Overview and Key Accomplishments

This is one of four fact sheets that detail how the FDA plans to use funds in FY 2022 to support food safety and nutrition. The budget provides increases to core food safety programs, as well as emerging issues of concern. The narrative below sets the stage with an overview of the current request and a look at the most significant achievements over the past fiscal year. Related documents outline how the FDA plans to make improvements with increased budget authority in the areas of New Era of Smarter Food Safety, Emerging Chemical And Toxicology Issues, and Maternal and Infant Health and Nutrition.

The FY 2022 Budget provides $1.6 billion in budget authority for food safety, an increase of $134 million, across human and animal products.

Of the increase of $134 million for food safety activities, $45 million is for efforts to support initiatives to advance the New Era of Smarter Food Safety, including $23 million for food safety requested as part of FDA’s Data Modernization and Enhanced Technologies initiative. The New Era initiative, announced in 2019, strives to leverage new technologies and approaches to create a more digital, traceable, and safer food system.

The budget also supports critical food safety initiatives that include $20 million for Emerging Chemical and Toxicology Issues, and $18 million for Maternal and Infant Health and Nutrition.

Additional funding will support the agency in keeping pace with the latest advances in science and technology and addressing issues of concern, such as maternal and infant health and nutrition and emerging chemical and toxicology issues. Likewise, without new resources for the New Era of Smarter Food Safety, the FDA’s ability to maintain the safeguards needed to help keep foods safe will significantly lag behind rapid, sweeping changes in the marketplace, potentially putting consumers at risk.

As the New Era of Smarter Food Safety blueprint states: “Many believe we will see more changes in the food system over the next 10 years than we have over the past several decades. Foods are being reformulated, new foods and new food production methods are being realized, and the food system is becoming increasingly digitized. We believe modern times require modern approaches.”

The FY 2022 food safety budget request also includes $54 million to support agency-wide capacity-building and infrastructure investments. Please see the FY 2022 FDA President’s Budget for more details on these agency-level investments.

Key Accomplishments

New Era of Smarter Food Safety
In July 2020, the FDA released the New Era of Smarter Food Safety Blueprint, which outlines the steps that FDA will take over the next decade to enhance food traceability, strengthen predictive analytics, promote best practices for food safety for new models of producing and delivering foods, reduce risks seen in retail food operations, and support the establishment of food safety cultures. This approach builds on the progress that continues to be made in the agency’s implementation of the FDA Food Safety Modernization Act (FSMA), while advancing the use of technologies that are currently used in society and business sectors all around us, such as blockchain, sensor technology, the Internet of Things, and artificial intelligence. The COVID-19 pandemic has accelerated the need for many of the goals in the blueprint, such as enhancing traceability to speed outbreak response and help industry create more digital, agile, and resilient supply chains, exploring the use of remote and virtual food inspections, exploring ways to address safety vulnerabilities for foods increasingly ordered online, and supporting strong food safety cultures on farms, in facilities, and in homes.

Food Supply Chain Continuity and Vaccine Distribution to Food and Agriculture Workers
To help ensure the continuity and resiliency of the food and agriculture sector, the FDA developed a new data analysis tool called 21 Forward to provide a comprehensive, data-backed understanding of how COVID-19 is currently impacting the food supply chain. Utilizing a combination of FDA and U.S. Department of Agriculture

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(USDA) data and Centers for Disease Control and Prevention (CDC) forecasting for COVID-19, the 21 Forward platform is used to help the FDA identify where there may be risks for interruptions in the food supply chain with the goal of conducting targeted outreach to the food industry to offer additional resources and consultations with FDA subject-matter experts. In collaboration with the Department of Health and Human Services, CDC, and USDA, data from 21 Forward are also being made available to assist states with their planning efforts for vaccine distribution to workers in the food and agriculture sectors.

**Produce Safety**

In March 2020, the FDA released the Leafy Greens STEC Action Plan to foster a more urgent and collaborative approach to preventing outbreaks of foodborne illness associated with the consumption of leafy greens. While millions of servings are consumed safely every day, fresh leafy greens have been repeatedly implicated in outbreaks of foodborne illness caused by Shiga toxin-producing *E. coli*, or STEC. While most strains of *E. coli* are harmless, STEC infections can be life-threatening. Between 2009 and 2018, the FDA and CDC identified 40 foodborne outbreaks of STEC infections with a confirmed or suspected link to leafy greens in the United States.

In 2020, the FDA made significant progress on the Leafy Greens STEC Action Plan by enhancing prevention strategies, improving response activities by the agency and other entities, and identifying and addressing the knowledge gaps that exist around STEC contamination of leafy greens. The FDA launched the California Longitudinal Study, collaborated with the Environmental Protection Agency (EPA) in its development of an efficacy protocol for the registration of antimicrobial treatments for pre-harvest agricultural water, and took critical steps to advance traceability of leafy greens. The FDA worked with the California Department of Agriculture to conduct several focused inspections, follow-up investigations, and sampling assignments to determine and evaluate potential sources of contamination.

In April 2021, the FDA took additional steps to advance the safety of leafy greens. The FDA released a report on the investigation into the fall 2020 outbreak of *E. coli* O157:H7 illnesses linked to the consumption of leafy greens. The report describes findings from the investigation, as well as trends key to understanding leafy greens outbreaks linked to the California Central Coast growing region (encompassing the Salinas Valley and Santa Maria growing areas) that have occurred every fall since 2017. The trends include the identification of a recurring strain of *E. coli*, and recurring issues around the presence of cattle on adjacent land.

The FDA also released an updated version of the Leafy Green STEC Action Plan, reaffirming the need for collaborative action to improve the safety of leafy greens, and building on the work accomplished in 2020. The updates for 2021 include a renewed emphasis on actions to help prevent contamination from adjacent land, and new actions that build on the accomplishments and learnings from the 2020 plan. They also renew our commitment to actions that were difficult to accomplish in 2020 due to challenges presented by the COVID-19 pandemic.

**FDA-Mexico Food Safety Partnership**

In October 2020, the United States and Mexico officially launched the FDA-Mexico Food Safety Partnership (FSP), broadening and strengthening the scope of our existing partnership to include the safety of all human food regulated by the FDA. The earlier Produce Safety Partnership, signed in 2014, had created a framework for Mexico and the U.S. to work together to contain potentially serious outbreaks related to produce and to lessen consumer exposure to foodborne disease. The FSP embraces the use of new and emerging technologies, including elements of the FDA’s New Era of Smarter Food Safety initiative, to solve complex public health challenges. Further, it strengthens collaboration with academia, consumer groups, and other governmental offices in the U.S. and Mexico.

**Increasing the Safety of Foods for Babies and Young Children**

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.

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. The FDA has prioritized babies and young children because their smaller body sizes and metabolism make them more vulnerable to the harmful effects of

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these contaminants. 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.

**Consumer Education Initiatives**

The Center for Food Safety and Applied Nutrition (CFSAN) launched two new consumer education campaigns in 2020.

In March 2020, the FDA announced "The New Nutrition Facts Label: What’s in it for You?" education campaign, which was developed to raise awareness about the changes to the Nutrition Facts label, increase its use, and help consumers, health care professionals, and educators learn how to use it as a tool for maintaining healthy dietary practices. The education campaign includes outreach through many channels including social media, indoor/outdoor advertising, videos, and consumer-friendly downloadable educational materials.

In March 2020, the FDA also launched the "Feed Your Mind" initiative in partnership with the U.S. Department of Agriculture and the U.S. Environmental Protection Agency (EPA) to provide science-based information on genetically engineered foods, commonly called GMOs. The campaign features a wide range of resources designed specifically for consumers, health care professionals and students. These materials feature new web content, fact sheets and videos, engaging graphics and stories to provide information about genetically engineered foods. This initiative is an ongoing effort, with additional materials planned for release later in 2021.