President's FY 2022 Budget Request: Key Investments for Food Safety

U.S. FOOD & DRUG ADMINISTRATION

Maternal and Infant Health and Nutrition: +$18 million/26 full-time equivalents in staffing

The FDA will invest across the centers and offices involved in its foods program to make improvements in key areas related to food safety and nutrition. One of those areas is Maternal and Infant Health and Nutrition.

Nutrition during pregnancy and in early childhood is critically important in supporting health and wellbeing of mothers and their children. Establishing healthy dietary patterns in early childhood can influence eating behaviors and health throughout life. Nutrients vital for brain development and growth must be provided in adequate amounts during early years and certain dietary constituents should be limited or avoided to prevent potentially irreversible harm. Infants, young children, and the developing fetus are especially vulnerable to toxic elements (e.g., lead, cadmium, arsenic, and mercury) due to small body size and rapid growth and development. In addition, research has shown that reducing exposure to toxic elements is important to minimizing any potential long-term effects on the developing brains of infants and children.

FDA's food and nutrition programs are well-positioned to make progress in maternal and infant health and nutrition. The requested resources will facilitate FDA's regulatory and other actions to address issues of concern, such as toxic elements in foods consumed by babies and young children; premarket review of infant formula submissions to evaluate the safety and nutritional adequacy of infant formula, for which there is limited staff review capacity; and nutrition work specific to infants, toddlers, and pregnant and lactating women. The FDA is uniquely positioned to address these critical areas and meaningful progress will be accelerated by an infusion of new resources to perform this work.

Toxic metals such as lead, arsenic, mercury, and cadmium are present in water, and soil, so some exposure through food is unavoidable, but exposure for infants and young children could potentially be reduced. These actions can also work to advance health equity. Improving awareness of how to achieve healthy dietary patterns while reducing toxic elements during pregnancy and for infants and young children is likely to benefit to a greater degree certain racial, ethnic and socioeconomic subgroups, who may be at increased risk for nutrition-related chronic diseases and dietary exposure to toxic elements.

Goals in FY 2022 Budget Authority Request Include:

Increase staffing

- With additional resources, the FDA will recruit risk analysts, consumer safety officers, data analysts, public health information specialists, toxicologists, and chemists, among others.
- Increased staffing in these areas will allow the FDA to expand research on the occurrence of multiple toxic elements in foods and impacts on the development of the nervous system and evaluate how laboratory procedures and methods can be improved to detect levels of concern.

Establish action levels for toxic elements

- The FDA plans to establish reference levels for exposure to toxic elements from foods, set expectations to strive for continual improvement, and provide action levels with the expectation that, if supported by the evidence, they will decrease over time for lead, arsenic, cadmium, and mercury for different categories of foods consumed by babies and very young children.
- The FDA is scheduled to publish a draft guidance that will establish action levels for lead in juice.
    - (Action levels are a level of contamination at which a food may be regarded as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act. The FDA considers action levels, in addition to other factors and scientific evidence, when considering whether to bring enforcement action in a particular case. A reference level is a measure of exposure to a substance from food that the FDA may use to determine if the amount of exposure to an individual substance across foods could result in a specific health impact.)

Develop communications materials and guidance

- Increased resources will also allow the FDA to create risk communication and education materials for

consumers on the risks from toxic elements in foods, and the importance of healthy dietary patterns and variety as a strategy for reducing toxicants in the diet.

- The FDA will also develop education and outreach materials for industry which outline ways to manage and minimize the presence of toxic elements in their products.

Review infant formula submissions

- Infant formula is a significant or even sole source of nutrition for many infants during a critical period of growth and development. Increased resources will allow the expansion of agency capacity to review the increasing number, size, and complexity of infant formula submissions.
  - Under the FD&C Act and implementing regulations, a person who introduces or delivers for introduction into interstate commerce a new infant formula must provide to FDA, at least 90 days before marketing such new infant formula, a submission that includes information about the formulation and assurances relating to its manufacture.

Promoting understanding of the Dietary Guidelines for Americans

- The FDA will partner with USDA, other agencies in the Department of Health and Human Services and others to explore opportunities to better help consumers understand information contained in the new 2020-2025 Dietary Guidelines specific to pregnant and lactating women and early childhood while also reducing dietary exposure to toxic elements.

Accomplishments Achieved with Current FY 2021 Funds

Letter to manufacturers and processors of baby and toddler food

- In March 2021, the FDA issued a letter to baby and toddler food manufacturers and processors covered by the preventive control provisions of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule. The letter reminds them of their existing responsibility to consider risks from chemical hazards—including toxic elements—when conducting a hazard analysis.

Closer to Zero

- In April 2021, the FDA announced a comprehensive plan to further reduce levels of toxic elements such as lead, cadmium, mercury, and arsenic in foods for babies and young children. The "Closer to Zero: Action Plan for Baby Foods" identifies actions the agency will take to reduce exposure to toxic elements from foods eaten by babies and young children to as low as possible.