

Fluoride Action Network
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Re: Comment on "Beverages: Bottled Water"
A Proposed Rule by the Food & Drug Administration
Docket No. FDA-2018-N-1815

In the Federal Register: <https://www.federalregister.gov/documents/2019/04/03/2019-06201/beverages-bottled-water>

Summary of proposal: The Food and Drug Administration is proposing to revise the quality standard for bottled water to specify that bottled water to which fluoride is added by the manufacturer may not contain fluoride in excess of 0.7 milligrams per liter (mg/L). This action, if finalized, will revise the current allowable levels for fluoride in domestically packaged and imported bottled water to which fluoride is added. We are taking this action to make the quality standard regulation for fluoride added to bottled water consistent with the recommendation by the U.S. Public Health Service (PHS) for community water systems that add fluoride for the prevention of dental caries. This action, if finalized, will not affect the allowable levels for fluoride in bottled water to which fluoride is not added by the manufacturer (such bottled water may contain fluoride from its source water).

I am submitting the following comments on behalf of the Fluoride Action Network, a non-profit advocacy group that continues to work for rational dialogue for ending the intentional addition of fluoride into drinking water, whether it be through fluoridation schemes or via bottled water.

1. It is not appropriate to allow this proposal to proceed on the basis that no federal regulatory agency, including the FDA and the EPA, has ever performed a health risk assessment on the effects of 0.7 mg/L fluoride in drinking water on the human fetus.

2. It is well known that pregnant women drink large quantities of water. In fact, the Institute of Medicine recommends that pregnant women drink about 10 8-ounce cups of water or other beverages each day (often constituted with fluoridated tap water). This would be an unacceptably high dosage of fluoride if the water contained 0.7 mg/L of fluoride.

Reference: Dietary Reference Intakes (DRIs): Recommended Dietary Allowances and Adequate Intakes, Total Water and Macronutrients. 2006. Food and Nutrition Board, Institute of Medicine, National Academies, http://nationalacademies.org/hmd/~media/Files/Report%20Files/2019/DRI-Tables-2019/3_RDAAITWM.pdf?la=en

3. The National Institutes of Health/National Institute of Environmental Health Science (NIH/NIEHS) funded the following studies that used urinary fluoride levels as biomarkers of exposure.

- **Bashash et al. (2017)** conducted a landmark 12-year study with 299 Mother-Offspring pairs. Urinary fluoride levels in the pregnant women were taken during the pregnancy. The authors reported a significant loss of IQ (5 to 6 points) in the offspring of the women who had a certain level of fluoride in their urine during pregnancy. Cognitive tests were taken with the offspring at 4 years of age and also between 6-12 years of age. This study confirmed, for the first time, that the fetus is at the highest risk to fluoride's neurotoxicity.

Reference: Bashash et al. (2017). Prenatal Fluoride Exposure and Cognitive Outcomes in Children at 4 and 6–12 Years of Age in Mexico. *Environmental Health Perspectives*, September. <https://ehp.niehs.nih.gov/doi/10.1289/ehp655>

- **Bashash et al. (2018)** performed this second study using the Mother-Offspring cohort from 2017 to examine ADHD (Attention Deficit Hyperactivity Disorder). The authors reported:
-- Higher concentration of maternal urinary fluoride was associated with more ADHD-like symptoms in school-age children. --Prenatal exposure to fluoride was most strongly associated with behavioral ratings of inattention, but not hyperactivity and impulse control. --Findings are consistent with the growing body of evidence suggesting neurotoxicity of early-life exposure to fluoride.

Reference: Bashash et al. 2018. Prenatal fluoride exposure and attention deficit hyperactivity disorder(ADHD) symptoms in children at 6–12 years of age in Mexico City. *Environment International*, December, Part 1: 658-666.

<https://www.sciencedirect.com/science/article/pii/S0160412018311814?via%3Dihub>

- **Till et al. (2018)** undertook a national sampling of urinary fluoride levels in pregnant women throughout Canada. The authors reported that the urinary fluoride levels for pregnant women living in fluoridated regions had similar levels to those in the Bashash et al. (2017) study above. Both Canada and the U.S. have the same optimal concentration of fluoride in drinking water: 0.7 mg/L. The authors also noted that pregnant women living in fluoridated communities had twice as high the level of fluoride in their urine compared to pregnant women living in non-fluoridated communities.

Reference: Till et al. 2018. Higher levels of urinary fluoride associated with ADHD in children. *Environment International*, December, Part 1: 667-674.

<https://reader.elsevier.com/reader/sd/pii/S016041201830833X?token=DA9EC7731F2C1A0BB41608B7A4123112E9F3A31CDA1ED4ECA256E904844C242F88F6F771480D39907CD9E4D11AB34D09>

4. There are many studies that have been performed on fluoride's neurotoxicity. See

- 53 human studies linking moderately high fluoride exposures with reduced intelligence, <http://fluoridealert.org/studies/brain01/>

- 3 human studies linking fluoride exposure with impaired fetal brain development, <http://fluoridealert.org/studies/brain05/>

- Over 125 Human studies on the brain, http://fluoridealert.org/studytracker/?effect=brain-2&sub=&type=human&start_year=&end_year=&show=10&fulltext=&fantranslation=

- Over 230 Animal studies on the brain, http://fluoridealert.org/studytracker/?effect=brain-2&sub=&type=animals&start_year=&end_year=&show=10&fulltext=&fantranslation=
- 34 Cell studies on the brain, http://fluoridealert.org/studytracker/?effect=brain-2&sub=&type=cell&start_year=&end_year=&show=10&fulltext=&fantranslation=

We urge the FDA to refuse to allow any intentional addition of fluoride into bottled water until it performs a basic health risk assessment on fluoride's effects on the fetus.

In the interim it is the responsibility of public health officials to inform pregnant women of the results of the above tests.

Ellen Connett
On behalf of the Fluoride Action Network