



March 25, 2019

Doreen Chen-Moulec  
U.S. Department of Agriculture  
Sent by email to [doreen.chenmoulec@osec.usda.gov](mailto:doreen.chenmoulec@osec.usda.gov).

Re: Support for inorganic arsenic listing in *Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)*.

Dear Ms. Chen-Moulec,

The Environmental Defense Fund (EDF) is responding to U.S. Codex Program's request for comments in the [January 29, 2019 edition of the USDA Codex News](#) on the *Priority List of Contaminants and Naturally Occurring Toxicants for Evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)*. The request indicated that we needed to send comments to you by March 27, 2019.

EDF's mission is to preserve the natural systems on which all life depends. We have more than two million members and a staff of 700 scientists, economists, policy experts, and other professionals around the world. Guided by science and economics, we find practical and lasting solutions to the most serious environmental problems. This has drawn us to areas that span the biosphere: climate, oceans, ecosystems and health. Our Health Program seeks to safeguard human health by reducing exposure to toxic chemicals and pollution.

We support the U.S. delegations recommendation that inorganic be added to the priority list for JECFA review of non-cancer effects.

**Evidence of harm from inorganic arsenic on children's neurodevelopment has grown more compelling**

Inorganic arsenic is a known water and food contaminant. FDA has measured it in many foods included in its [Total Diet Study](#), but it's mostly known for its presence in baby and infant foods such as [rice](#) and [fruit juices](#). The presence of inorganic arsenic in [staples of children's diets](#) is concerning due to its risk of potential lasting health effects. The risks posed by inorganic arsenic on fetal and child brain development has become increasingly clear since the early 2000s as epidemiological studies began to scrutinize more subtle effects such as learning disorders and epigenetic effects. Earlier studies mostly focused on gross measures such as low body weight or increased stillbirths.

In 2013, [David Bellinger](#) authored a review of the evidence on children's neurodevelopment, concluding that, "The pace of research on the developmental neurotoxicity of arsenic is increasing, with the current evidence providing few firm conclusions but ample reason to be concerned about the neurodevelopmental impact of this chemical." However, the review said "at present, the epidemiological data do not permit firm conclusions to be drawn regarding these issues," and suggested that consistent measurements of exposure and of a core set of endpoints would allow firmer conclusions.

Three years later, FDA released a [risk assessment for inorganic arsenic](#) in rice and rice products and proposed a draft limit for the substance in rice based on the cancer risk. However, tucked in the last pages of the risk assessment is an updated literature search for non-cancer endpoints conducted by the agency's scientists. Even though they stated that the search was not exhaustive, it allowed them to conclude that the "studies support our conclusion that exposure to inorganic arsenic either *in utero* or in early childhood has

adverse effects on neurobehavioral development.” The agency acknowledged that, like low level exposure to lead and mercury, the harm from inorganic arsenic may be “[manifested in intelligence test results in children](#).” However, the evidence was not yet sufficient to develop a dose-response relationship necessary to quantify the harm and societal cost.

In 2017, in a study commissioned by [Healthy Babies Bright Futures](#), [Abt Associates](#) updated the literature search for inorganic arsenic effects on neurodevelopment and proposed a dose-response model that estimated IQ loss associated with increased inorganic arsenic exposure. Abt “concluded that, while there are uncertainties, it is feasible to draw upon the relationships from the peer-reviewed literature to quantify and monetize IQ loss associated with exposures to [inorganic] arsenic from infant rice cereal, rice, and other rice products.” Based on this relationship it estimated that, “In the U.S. population of children aged 0-6 [years], replacing all rice and rice products with alternate foods containing no arsenic would result in additional annual earnings of approximately \$12 to \$18 billion by avoiding losses of more than 9 million IQ points per year.”

#### **FDA is conducting additional studies on neurodevelopmental effects**

FDA’s National Center for Toxicological Research is also studying the effects of *in utero* inorganic arsenic exposure in rats. In January 2-19, it [published results of a study](#) showing a direct relationship between ingestion of the substance and the concentration found in the pup’s brains. The researchers saw motor function development delay and delays in other developmental milestones such as bilateral eye opening and incisor eruption, concluding that these effects “may indicate thyroid alterations, as endocrine disruption of thyroid hormones” are associated with delays in eye opening and tooth eruption in both rats and humans.

Using a [nematode model](#), scientists at FDA’s Office of Applied Research and Safety Assessment have also shown that, as in humans and rodents, arsenic causes developmental hyperactivity in the nematodes, as well as marked growth delay as the doses increased.

Recognizing that heavy metals often occur in food in combination, FDA has established a [Toxic Elements Work Group](#) to prioritize efforts in this area. The Work Group charged agency scientists with assessing cumulative effects of lead, cadmium, mercury and inorganic arsenic on children’s neurological development. The analysis will enable the agency to prioritize setting limits for specific foods that significantly contribute to exposure and developing preventive controls and best practices to reduce that exposure.

#### **Conclusion**

We support adding inorganic arsenic to the priority list for JECFA review. Rather than wait for JECFA to complete the review, we encourage FDA to build on the dose response model developed by Abt Associates and incorporate this evidence into its [long-awaited standards](#) for inorganic arsenic in rice.

Thank you for your consideration of these comments.

Sincerely,



Tom Neltner, JD  
Chemicals Policy Director