



June 22 2017

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U.S. Food and Drug Administration
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Subject: Strengthening and promoting FDA initiatives to better protect pregnant women and infants from mercury and arsenic pollution in food

Dear Dr. Mayne:

At FDA's recent Science Forum, Commissioner Gottlieb spoke about the need for FDA to tackle novel risks posed by the growing complexity of products you regulate. He spoke of the emerging societal challenges FDA faces, and charged his staff with embracing new advances in science and technology to keep pace with the nation's needs.

As an alliance of non-profit organizations working to protect people from the health impacts of toxic chemicals, we appreciate these aims. We know that a clear view of new data and tools can advance public health protection. But we are writing to urge you also to finish basic, vital business that has lingered unfinished at FDA for years.

During the past week, news of lead in baby food captured national attention, following the publication of an important study by Environmental Defense Fund. But foods eaten by pregnant women and infants are also commonly polluted with mercury and arsenic. All three of these pollutants harm the developing brain. The issue of neurotoxic pollutants in food is not technologically enticing, novel, or emerging. It's a decades old issue that has sputtered at FDA. And it is critically important to public health.

In January 2017 FDA and EPA issued new fish consumption advice for pregnant women and parents, to help educate consumers about low-mercury seafood varieties and amounts of fish that are safe to eat. The advice bolsters previous versions published since 2001. We urge you to broaden the distribution of this critical advice.

But we also urge you to strengthen it. The new advice leaves some women at risk. Women who eat seafood as often as FDA and EPA claim is safe – two to three times per week of lower mercury varieties, for example – can expose a developing child to excessive levels of mercury. Your fish consumption advice must be strengthened in order to protect women for whom seafood is a dietary staple.

Similarly, FDA's efforts on arsenic in infant rice cereal and other rice products leave pregnant women and infants vulnerable to arsenic exposures in amounts that may cause neurodevelopmental damage. FDA has yet to finalize an enforceable limit for this common pollutant in rice cereal. FDA's proposed, unenforceable limit is too weak to protect children who eat rice cereal frequently. Notably, the proposed limit does not protect infants from IQ loss and other impacts to the developing brain, despite the fact that at least 13 studies have now measured neurological damage among children exposed to arsenic *in utero* or soon after birth.

As we noted in prior comments to FDA, infant rice cereal combines worrisome contamination levels, exposure, and toxicity. It is high in arsenic, is a staple in infant diets, and is eaten daily at a time in life when the brain is intensely sensitive to chemical insult. This combination creates a perfect storm of risk for babies.

A preliminary study commissioned by Healthy Babies Bright Futures (HBBF) estimates that among infants who eat rice cereal often, resulting IQ loss may rival typical IQ declines among children exposed to lead paint. Lifetime impacts of IQ loss are well documented, including both the health and economic costs stemming from a child's eroded capacity to learn and prosper later in life.

In his first remarks to FDA staff, the Commissioner said he let his daughters know that in his new job, he will be working to make sure that the food they eat is safe. Bolstering FDA's initiatives on arsenic, mercury, and lead will be key to that goal. Progress will help ensure a productive future for all of this country's children.

We are excited to work with you to help protect pregnant women and young children from these toxic substances in food. And we appreciate all of your efforts to date to advance public health protection in this area.

We would appreciate the opportunity to meet with you in the near future to discuss our current research on arsenic and mercury in food, and to discuss how FDA could bolster its own initiatives in these critical areas. HBBF's research director, Jane Houlihan, will call your office in the next week to discuss scheduling that meeting.

Sincerely,

Jane Houlihan
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