

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



New Era of Smarter Food Safety: +\$44.8 million/46 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 the New Era of Smarter Food Safety.

The goal of the [New Era of Smarter Food Safety](#) initiative, as outlined in the [blueprint](#) released on July 13, 2020, is to bend the curve of foodborne illness in this country by reducing the number of illnesses. The New Era envisions leveraging the use of new and emerging technologies and approaches to help enhance traceability, improve predictive analytics, expand collaboration with our regulatory and public health partners when possible, respond more rapidly to outbreaks, explore ways to address new business models (such as online ordering and direct delivery of foods, which has accelerated during the COVID-19 pandemic), advance the safety of foods sold in traditional retail establishments, and foster strong food safety cultures.



This approach builds on the modernized food safety regulatory framework created by the FDA Food Safety Modernization Act (FSMA) and is closely connected with FDA's response to the unprecedented challenges of the COVID-19 pandemic by helping to ensure the safety of food and prevent disruptions in the food supply when public health emergencies arise in the future.

Among the ways in which the FDA will work toward the goals of the New Era of Smarter Food Safety, the agency will invest in enhanced technologies and data analytics to strengthen prevention of human and animal foodborne illnesses, enable food contamination to be rapidly traced to its source, and better understand food safety challenges. The FDA's request for New Era funding includes the \$22.8 million food safety component of the agency's Data Modernization and Enhanced Technologies initiative.

The FDA will promote and support industry adoption of new traceability technologies and invest in predictive analytics to ensure that FDA can receive, efficiently process, and share new data streams, particularly in emergency response and outbreak scenarios. Improved traceability will help FDA respond more quickly to outbreaks, as well as expedite recalls. Beyond outbreaks, the current lack of traceability is also a barrier to the transparency needed to create in the long-term a more resilient and interoperable food system that can nimbly adjust supply chains during public health crises, such as the COVID-19 pandemic.

The FDA's investment in the New Era of Smarter Food Safety will also strengthen the animal food inspection system. Domestic mutual reliance is a critical component of the New Era of Smarter Food Safety as it strengthens partnerships with states to ensure optimal use of resources and maximize food safety reach.

Working through FDA's Center for Veterinary Medicine and the Office of Regulatory Affairs, the FDA will provide funding to the states to help them build modern, prevention-oriented systems. Animals have died and people have been sickened because animal food has been contaminated by preventable hazards. Historically, state partners have conducted up to 80% of the FDA's animal food safety inspections. The FDA and its state partners need these resources to help us provide risk-based oversight for the existing inventory of approximately 34,000 animal food facilities subject to FDA's food safety regulations, including the Preventive Controls for Animal Food rule established in part by FSMA.

Goals for FY 2022 Budget Authority Request Include:

Goals in the New Era of Smarter Food Safety blueprint

- Tech-Enabled Traceability: Enhance preparations to implement the Food Traceability Rule to be published in late 2022.
- Smarter Tools and Approaches for Prevention and Outbreak Response: Formalize root cause analysis procedures with federal, state, local, tribal, and territorial partners to broaden the use of rapid deployment tools. Further develop new predictive analytical capabilities to integrate rules-based and machine learning

systems to target potential sources of public health concern. Increase investments in domestic mutual reliance to create a more comprehensive food safety oversight system. (See Goals for Domestic Mutual Reliance/Animal Food Safety Oversight below.)

- **New Business Models and Retail Modernization**: Conduct outreach with stakeholders and complete an evaluation of the current regulatory landscape to assess needs for future guidance, education and outreach efforts, and compliance activities to support new business models.
- **Food Safety Culture**: Develop food safety culture goals, including learning about tools available for assessing and measuring progress. Develop and launch internal training for FDA inspectional staff on the behavioral and organizational principles of food safety culture.
- **Cross-cutting Investments**: Meet the goals of the blueprint by strengthening project management capabilities, IT development support for critical analytics tools, and stakeholder engagement. This initiative also includes funding for FDA's National Center for Toxicological Research to work on the development of data-driven tools to better understand foodborne pathogens.

Goals for Domestic Mutual Reliance/Animal Food Safety Oversight

- Provide funding to states to expand efforts to modernize, harmonize, and transform the U.S. animal food inspection system into one that is comprehensive and preventive.
- Update inspection and enforcement programs, develop outreach and training initiatives, and devote resources to the analysis of controls for expected animal food hazards and to understanding unknown animal food hazards.

Accomplishments Achieved with Current FY 2021 Funds

- In September 2020, the FDA issued the Food Traceability Proposed Rule. This proposed rule, mandated by FSMA, is also part of the New Era of Smarter Food Safety. Following the publication of the proposed rule, the FDA conducted three public meetings to discuss the proposal and accepted public comments through the Federal Register. The proposed rule, when finalized, would establish a standardized approach to traceability recordkeeping for certain designated foods. While the proposed rule would not require electronic recordkeeping, it would pave the way for industry to adopt, harmonize, and leverage more digital traceability systems in the future.
- As part of efforts to better leverage predictive analytics, the FDA implemented a pilot program to understand the abilities of artificial intelligence (AI), specifically machine learning (ML), to rapidly analyze data for screening foods imported into the United States. In August 2020, the FDA announced the results of the proof-of-concept for imported seafood, which demonstrated that machine learning could almost triple the likelihood of identifying a shipment containing potentially contaminated products. In February 2021, the FDA launched the second phase of the AI/ML imported seafood pilot, applying the model to field conditions.