</sup> We

<sup>&</sup>lt;sup>31</sup> FDA 2014 note 12 above, p. 68 which states that 85% is the percentage of consumers that ate fish in the NHANES 30-day survey, and that FDA assumes that the percentage of consumers who eat fish over a one year period is within a range of 85-95%. The US population is 329.5 million, and 85% of that is 280 million.

<sup>&</sup>lt;sup>32</sup> Groth, E., 2008. Over the Limit: Eating Too Much High-Mercury Fish. Mercury Policy Project, Montpelier, VT.

<sup>&</sup>lt;sup>33</sup> Silbernagel, S., Carpenter, D.O, Gilbert, S.G., Gochfeld, M., Groth, E., Hightower, J.M., and Schiavone, F.M., 2011. Recognizing and preventing overexposure to methylmercury from fish

urge FDA to make a concerted outreach effort to reach out with educational materials to physicians of many sub-specialties—including ob-gyns, pediatricians, cardiologists, neurologists, internists, GPs and others.

(f) **Sport and subsistence anglers**. People who catch and often eat fish, rather than buying commercial seafood, can be at risk for overexposure to methylmercury. State governments issue advisories about mercury contamination of local lakes and streams, and the EPA coordinates the efforts. However, that warning system has not fully protected anglers, and their families, from eating contaminated fish.<sup>34</sup> The 2019 Advisory does flag the need for anglers to seek out and heed state and local advisories. We urge FDA and EPA to consider whether educational materials might also serve as a template for state advisories, and would be particularly useful for states that do not yet have them. FDA/EPA materials on commercial fish and shellfish would also usefully be incorporated in state advisories that do not already contain that information.

# (2) Information to Include in the Educational Materials

The evidence we have reviewed above shows beyond much doubt that many Americans are now eating fish at or above recommended amounts and are over-exposed to mercury, at doses that may pose significant health risks. Educational materials should help people choose low-mercury fish more effectively.

Target audiences are usually aware of both the nutritional benefits of eating fish and in general the risks posed by contaminants. They know less about the relative benefits and risks of specific seafood choices. When consumers are given a clear, focused list of fish to eat and fish to avoid, decision-making improved significantly.<sup>35</sup>

CSPI therefore urges that the primary focus of the educational materials should be to provide just such a list of recommended low-mercury seafood choices, highlighting items rich in omega-3 fatty acids. Materials should also include a list of higher-mercury fish to avoid.

# Recommendation: Criteria for Listing Seafood Choices to Choose, and Those to Not Choose

<u>Omega-3s</u>. There remains some uncertainty about whether omega-3 fatty acids are the most important nutrients in fish, and seafoods also contain other essential nutrients. However, evidence that omega-3s specifically benefit neurocognitive developmental functions is convincing enough that most dietary advice includes a suggested daily intake of omega-3s for pregnant women. For example, the current *Dietary Guidelines* suggest an intake of 250 mg/day, or 1,750 mg/week, for cardiovascular health, and advise pregnant women to eat 8 or more ounces of seafood weekly, and to choose omega-3-rich varieties.

While the Advisory currently offers consumers no guidance on the omega-3 content of seafood items, CSPI believes omega-3 levels should be one of the criteria for choices recommended in the educational materials you develop. We suggest differentiating between "excellent" sources

and seafood consumption: information for Physicians. *Journal of Toxicology* 2011:1-7, doi:10.1155/2011/983072.

<sup>&</sup>lt;sup>34</sup> See Knobeloch et al., 2006, and Groth 2008, notes 26 and 32, above, for case reports.

<sup>&</sup>lt;sup>35</sup> Oken et al. 2013, note 5 above; also Teisl et al. 2017, note 9 above.

(defined as those providing 1750 or more mg in 12 ounces per week), and "good" sources (providing at least half that target intake in 12 ounces.)

Importantly, a seafood variety should not be recommended based on its omega-3 content unless it also meets the criterion for "low-mercury."

<u>Mercury</u>. The maximum mercury level that a seafood variety can have and still contain less than 21  $\mu$ g in 12 ounces per week (i.e., to stay within the prudent upper intake guideline of half of the current RfD) is 0.06 ppm. We urge that this be set as the upper limit for "low mercury" designation in educational materials. Women who are or may become pregnant and want a wider margin of safety could keep their exposure to less than one-quarter of the RfD by choosing only seafoods designated as "lowest mercury" in our chart (the first 11 items in the left-hand column have 0.03 ppm mercury or less).

Any fish with more mercury than half of the RfD for the standard woman of childbearing age (i.e., 21 µg) *in one 4-oz serving* should be on the "Don't Choose" list. In applying that lower guideline, we added about a dozen varieties, beyond the seven FDA says to avoid, to our "Don't Choose" list. At the top of the right-hand column of CSPI's chart are the seven varieties that are "Highest Mercury" [FDA's "Avoid" list] and below that, the "Moderately High Mercury" [those we added.]

<u>Recommended Seafood Choices</u>. The current *Dietary Guidelines* offer a minimalist prototype of the kind of explicit, focused advice consumers need. They recommend that pregnant and breastfeeding women choose among nine seafoods that are both good omega-3 sources and low in mercury, including *salmon, herring, shad, sardines, trout, anchovies, Pacific oysters and Atlantic and Pacific (but not King) mackerel.* In contrast, the FDA/EPA Advisory lacks such focus; it simply presents the deeply flawed seafood choice chart and promotes 59 seafoods it calls "dozens of healthy and safe options."

The Advisory thus incorrectly informs consumers that almost every kind of seafood is at least a "good" choice, and 38 items are "best" choices. We firmly disagree. Many fish that FDA/EPA list as "best" or "good" choices contain far too much mercury to bear those labels. Sound advice, based on current understanding of mercury risks, must define tolerable exposure more protectively.

CSPI applied the criteria explained above to the omega-3 and mercury data in Table V-8 of the 2014 FDA benefit-risk analysis<sup>36</sup> to generate our list of 18 Recommended Choices displayed in chart form on Page 4. Our list includes five "excellent" omega-3 sources and three "good" sources of those fatty acids. All 18 items are low mercury ( $\leq 0.06$  ppm), while 11 are "lowest mercury" ( $\leq 0.03$  ppm). We also expanded our "Don't Choose" list to include all fish varieties that contain more than 21 µg of mercury in a 4-ounce serving (*i.e.*., they have >0.184 ppm Hg).

Recommended seafood choices should be widely available and reasonably affordable as well as low in mercury. Using data on market shares for the varieties in FDA's seafood database,<sup>37</sup> we calculated that the nine varieties recommended in the *Dietary Guidelines* represent 38 percent of

<sup>&</sup>lt;sup>36</sup> FDA 2014, note 12 above.

<sup>&</sup>lt;sup>37</sup> FDA 2014, ibid, Table II-1.

the US seafood market. CSPI's 18 varieties capture more than two-thirds of the national market. Seven of our recommended items are in <u>the ten top-selling seafood items</u>; those seven account for 10.03 pounds (62.7 percent) of total per capita annual consumption of 16.0 pounds. And our list includes 11 more choices that FDA says comprise an additional 5.4 percent of the market.

This suggests that, with effective guidance, consumers can meet all or most of their omega-3 needs, avoid excessive mercury exposure, and keep eating familiar, popular, widely available, affordable seafood items.

Importantly, availability and affordability are not reasons to recommend an item that is not lowmercury (for instance, canned light tuna and cod are not on our recommended list).

CSPI's "Don't Choose" list includes canned albacore tuna and fresh and frozen tuna, both popular items, with a combined market share of 4.9 percent. These two types of tuna are the largest and third-largest sources of Americans' mercury exposure from seafood; canned light tuna ranks second.<sup>38</sup> The three varieties of tuna are collectively the source of 45 percent of all the mercury Americans get from seafood.<sup>39</sup> It seems obvious that if Americans are to eat more fish and simultaneously to be exposed to less mercury, eating less tuna—and more of other kinds of fish--are critical strategies. The other 17 items on CSPI's "Don't Choose" list have a combined market share of 1.3 percent;<sup>40</sup> *i.e.*., the list generally tells people not to eat varieties they are already hardly eating at all.

A caveat is required here: Many communities with high-fish diets may have seafood consumption patterns that are not reflected in national market share data. Thus, whether a given list of recommended choices is sufficient to offer a range of familiar options to a sub-population with specialized preferences should be determined as the agency develops culturally appropriate materials for each specific target audience.

# Choices That Are Neither Recommended nor on the "Don't Choose" List.

In CSPI's chart, seafood choices not listed are covered by a general statement, with examples, in a Note below the chart. If FDA provides a similar list, the agency might similarly cover unlisted items with a generic statement. It could also refer users to the FDA website for more detailed data on choices not listed in the educational materials. Materials should be kept simple.

<u>Do other target audiences need different advice?</u> Both the *Dietary Guidelines* and the Advisory are specifically, explicitly addressed to "Women who are or may become pregnant, breast-feeding mothers, and young children." The 2001 RfD is also explicitly applicable only to that target population. What advice then, should consumers who are not members of that target audience, but who are frequent fish consumers, follow?

On the one hand, men and women past their child-bearing years are not subject to the same risks as those targeted by the current Advisory. On the other, even within otherwise low risk populations, there are individuals with very high fish intakes.

<sup>&</sup>lt;sup>38</sup> Groth 2017, note 1 above.

<sup>&</sup>lt;sup>39</sup> Groth 2017, note 1 above

<sup>&</sup>lt;sup>40</sup> FDA 2014, note 12 above, Table II-1.

CSPI has concluded that there is, unfortunately, no scientific basis at this time for defining "tolerable" mercury exposure limits for populations other than those targeted by the current Advisory. We urge FDA to ensure, by developing and broadly distribution educational materials, that all consumers who need it have basic information on seafood choices that are genuinely low in mercury.

<u>Other information that might be included.</u> Our most critical recommendation to FDA is that the educational materials should focus on providing lists of seafood items to eat, and those not to eat. Beyond that most critical purpose, we recommend certain other material that might be included:

**General background material on benefits and risks of eating fish**. We urge that educational materials refer to the *Dietary Guidelines* and other authoritative sources. The message of these materials should be, "You know eating fish is good for your health. These materials are designed to help you choose wisely, so you can eat more fish and also reduce your mercury exposure."

**Mercury testing.** Materials might suggest that consumers who are at high risk for exposure to mercury from the fish they eat consider getting their blood or hair tested for mercury. Most doctors can order this inexpensive test, which in most cases provides reassurance of acceptable mercury exposure. A result higher than expected may persuade the affected individual to choose lower-mercury fish.

**Online database**: For motivated individuals who might want the information, FDA should maintain on the CFSAN website a table showing the omega-3 and mercury content of all seafood varieties in its database. Printed materials could refer readers there.

List of variations on seafood names. In addition to culturally appropriate educational materials, FDA should create a table listing all seafood items in its database by their common English names, and displaying names by which the same species are known in every other language (or dialect) relevant to American subpopulations with high-fish diets. To help make this information accessible, images of each variety could be included (see next section for a discussion on graphics).

**Invitation to provide feedback**. FDA should invite users of these educational materials to take an online survey, answering questions such as what they learned from the materials, how their fish-consuming behavior might change as a result, and similar issues. While respondents would be self-selecting, their input could help FDA understand whether the materials are having the intended effects, and support revisions in future editions.

# (3) Effective means of communicating and disseminating the information

Additional materials FDA should develop include graphic presentations, such as charts and posters; leaflets, pamphlets and flyers; newspaper and magazine articles of varying lengths and degrees of detail; audio and video presentations (both for broadcast use and for internet sites like YouTube); online databases and scientific reports; and recipes for preparing recommended seafood choices. Below we offer some suggestions.

# (a) Graphics and Images

- The seafood choice chart in the Advisory must NOT be used in any educational materials FDA develops.
- The simplest options include listing recommended seafood choices and choices to avoid in chart form.
- Charts presented as scatter plots can also clearly and usefully display two kinds of facts including omega-3 content and mercury content.
- Charts that display both the names of seafood varieties and images of those varieties convey more information. Images have the added advantage of not needing translation into multiple languages. Images of seafood varieties as they look when swimming in the ocean are less useful than images of the same choices as consumers encounter them at the fish market. For example, swordfish steaks, salmon and tilapia fillets, sardines in a can, etc. Some varieties would require multiple images (salmon fillets, steaks and sushi, for instance.)

# (b) Leaflets, pamphlets and posters

- Educational materials for most audiences should fit in leaflet format or in a poster that can be incorporated in a leaflet or displayed on its own. Some might be simple enough to fit on a wallet card.
- Variations could include, for example, a poster sorting a sushi and sashimi menu into recommended choices and choices to avoid, based on omega-3 and mercury content.
- Pamphlets should be prepared for a range of audiences (such as the medical community).

# (c) Newspaper, TV, radio & magazine articles, internet sources

- FDA should create short articles summarizing fish consumption risks and listing recommended choices for use in blogs and local papers, and offer them to local newspapers willing to publish them. Community and neighborhood newspapers may be an effective way to reach important target audiences, such as cultural groups with high-seafood diets. Local TV and radio stations (including those reaching specific target cultural audiences) may also be interested in these materials.
- YouTube videos on "healthy fish consumption advice" vary widely in both soundness of their advice and production quality. FDA should consider the substantial audience that gets information in online videos and create materials in this format.
- FDA should maintain detailed information on omega-3 and mercury levels across all seafood varieties and create a new database of names that different fish are called in diverse languages and cultures.
- FDA's website should link to other sources of useful data, such as National Marine Fisheries Service's annual reports on "Fisheries of the United States," and the Monterey Bay Aquarium's listings of fish by mercury content and health of the fisheries.

# (e) Recipes

• We urge FDA to make recipes an important element of the materials it develops. Offering recipes can improve the chances that more consumers will buy and enjoy the recommended seafood choices.

# (f) Dissemination

- What to distribute. The basic types of information in FDA's educational materials will likely be leaflets, pamphlets, posters, suitable for wall displays; prepared articles for distribution to local newspapers and TV stations; and links to additional resources on FDA's website.
- Where to distribute. This is not a complete list:
  - --<u>Seafood markets and fish departments in supermarkets</u>. FDA should urge supermarkets to provide clear information at the fish counter, where consumers can see it, and provide a standard health communication that all fish retailers can use. Having these recommendations available at the point of sale would enhance their impact. Some retail chains (e.g., Safeway) have experimented with voluntarily posting this kind of information. Others may be interested in collaborating with FDA to help develop and use materials.
  - --<u>Health care providers</u>. Physicians, physicians' assistants, nurse practitioners, and nurses, as well as many specialists could be asked to display posters in their waiting areas and distribute literature to their patients. Specialties that should be considered for outreach efforts include obstetricians, gynecologists, pediatricians, internists, cardiologists, neurologists, and geriatricians.
  - --<u>Community centers</u>, including in communities in which high-fish diets are common.
  - --<u>Nutrition clinics and nutritionist's offices</u>. Many nutritionists and dietitians are not physicians but advise clients and patients on healthful diets.
  - --<u>Alternative medicine practitioners</u>, such as chiropractors, osteopaths, acupuncturists and herbal medicine providers. Many patients consult these providers. This may especially be the case in some cultural communities.
  - --<u>WIC clinics and SNAP program offices</u>. Every federally funded nutrition program should display these educational materials.
  - --<u>Medical schools</u>. The materials should be promoted for use in nutrition education of future doctors.

**Partnerships**. Some medical professional associations, including the American Academy of Pediatrics have issued <u>detailed reports</u> on this subject and are excellent candidates to work with FDA. Outreach to such possible partners offers the potential for focusing additional resources, expertise and ideas about how to communicate with, and reach various specialized audiences.