Docket No. FDA-2021-N-0966
Comments to the U.S. Food & Drug Administration (FDA) on "Closer To Zero" Action Plan.

We are members of Project TENDR (Targeting Environmental Neuro-Development Risks), an alliance of scientists, health professionals, and children's and environmental advocates concerned about the contributions of environmental chemicals to neurodevelopmental disorders such as intellectual and learning disabilities, autism spectrum disorder, and attention deficit hyperactivity disorder. Heavy metals, including inorganic arsenic, lead, cadmium, and mercury, are chemicals of particular concern to children's health. There is no "safe" level of these toxicants. These are non-essential elements with extensive evidence of human toxicity, most notably neurodevelopmental disorders in children.

We urge FDA to expedite efforts to minimize levels of these neurotoxic metals toward elimination from foods babies eat through its Closer to Zero Action Plan. Here, we focus particularly on the overwhelming evidence that arsenic and lead can do lasting harm to babies' brains even at extremely low levels of exposure, and that children of color and those living in poverty are at greatest risk of harm.

Arsenic
Arsenic is ubiquitous in our food and drinking water systems and associated with a wide range of health effects. Young children consume higher amounts of arsenic for their body weight than adults[i], i.e., through infant rice cereal and other foods[ii], as well as formula reconstituted with arsenic contaminated water. Emerging evidence indicates that higher temperatures resulting from climate change could alter levels of arsenic in foods due to shifts in growing conditions and water demands in some areas, which makes it imperative for FDA to take preventive measures now to ensure arsenic is kept out of baby foods.

Referenced by the FDA in 2016, the National Research Council report that stated: "Consideration should also be given to the growing evidence from human and animal studies that suggests that early-life exposure to arsenic may increase the risk of adverse health effects and the risk of impaired development in infancy and childhood and later in life." The report further noted: "A growing body of literature on both animals and humans suggests that low to moderate concentrations of arsenic are associated with neurologic deficits, particularly in IQ tests in children." Mounting research since this report further supports associations with neurocognitive deficits, including reduced IQ, motor development and neurobehavioral outcomes. These include studies of the general population of the U.S. and those for which dietary sources likely are the primary source of exposure. To date, no safe level of arsenic has been established. [iii],[iv],[v],[vi].

Lead:
Exposure to any amount of lead threatens the developing brain. In 2012, the National Toxicology Program found lasting effects on children's academic achievement, IQ, attention,

and behavior at children's blood lead levels below 5 ug/dL.[vii] No level of lead is safe in children, according to the CDC. In setting levels for lead in foods babies eat, FDA should clearly state that no amount of lead should be allowed in these foods, and that any standard is an interim marker toward complete elimination, as any and all levels are harmful.

A study of more than 1.4 million U.S. children published in *JAMA Pediatrics* in September 2021, found more than half of U.S. children have detectable lead in their bodies.[viii] Children living in predominantly Black communities were significantly more likely to have detectable lead levels, and children with public insurance were more than twice as likely to have detectable lead levels.

Lead poisoning has provided a terrible case study in environmental injustice and systemic racism, as children of color have suffered the greatest burden from this toxicant. The EPA's 2019 report on children and the environment found that Black children had higher median and 95th percentile blood lead levels than White or Hispanic children.[ix] Children living in poverty had higher blood lead levels than children above the poverty line, and Black children living below the poverty line had higher blood lead levels than White or Hispanic children living below the poverty line. These differences can have life-long consequences.

In October 2021, the U.S. Centers for Disease Control and Prevention (CDC) issued a new reference value[x] for the level of lead in children's blood considered to be elevated, tightening the standard from 5 ug/dL to 3.5 ug/dL. The new CDC standard should catalyze a government-wide effort to identify and eliminate all sources of lead affecting children – including baby food. We call on FDA to leverage the CDC's tightened lead standard toward protecting the children most at risk of harm – those living in poverty and Black children. These exposures are preventable and should not be tolerated in a just society.

We strongly urge FDA to take immediate action to minimize levels of lead, arsenic, cadmium, and mercury in foods babies eat, with continual progress to complete elimination. Levels should be set to protect child brain development, an exquisitely sensitive endpoint. FDA's swift implementation of the Closer to Zero program, with priority given to safeguarding children at greatest risk, and clear characterization of what interim levels mean, will serve to protect generations of children from harm.

Sincerely,

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