



March 27, 2023

U.S. Food and Drug Administration  
Dockets Management Staff  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: *Public Comment on "Draft Guidance for Industry: Action Levels for Lead in Food Intended for Babies and Children"; Docket No. FDA-2022-D-0278*

On behalf of Children's Wisconsin, I am writing regarding the Food and Drug Administration's proposed guidance to industry regarding the levels of lead in food for children.

Children's Wisconsin (Children's) is the state's only independent health system dedicated solely to the health and well-being of kids. We serve children and families in every county across the state, with two inpatient hospitals and more than 30 primary, specialty and urgent care clinics. We care for every part of a child's health, from critical care at one of our hospitals, to routine check-ups in our primary care clinics. Children's focuses on all elements of pediatric well-being by providing dental care, school health nurses, foster care and adoption services, family resource centers, child health advocacy, health education, family preservation and support, mental health services, pediatric medical research and the statewide poison hotline.

Lead is a significant public health issue in our communities across the state. At Children's, we understand firsthand the effects lead poisoning can have on a child's health and well-being, including learning difficulties, developmental delays and behavioral issues. There is no "natural" level of lead that comes from our diet or nature; therefore, any detectable level of lead in a person's bloodstream is there as environmental contamination. When it comes to lead and children, no level can be considered "safe." While much of Wisconsin's lead poisoning continues to stem from degrading paint, soil and plumbing/water sources, identifying and mitigating other potential sources of lead, including those in food, is critical to reducing incidence of this harmful condition.

At Children's, we are dedicated to providing the best care for children and we have implemented measures to increase testing to better identify children in need of care, as well as creating an integrated lead care management program to more holistically support children and families with coordinated care. We follow Wisconsin Lead Poisoning Prevention Program guidelines and recommendations for testing, including enhanced testing for children who live in areas with elevated lead poisoning risk, including children covered by Medicaid and those residing in the cities of Milwaukee and Racine. We have equipped each of our Primary Care sites with point-of-care instruments so lead results can be shared with both families and the local health department and any follow-up testing and care can be initiated. In addition to comprehensive work across Children's system to close lead care gaps for our patients, we're proud to be partnering with several community organizations to implement community-based lead testing and better coordinating care with the City of Milwaukee Health Department. Despite our enhanced efforts, Children's continues to see children who are hospitalized for chelation therapy due to lead poisoning. This is an issue we cannot ignore; lead poisoning of children must be addressed.

Our children face so many potential threats to health and well-being during the first years of life – years that are foundational to their growth and development. Lead exposure is one threat that we have the ability to control and mitigate the risks. We appreciate the FDA’s *Closer to Zero* action plan and believe this proposed draft guidance is an important step to decrease lead exposure. However, we would see value in more stringent action levels and regulations or standards for food manufacturers in order to get closer to the FDA’s stated goals in the action plan to better support lead poisoning prevention. To supplement the draft guidance proposed, we believe enhanced parent education around food preparation at home is another critical component to this issue. We encourage interagency collaboration to assess and mitigate potential impacts to food access and nutrition programs that families depend on. Balancing good nutrition and food access with food safety and lead mitigation efforts is incredibly important.

Eliminating the sources of lead in our community will continue to take committed and coordinated action by community, health and government entities. We appreciate local, state and federal officials looking at this as a public health issue and we encourage increasing focused efforts and resources aimed at lead poisoning prevention. Thank you for the opportunity to share comments on the proposed draft guidance.

Sincerely,

A handwritten signature in cursive script that reads "Robert T. Rohloff".

Bob Rohloff, MD  
Lead Program Medical Consultant  
Children’s Wisconsin