

August 19, 2014

Michael Taylor Deputy Commissioner for Foods U. S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Deputy Commissioner Taylor:

We are writing to urge the Food and Drug Administration (FDA) to immediately repost its chart "Mercury Levels in Commercial Fish and Shellfish (1990-2010)," in its original form, divided into Tables 1, 2 and 3, with Table 2 listing Lower Levels of Mercury, which was removed from the FDA website earlier in August. Table 2 enabled vulnerable groups including women of childbearing age to understand and follow FDA's specific advice to consume fish that are "lower" in mercury, included in your June 2014 draft guidance, "Fish: What Pregnant Women and Parents Should Know." The original chart is attached for your reference.

We are very concerned that on August 8th, following several discussions with Consumer Reports' staff, FDA eliminated the chart, which provided a list of 32 "lower-mercury" fish, and instead substituted a chart that lists fish in alphabetical order, with no indication as to which are lower in mercury. We believe it is critical for you to be as protective as possible of public health and to make as easy as possible for women in vulnerable groups, to identify lower mercury fish.

Background

In June of this year, FDA issued new draft advice for women of childbearing age, pregnant women and young children on how to get the health benefits of eating fish without the risks of consuming too much mercury. FDA reiterated its 2004 advice to avoid four kinds of high mercury fish—shark, swordfish, king mackerel and Gulf tilefish--but added advice to eat 8 to 12 ounces of "lower mercury" fish. Previously FDA indicated these groups could eat up to 12 ounces of lower mercury fish but did not urge a minimum level of consumption.

In June 2014 draft advice, the FDA mentions seven "lower mercury" fish: shrimp, canned light tuna, salmon, pollock, catfish, tilapia and cod. These seven species, however, by no means represent all low mercury fish. Further assisting the public, the FDA continued to link to its chart entitled "Mercury Levels in Commercial Fish and Shellfish" which had been on its website since 2004. The chart was divided into three tables, Table 1. Fish and Shellfish With Highest Levels of Mercury, Table 2. Fish and Shellfish with

¹ Current FDA chart entitled Mercury Levels in Commercial Fish and Shellfish (1990-2010) located at: http://www.fda.gov/Food/FoodbornelllnessContaminants/metals/ucm115644.htm

Lower Levels of Mercury, and Table 3. Mercury Levels of Other Fish and Shellfish. FDA had updated these tables with additional data in 2011.

Although FDA never stated what criteria it used to classify fish into one group or another, all 32 fish in Table 2, "Lower Mercury" averaged .128 ppm of mercury or less. The Environmental Protection Agency (EPA), which jointly issues the fish consumption advice with FDA, has stated that a level of .12 ppm is approximately the mercury concentration that an average adult who eats 2 to 3 fish meals a week could consume without exceeding the EPA reference dose (.1 micrograms/kg of bodyweight). The 32 types of lower mercury fish included, for example, sardines, scallops, clams and flounder.

Elimination of Lower Mercury Fish Table

About three weeks ago a reporter from Consumer Reports emailed FDA asking for an explanation of FDA's advice on various kinds of tuna, where we have long differed from the agency. After some emails back and forth, and phone conversations, including queries from us as to whether the EPA reference dose was used as the basis for selecting lower mercury fish listed in Table 2, FDA abruptly on Friday, August 8th, eliminated Tables 1, 2, and 3 from its website and substituted a chart that simply listed in alphabetical order all types of fish and their mercury concentrations.

Consumers Union is disappointed that FDA has taken this action, which will only make it harder for vulnerable groups to identify lower mercury fish. While Consumer Reports is providing a list that helps them do this in its forthcoming October issue, we believe the FDA has an obligation to provide the public with the most helpful information to make decisions. FDA staff indicated to us that with the fish now listed in alphabetical order, concerned women could themselves identify and choose fish that were lower in mercury. However, FDA now provides no guidance as to what is considered low and what is not, aside from mentioning a few examples of lower mercury fish, and identifying the four highest in its draft guidance. It is really asking a lot of pregnant women and young mothers to determine, for themselves, what constitutes an appropriate threshold for lower-mercury fish. Adding further confusion, in its June draft guidance, FDA includes a chart obtained from USDA that lists fish in descending order of omega-3 content along with mercury content, leaving consumers to decipher what mercury levels might pose too much risk.

FDA Action Needed

We believe that vulnerable groups will benefit if they consume 8 to 12 ounces per week of lower mercury fish, as FDA advises. We therefore find it difficult to understand why FDA has taken actions that make it more--rather than less--difficult to identify the fish that provide the benefits with the least risk. Consumer Reports has identified a list of about 20 fish that women of childbearing age can consume 18 ounces of—and for some fish even more—per week and not exceed the EPA reference dose. We will be providing comment in detail on the draft guidance to the FDA docket indicating how we created such a list and urging FDA to do something similar. We will also comment on how we believe FDA's advice on tuna is not sufficiently protective of pregnant women, and why for this group we believe tuna should also be on the "do not eat" list. We will comment as well on why we think FDA

should expand its definition of vulnerable groups to include people who are at risk because they eat a great deal of fish, often in the belief that it will confer great health benefits.

In the meantime, however, to provide the public with the best, most useful information, we urge FDA to immediately restore its chart summarizing "Mercury Levels in Commercial Fish and Shellfish (1990-2010)" to its original form, divided into Tables 1, 2 and 3, with Table 2 listing Lower Levels of Mercury.

We would also appreciate having an opportunity to meet with you to discuss these issues at your earliest convenience.

Sincerely,

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