Emerging Chemical and Toxicology Issues: +$19.7 million/40 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 Emerging Chemical and Toxicology Issues.

Over the last decade, the FDA has placed a major emphasis on implementing the 2011 FDA Food Safety Modernization Act (FSMA), which sets requirements for industry and transformed the nation’s food safety laws for the first time since the 1930’s. In that time, however, many food safety programs, such as pre-market programs and our capacity to mitigate risk due to chemical hazards across our products, which fall mostly outside of FSMA’s purview, have been falling further behind in their ability to keep pace with increasing innovation by industry and advances in science. Data gaps exist in understanding the thousands of chemicals that are contained in foods, dietary supplements, and cosmetics, and the FDA needs additional resources to identify, prioritize, and manage the smaller subset of potentially dangerous chemicals that may present health hazards.

These programs have received little if any new funding during the last 10 years and there is a critical need for resources to modernize and streamline regulatory frameworks for products that in certain cases pose potential chronic risks to human health. With new resources, the FDA will enhance and update its approach to chemicals—both those directly added as food ingredients and those that come into the food supply through food contact and environmental contamination. In addition, FDA will work on issues such as: food additives and substances added to food, and chemicals used in food contact, such as phthalates, as well as allergens, dietary supplements, and contaminants in cosmetics, which continue to receive major attention from the public as new potential health concerns emerge. Without significant new resources to address these critical issues the FDA will be unable to acquire and use emerging science and risk-based assessments to ensure food and cosmetic safety and protect public health.

Goals in FY 2022 Budget Authority Request Include:

Hiring additional experts
- Increased staffing will build capacity to use science and information technology advances to make product safety determinations more quickly.
- The FDA will recruit additional experts such as toxicologists and environmental scientists to help detect per- and Polyfluoroalkyl Substance (PFAS) in the food supply, understand associated risks, and reduce the public’s exposure to those health risks. PFAS are human-made chemicals that have been used in consumer and industrial products because of their resistance to grease, oil, water, and heat. Some PFAS have been shown to accumulate in the human and animal body and, evidence suggests, may cause serious health conditions.
- The FDA needs additional staff to assess the public health importance of allergens other than the nine major food allergens for which additional controls may be needed, including manufacturing controls and labeling. Staff are also needed to develop and implement new allergen and gluten testing methods and conduct additional research to inform the FDA’s regulatory work on allergens and gluten.

Supporting data- and risk-based safety evaluations
- Additional funding will enable the FDA to acquire new tools to support science- and risk-based pre-market and post-market safety evaluations.

Monitoring the food supply
- The goal is to identify, manage, and gather relevant toxicology data on the smaller subset of potentially dangerous chemicals that may present public health hazards.

Supporting cosmetics and dietary supplement programs
- New funding would provide modest increases to FDA’s programs for cosmetics and dietary supplements.
Accomplishments Achieved with Current FY 2021 Funds

• The FDA has initiated a comprehensive review of available toxicological data on PFAS to determine which information is applicable to the specific PFAS chemicals found in food and to use this information to both assess exposures and determine if actions are needed to address safety concerns.

• In March 2021, the FDA issued a Consumer Update and Fact Sheet warning consumers about the potential hazards of formaldehyde in hair smoothing products. Currently, the agency has formed a working group to formulate next steps to take.