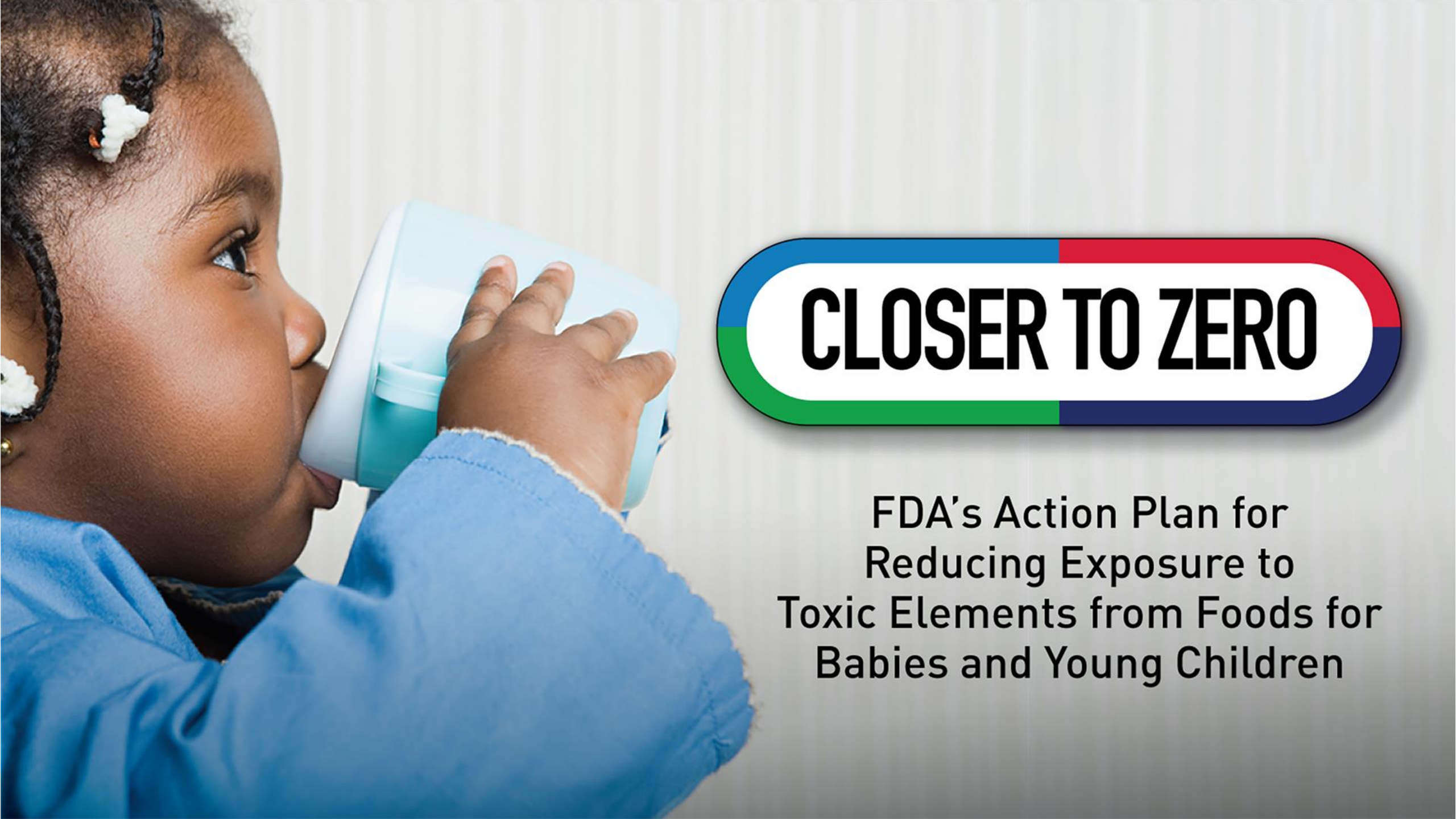


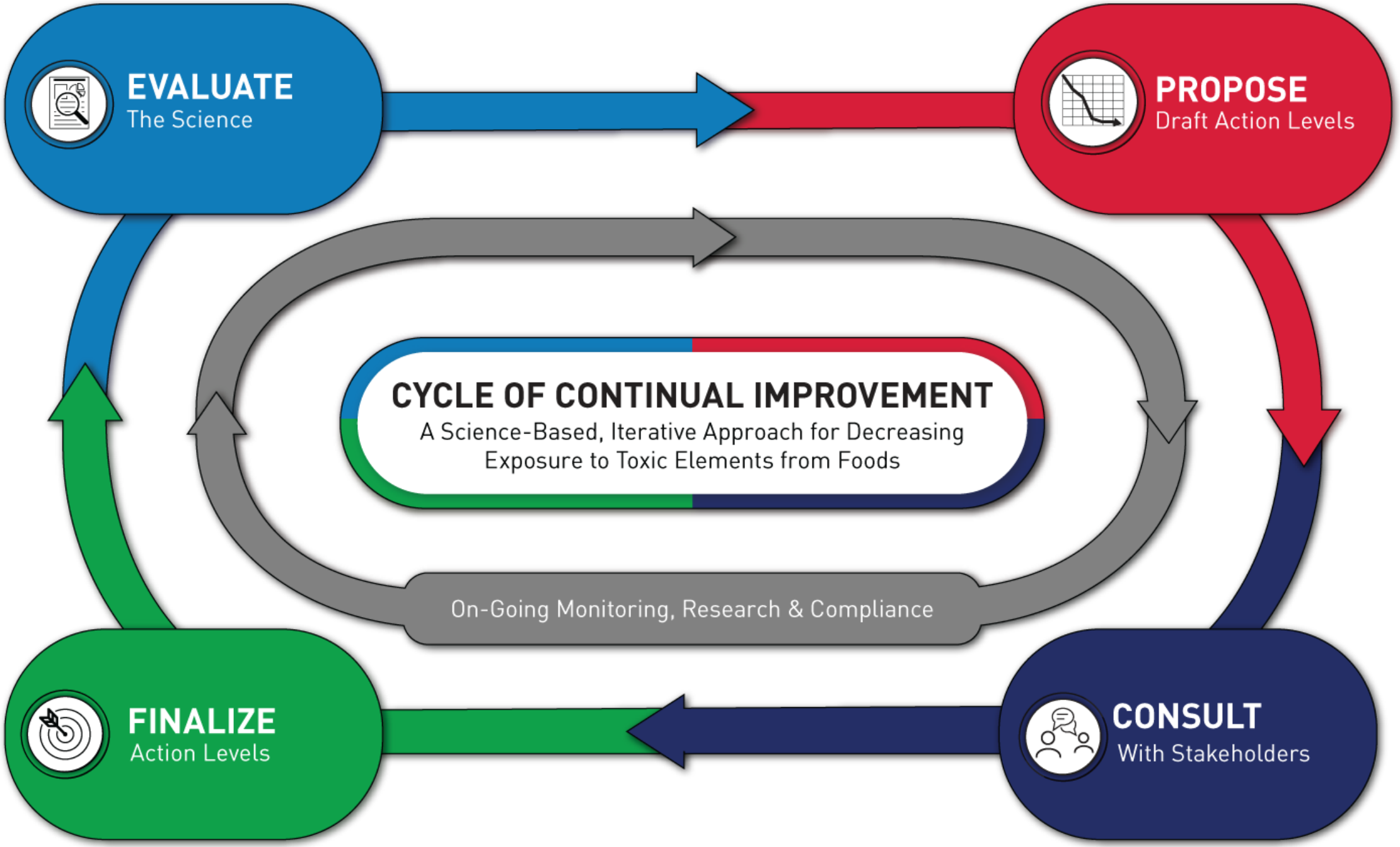
CLOSER TO ZERO

FDA's Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies and Young Children

Overview of Risk Assessment

- **Risk assessment** is the systematic scientific evaluation by which hazard, exposure, and risk are determined.
- **Hazard** means the ability of a substance to cause harm.
- **Exposure** is determined by the duration and frequency of a route of contact to a substance.
- **Risk** is the probability of an adverse outcome based on the exposure and potency of the hazard.
  - Risk can be reduced or eliminated by reducing exposure.
  - "Dose makes the toxin" —Paracelsus, 1538.

Risk = Hazard x Exposure


EVALUATE
The Science
PROPOSE
Draft Action Levels
CYCLE OF CONTINUAL IMPROVEMENT
A Science-Based, Iterative Approach for Decreasing
Exposure to Toxic Elements from Foods
On-Going Monitoring, Research & Compliance
FINALIZE
Action Levels
CONSULT
With Stakeholders

Regulatory Toxicology and Pharmacology

Volume 133, August 2022, 105202

Updated interim reference levels for dietary lead to support FDA's Closer to Zero action plan

Brenna M. Flannery, Karlyn B. Middleton

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https://doi.org/10.1016/j.yrtph.2022.105202

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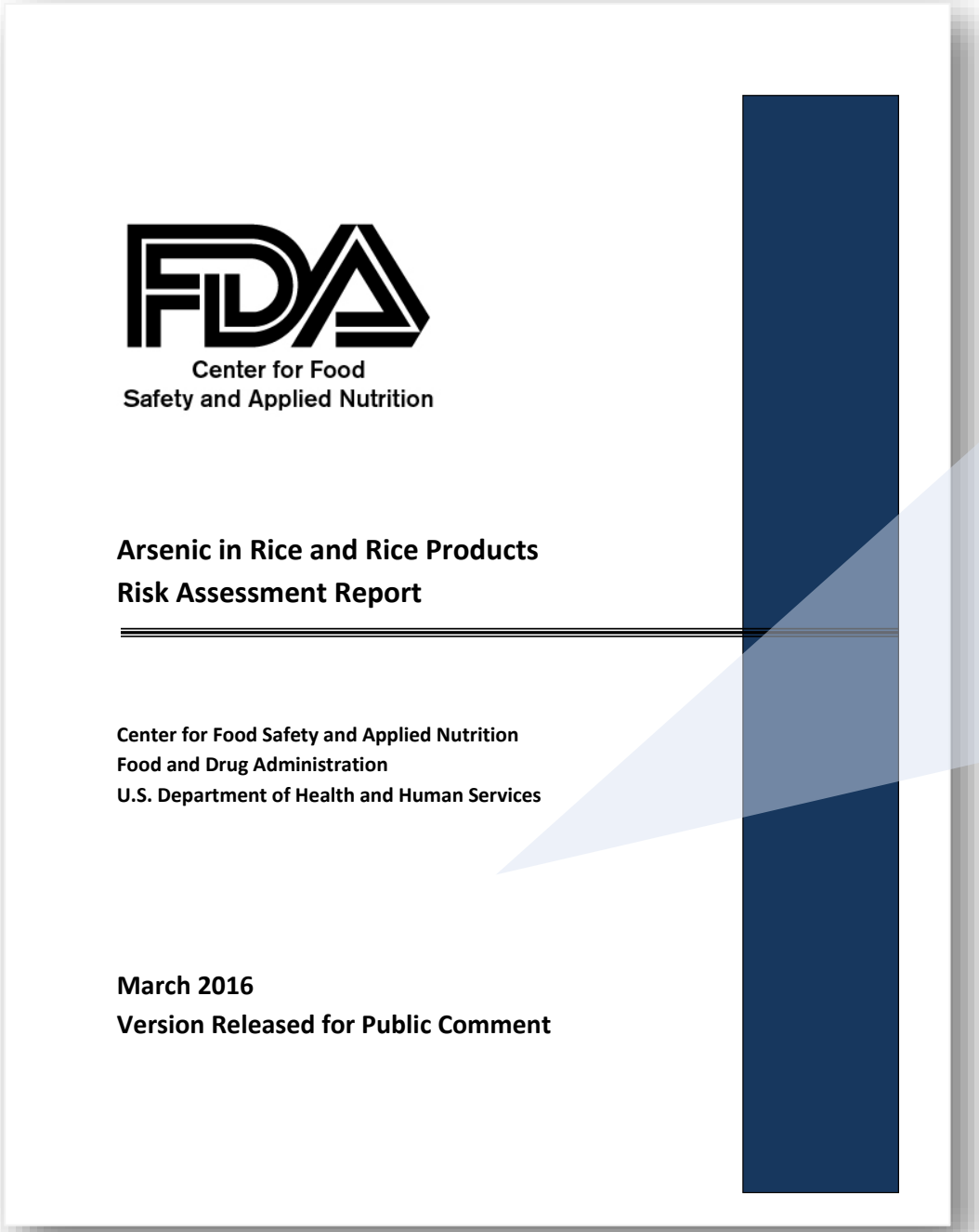
Highlights

- The FDA lowered its IRLs for dietary lead to 2.2 μg/day for children and 8.8 μg/day for females of childbearing age.
- The updated IRLs correspond to a blood lead level (BLL) of 0.35 μg/dL.



"... fetuses may have increased susceptibility to adverse health effects from maternal inorganic arsenic intake."

"...exposure to inorganic arsenic during infancy and early childhood can have neurotoxic effects, although whether these effects are lasting is unclear."

Cadmium Manuscripts

Completed

Cd Mitigation:
Cadmium: Mitigation strategies to reduce dietary exposure
https://pubmed.ncbi.nlm.nih.gov/31957884/

Cd scoping Review for children:
A scoping review of infant and children health effects associated with cadmium exposure
https://www.sciencedirect.com/science/article/pii/S0273230022000423/pdf

Children's Exposure:
Children's Exposure to Lead and Cadmium
https://pubmed.ncbi.nlm.nih.gov/30985263/

Cd Systematic Review:
A Systematic Review of Adverse Health Effects Associated with Oral Cadmium Exposure
https://www.sciencedirect.com/science/article/pii/S0273230022001301?via%3Dihub

Biomarker to Health Endpoint Quantitative Model
Relating urinary cadmium level to low bone mass & osteoporosis risk
Modeling the risk of low bone mass and osteoporosis as a function of urinary cadmium in U.S adults aged 50–79 years
https://www.sciencedirect.com/science/article/pii/S0013935122006429

Cd PBPK Quantitative Model for Forward & Reverse Dosimetry
Cadmium physiologically based pharmacokinetic (PBPK) models for forward and reverse dosimetry: Review, evaluation, and adaptation to the U.S. population
https://www.sciencedirect.com/science/article/pii/S0378427422009675

FDA and Federal Partners Launch Study on the Role of Seafood Consumption in Child Growth and Development

NATIONAL ACADEMIES Sciences Engineering Medicine

The Role of Seafood in Child Growth and Development

- About
- Publications
- Description
- Sponsors
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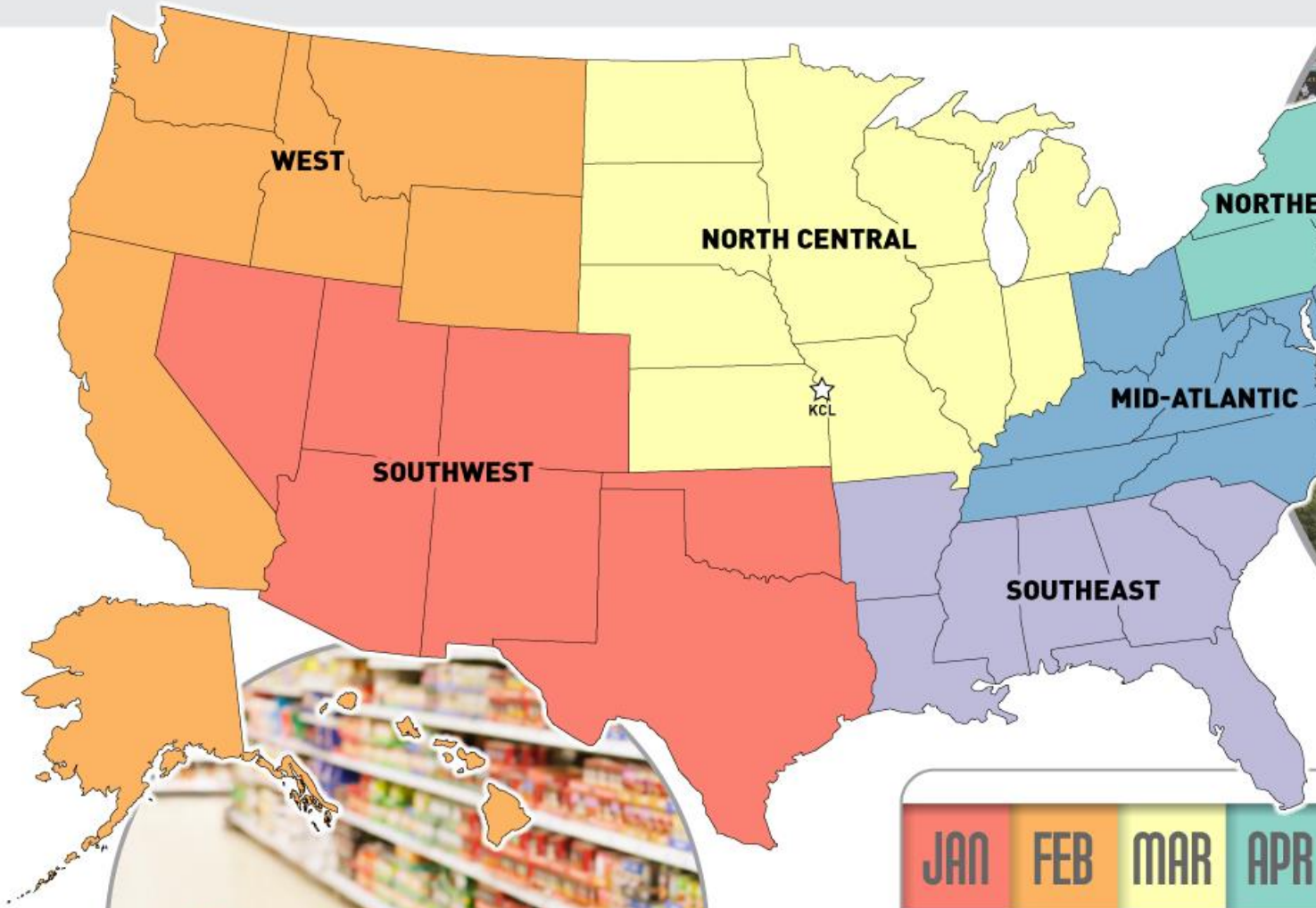
The National Academies of Sciences, Engineering, and Medicine will conduct a study to review the state of scientific evidence in nutrition and toxicology of associations between seafood intake and child growth and relevant aspects of development. This review will include a study of the associations between seafood intake (maternal and child) and child growth and development. The goal is to have the most up-to-date understanding of the science on fish consumption in a whole diet context.

FDA'S TOTAL DIET STUDY

Sampling Plan by Calendar Year



JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Region 1 Collection #1	Region 2 Collection #2	Region 3 Collection #3	Region 4 Collection #4	Region 5 Collection #5	Region 6 Collection #6	Region 1 Collection #7	Region 2 Collection #8	Region 3 Collection #9	Region 4 Collection #10	Region 5 Collection #11	Region 6 Collection #12
	WINTER				SUMMER					WINTER	

Action Levels for Lead in Juice: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

April 2022

FDA U.S. FOOD & DRUG ADMINISTRATION

What You Can Do to Limit Exposure to Arsenic and Lead from Juices

Eat a Varied and Nutritious Diet

Eating a variety of age-appropriate healthy foods is good for nutrition and for food safety. This approach helps you and your children get important nutrients and may reduce exposure to and potential harmful effects from contaminants that foods can absorb from the environment.

Healthy Beverage Recommendations by Age from the *Dietary Guidelines for Americans*

Birth- about 6 months

Give your baby only breast milk – no other drinks or foods. If you're not breastfeeding, give iron fortified infant formula. Use only store-bought infant formula and never homemade or toddler formula. Learn more about choosing infant formula at Choosing an Infant Formula | CDC.

6-12 months

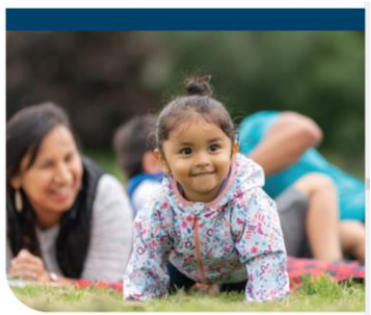
Keep giving your baby breast milk until at least age 12 months, and as long as you want

What You Can Do to Limit Exposure to Arsenic

Tips to limit exposure to Arsenic

Get strategies for rice and infant rice cereal

Rice tends to absorb arsenic more readily than other crops, however, consumers can certainly eat rice as part of a well-balanced diet. For infants, this includes infant rice cereal. The AAP advises parents to feed infants and toddlers a variety of grains as part of a well-balanced diet. Rice cereal fortified with iron is a good source of nutrients for your baby, but it shouldn't be the only source and does not need to be the first source. Other iron fortified infant cereals include oat, barley and multigrain. In addition to being nutritious, they are similarly effective as rice for infants with esophageal reflux tendencies.



DGA Dietary Guidelines for Americans 2020 - 2025

ENCOURAGE A VARIETY OF FOODS FROM ALL FOOD GROUPS TO INFANTS STARTING AT ABOUT 6 MONTHS OLD

Grains, including iron-fortified infant cereal, play an important role in meeting nutrient needs during this life stage. Infant cereals fortified with iron include oat, barley, multigrain, and rice cereals. Rice cereal fortified with iron is a good source of nutrients for infants, but rice cereal shouldn't be the only type of cereal given to infants. Offering young children whole grains more often than refined grains will increase dietary fiber as well as potassium intake during the second year of life and help young children establish healthy dietary practices.

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Closer to Zero: Partnership to Protect Our Food

Posted by Dr. Pamela Starke-Reed, Deputy Administrator, Agricultural Research Service and Dr. Melanie Abley, Senior Advisor, Office of the Chief Scientist in Research and Science

Jan 31, 2022

U.S. FOOD & DRUG
ADMINISTRATION