October 20, 2014

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FDA Risk Communication Advisory Committee:

Environmental Working Group is pleased to comment on the Food and Drug Administration's efforts to communicate the risks and benefits of seafood consumption during pregnancy and childhood.

FDA and the Environmental Protection Agency have said that because of the important developmental and health benefits, pregnant and breastfeeding women, and those who might become pregnant, should eat eight to 12 ounces (two or three servings) a week of fish with lower levels of mercury contamination (FDA/EPA 2014a). The draft guidelines instruct children to also eat two or three servings, but in smaller portion sizes. Two long-chain omega-3 fatty acids found primarily in seafood, docosahexaenoic acid and eicosapentaenoic acid, often denoted as DHA and EPA have been shown to aid fetal and neonatal brain development. However, mercury in some seafood species can erode or outweigh the omega-3 benefits, and the draft guidelines fail to make clear the important differences among species of commercial seafood.

Environmental Working Group has long advocated that FDA and EPA should provide consumers a more comprehensive list of fish and shellfish that may be too high in mercury, and to reduce the maximum amount of canned tuna that women are advised to eat during pregnancy (EWG 2001, 2002, 2009, 2014). The risk of ingesting excessive mercury is even more dire if pregnant women and children seek out seafood as a result of the new draft guidelines..

Furthermore, while research into the neurological benefits of omega-3 fatty acids in seafood has strengthened over the past decade, the draft FDA/EPA guidance is not sufficient because it doesn't do enough to help consumers identify the fish and shellfish species that pose the greatest health benefit.

In our assessment, the Risk Communication Advisory Committee is being asked to review and approve guidance that is incomplete and will not be effective. The FDA and EPA must improve the draft guidelines to better reflect the state of the science on benefits and drawbacks of seafood consumption for pregnant women and children.

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New research highlights the adverse effects of low-dose mercury exposure

Since 2004, FDA and EPA have recommended that pregnant women and children limit or avoid five types of seafood with high levels of mercury – shark, tilefish, swordfish, king mackerel and canned tuna. However, research shows that many other ocean and freshwater fish have too much mercury for pregnant women to eat frequently. The new draft guidance recommends that pregnant women and children significantly increase their consumption of seafood, but fails to provide additional recommendations of fish to limit or avoid. As a result, if consumers were to follow the advice in the draft guidance, they might well choose species that are too high in mercury.

FDA's inadequate advice about mercury risks is largely based on a multi-year quantitative assessment, published in May 2014, of the risks and benefits of seafood consumption during pregnancy (FDA 2014b). In nearly all scenarios it considers, the assessment concludes that the benefits of seafood consumption during pregnancy exceed the risks. While a technical review of FDA's quantitative assessment is beyond the scope of the Risk Communication Advisory Committee, it is sufficient to say that FDA's model conclusions are out of step with recent observational studies of seafood safety. This may result from FDA's use of less sophisticated methods to account for the independent and opposite effects of mercury and omega-3 fatty acids in seafood on fetal and neonatal neurodevelopment.

Over the past decade new research has confirmed and extended concerns about the impacts of low-dose mercury exposure during pregnancy on the developing fetal brain. More than a dozen epidemiological studies – four conducted in the United States – have documented that the fetus can be harmed by prenatal methylmercury exposure in amounts similar to or only slightly above the typical levels in American consumers (reviewed in Zero Mercury Project 2012, Julvez 2012). New analysis of data from long-term epidemiological studies in the Faroe and Seychelle Islands has illuminated the positive effects of omega-3 fatty acids and the hazards of methylmercury exposure in pregnant women and children with diets high in seafood. (Butz-Jorgensen 2007, Strain 2008)

Women who eat more fish and shellfish have smarter babies, but only if they also keep their mercury intake low. Emily Oken's Project VIVA examined 341 Boston-area women to determine the benefits and risks of seafood during pregnancy (Oken 2005, 2008). The study found benefits for children born to women who ate three or more seafood meals weekly, but negative effects for the 10 percent of study participants with the highest mercury levels in their bloodstream. Eating fish frequently boosted children's IQ measurements by about two to six points, but high mercury exposure during pregnancy dropped IQ scores by the same measure. Even in children whose overall health benefited from fish ingestion, mercury exposure reduced the potential cognitive gains. As a result, numerous experts conclude that the benefits of fish consumption are maximized by selecting species low in mercury (Budtz-Jorgensen 2007, Choi 2008, Domingo 2007, Ginsberg 2009, Mahaffey 2004, Mahaffey 2008, Oken 2010, Oken 2012, Sakamoto 2004, Stern 2005, Tsuchiya 2008).

Government guidelines for methylmercury exposure are out of date

The methylmercury content of commercial seafood varies widely among species. However, the draft advisory does not provide health-protective guidelines for consumers seeking to minimize their consumption of mercury. While there is no bright line between safe and unsafe exposure to methylmercury – the risk is proportional to the dose – in general, the less mercury a woman ingests during pregnancy the better.

EPA calculated a limit, or reference dose, for mercury ingestion in 1999. It was based on a study that found clearly harmful effects of methylmercury at a level of 58 micrograms per liter (μg/L) in newborns' umbilical cord blood. It calculated that an average-weight woman (132 pounds or 60 kilograms) could ingest up to 42 μg of methylmercury a week without any harmful effects to her fetus. Under this framework many commercial fish species have too much mercury to be eaten weekly. But more recent research has shown that the harmful effects of methylmercury occur at much lower doses than previously documented. EPA should reevaluate its mercury consumption guidelines in light of this new evidence.

Efforts to increase seafood consumption during pregnancy and childhood must consider the increased ingestion of methylmercury and other pollutants from fish and shellfish. EPA recently published a review of seafood consumption and mercury exposure for data from The Centers for Disease Control's NHANES biomonitoring data (EPA 2013). This included data from 10,000 American women of childbearing age. The review found that those who reported eating seafood most frequently were at the greatest risk for mercury exposure. In the most recent survey period (2009-2010), the group who reported eating six or more seafood meals a month – closest to the proposed FDA recommendation of eight to 12 meals a month – had the highest concentrations of mercury in their blood. More than 10 percent of this group had blood mercury levels above the target concentration of 3.5 μg/L. that was determined to protect a developing fetus from exceeding EPA's safety level for methyl mercury (Mahaffey 2009).

Advice to "eat more seafood" won't necessarily achieve the intended health benefits

Both mercury levels and amounts of beneficial omega-3 fatty acids vary widely from one variety of seafood. The draft guidance lists five high-mercury fish to limit or avoid, and nine species that are "lower mercury" choices, but these lists are incomplete and misleading.

EWG surveyed the omega-3 fatty acid and mercury concentrations of popular seafood on the U.S. market. We found that eight of the 10 species that make up 90 percent of the market are nearly devoid of the omega-3 fatty acids DHA and EPA. A pregnant woman would have to eat between 20 and 100 ounces of those eight varieties to consume 1,750 milligrams of omega-3s weekly – the amount the federal Dietary Guidelines have deemed ideal for a healthy pregnancy. The complication and expense of eating so much fish could be prohibitive for many Americans (USDA 2010).

FDA proposes a list of nine so-called "lower mercury" choices. However:

- Two are not low in mercury. A pregnant woman who frequently eats either canned light tuna (see below) or cod risks elevated methylmercury exposure.

- Seven of the FDA recommended species are poor sources of beneficial omega-3 fatty acids. Pregnant women would need to eat five to 20 servings a week of these species to get the 1,750 milligrams of DHA and EPA that the Dietary Guidelines recommends women consume weekly.

- Only one species on the list, salmon, can provide sufficient omega-3s with little mercury risk.

In addition, the new advice ignores the fact that some fish may contain other pollutants, so that three weekly servings of seafood could increase the risks of other adverse effects in pregnant women.

The new guidelines repeat erroneous advice about canned tuna

More than a third of Americans' exposure to methylmercury comes from tuna. Americans eat more than 400 million pounds of canned imported tuna. An average American eats an average of 2.5 pounds of tuna every year (NOAA 2012), making canned tuna the second most popular seafood in the U.S. after shrimp.

In the new guidelines, FDA and EPA stick to their 2004 advice that a pregnant woman can safely eat six ounces of canned albacore tuna a week and that light tuna is a "low-mercury" fish. The 2004 fish advisory, unchanged in the 2014 draft, says pregnant women should limit their consumption of albacore tuna to six ounces a week. However, EWG calculates that if a pregnant woman of light or average weight ate that much, she would exceed the EPA safe level. Children who ate a child-sized serving once a week would also exceed the EPA guideline.

Canned light tuna has less methylmercury, but it provides far less omega-3 fatty acids and thus is not a preferable alternative for pregnant women. "Light" tuna is usually skipjack but can also contain yellowfin. The 2004 advisory described canned light tuna as a "lower mercury" species, but it is not without risk. EWG calculates that an average-weight pregnant woman who eats eight ounces of light tuna with an average mercury concentration of 0.12 parts per million would consume half of EPA's safe level for methylmercury for the week – too much, according to many experts. Children of any weight could not eat two child-size servings of light tuna over a week without exceeding EPA's safe level. Since EPA's "safe" level may be too high, pregnant women and children should eat light tuna only rarely.

FDA should provide a more comprehensive list of fish women shouldn't eat frequently

FDA should recommend additional species that pregnant women and children should limit or avoid. Based on average methylmercury concentration, we calculate that in addition to the species named in the advisory, to avoid exceeding EPA's weekly reference an average weight woman could not (166 pounds) eat more 4 ounces a week of the marlin, orange roughy, walleye, bluefish, lingcod, Chilean seabass, big eye and bluefin tuna. A woman could not eat more than eight ounces a week of halibut, albacore tuna steaks, yellowfin tuna, Spanish mackerel, lingcod and grouper.

FDA should provide better advice about omega-3s in seafood

References to omega-3 fatty acids are buried in the announcement of the draft guidelines, and omega-3s aren't mentioned at all in a summary linked to the announcement page (FDA/EPA 2014a). The lack of emphasis on omega-3s is striking, as these beneficial fatty acids are one of the main reasons the government is encouraging people to eat more fish.

Consumers who dig deeper into the announcement will see a table of commonly eaten fish and their associated omega-3 and mercury levels, but they will find it very difficult to determine from this table how much of various fish varieties they *should* eat per week to get the recommended amount of omega-3s. Nor can they tell how much of each variety they *can* eat per week without consuming too much mercury.

Only one of FDA/EPA's recommended "lower mercury" species – salmon – have reasonably high concentrations of omega-3 fatty acids. FDA should inform the public about several other common species that have a very favorable nutritional profile. These include anchovies, sardines, farmed trout, Atlantic mackerel and mussels. Just one or two four-ounce servings of these species can supply a pregnant women with the entire weekly recommendation of omega-3 fatty acids (USDA 2010).

FDA must provide clearer information about beneficial species

High-risk populations –women of childbearing age and young children—are likely to benefit from eating more seafood, provided they select varieties with the least mercury and optimum omega-3 content. But they need specific and detailed information about omega-3s and mercury content of common varieties. FDA and EPA should replace the lower- and high-mercury advice with more thorough and detailed information that includes both the omega-3 and mercury content of common species.

EWG's review of mercury and omega-3 fatty acid levels found dramatic differences among species, Our *Good Seafood Guide,* published this year, divides seafood into five general categories of benefit, based on average concentrations of methylmercury and omega-3s (EWG 2014b). We advise adults to focus on the species that provide the most omega-3 fats and least mercury.

EWG Seafood Rating Category	Omega-3 content in 4-ounce serving*	Mercury content of one 4-ounce serving**
Best Choice	At least 50% of Dietary Guidelines weekly recommendation	Average Mercury = Less than or equal to 0.1 ppm. Average weight woman can eat 12 ounces per week.
Good Choices	At least 25% of Dietary Guidelines weekly recommendation	Average mercury = Less than or equal to 0.1 ppm. Average weight woman can eat 12 ounces per week.
Low Mercury, But Low Omega-3s	Less than 25% of Dietary Guidelines weekly recommendation	Average mercury = Less than or equal to 0.1 ppm. Average weight woman can eat 12 ounces per week.
Mercury Risks Add Up	Any	Mercury = 0.1 to 0.3 ppm. Average weight woman can eat 4 to 8 ounces weekly if no other seafood.
Avoid	Any	Mercury = greater than 0.3 ppm. Pregnant women should eat less than 4 ounces weekly.

* USDA Dietary Guidelines recommend pregnant women ingest 1,750 milligrams of DHA and EPA per week.

** Acceptable mercury intake for women weighing 166 pounds based on EPA's Reference Dose for methylmercury. EWG recommends pregnant women eat no more than 75% of the amount of methylmercury that EPA deems safe in its outdated Reference Dose

There is tremendous variability in both the omega-3 fatty acid and mercury content of species. Region, season of harvest, and age of the fish or shellfish modify the fat content. Federal agencies should gather additional information about the omega-3 fatty acid content of common species to make guidance based on more robust data.

Methylmercury intake guidelines are based on a person's bodyweight. Lighter women and children should be advised to further limit their mercury intake. EWG provides an online

calculator that gives body-weight adjusted advice on methylmercury intake. Because of uncertainties about methylmercury toxicity, EWG's calculator uses 75% of EPA's Reference Dose as a guideline for methylmercury during pregnancy and childhood.

Despite these complexities it is possible to provide Americans with clear and specific guidelines about how best to optimize the health benefits of seafood in their diet. We hope you consider these important factors, to ensure our shared goal of improving and protecting public health.

Sincerely,

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