



**U.S. FOOD & DRUG  
ADMINISTRATION**

**Statement from FDA Commissioner Scott Gottlieb, M.D., and Deputy Commissioner Frank Yiannas  
on new steps to strengthen FDA's food safety program *for 2020 and beyond***

The President's 2020 Budget includes new resources to advance the agency's food safety program, and expand food safety monitoring

March 19, 2019

**Release**

When it comes to the foods we eat, we live in an unprecedented time of technological change. Thanks to innovations in technology and the new requirements of the U.S. Food and Drug Administration Food Safety Modernization Act (FSMA), we now have more opportunities to strengthen public health and bring innovative food products to consumers than perhaps at any other time in our history. But our ability to fulfill these responsibilities becomes more challenging every year with increased globalization, advances in science and technology, and shifts in consumer expectations that drive change throughout the food system. We must continue to embrace innovation across the food safety system to make sure we secure our public health mission.

That's why as part of the President's 2020 Budget, we've proposed new funding across multiple aspects of our food safety system. We must invest to prevent problems from happening by solidifying the agency's tools under FSMA. We must also embrace new innovations to improve our ability to secure the food supply chain and engage in more effective tracking and tracing of food from farm to fork. This includes continuing to improve our capabilities for both detecting and responding to food contamination when preventive measures alone are insufficient. The funds we're requesting for food safety represent the FDA's commitment to the promises we've made to help keep people and animals safe from contaminated food, and our vision of a future in which both human and animal health is protected and strengthened by new and emerging technologies that will create a more digital, traceable, diverse, and safer food system.

A smarter, more technologically advanced food safety system will always stand on the shoulders of the preventive framework of FSMA. This landmark piece of legislation represented a sea change in food safety. It moved the FDA from a posture of response to one that prevents problems from occurring in the first place. States are critical partners in creating a prevention-based food safety system as part of our integrated national food safety system. To advance these goals, we're proposing new resources to fund human and animal preventive controls and produce safety inspections through the State Cooperative Agreement Program. The FDA's funding supports the states in conducting more than half of the domestic food and more than 80 percent of animal feed facility inspections required by FSMA.

We also recognize that our most effective toolkit for domestic food safety is not identical to the optimal toolkit for imported food safety. Our budget request reflects those differing needs. Our proposed budget makes other critical investments to help the FDA ensure a more secure and modern food safety framework.

### **Investing in Modern Food Safety**

The work under FSMA is just one part of our food safety net. We also need to invest in and further modernize our ability to detect and respond to problems in the food supply. For Fiscal Year 2017, our Center for Food Safety and Applied Nutrition responded to 794 recall events due to issues such as microbial contamination and undeclared allergens and oversaw the recall of 3,609 products, more than any other FDA Center.

We know that additional resources are required to ensure that contaminated food is detected and removed from the marketplace as quickly as possible, using the most modern technologies. For example, Whole Genome Sequencing (WGS) has been a game changer for the way we find and address microbial contamination in foods. This technology has made it easier determine the source of contaminated food associated with human illness, and to better identify foodborne outbreaks that previously would have gone undetected. WGS continues to be put into widespread use as the technology itself becomes more accessible, affordable, and much less bulky. We need to expand our use of these modern tools.

At the same time, the more widespread use of WGS has also increased the number of detected outbreaks and subsequent investigations. This is good news. We are identifying more sources of potential food contamination and taking steps to reduce risks to consumers. But at the same time, the success of WGS in identifying sources of food contamination and outbreaks has also greatly increased the FDA's workload to identify and mitigate potential food safety concerns. In Fiscal Years 2017 and 2018, the [FDA's Coordinated Outbreak Response and Evaluation Network](#) evaluated nearly 120 potential human food safety outbreak incidents per year. This is nearly double what was reviewed in Fiscal Years 2015 and 2016. The increase requested in the 2020 Budget will allow the agency to add new staff and resources to enhance signal detection, response to outbreaks and post-response evaluations.

As part of the President's 2020 Budget, we're also requesting additional resources to support the use of WGS and expand our ability to respond when we identify food contamination.

These additional resources also will increase the FDA's ability to leverage other new technologies that make it easier to track and trace products throughout the product lifecycle, from the time that they're grown or manufactured, until a consumer uses them. Efficiently tracking and tracing regulated products will enable the FDA to work with stakeholders, including industry producers, to more quickly remove harmful products or ingredients from the supply chain. Over the last year alone, we faced challenges dealing with the complexities of supply chain tracking and management related to two outbreaks of E. coli O157:H7 in romaine lettuce where records were being kept mostly on paper. In the wake of these two incidents, we worked with industry on common sense changes, like providing greater clarity on package labeling by including harvest date and location, and calling for industry to better improve traceability.

In recent years, we've seen emerging track and trace technologies that can assist response efforts to allow the FDA to intervene in time to alert consumers, implement recalls, and avoid human illnesses. This includes blockchain technology. This technology uses a decentralized, secure, ledger that's shared by all parties in

the supply chain to provide transparency on a product's origins. It can greatly assist in warning consumers about risks with specific foods and in implementing more targeted and efficient recalls.

Such technologies can reduce the time it takes to find a food source from days or weeks, to minutes or even seconds, in certain cases. While our primary goal in enhancing track and trace is protecting public health, this new technology will also assist industry by minimizing the number of products implicated in outbreaks of foodborne illness and other product problems that could result in the loss of millions of dollars in profits.

When the lack of transparency in supply chains delays the identification of contamination sources and the root causes of product problems, the economic and public health costs can be considerable. An enhanced ability to trace foods to source during an outbreak will also allow us to conduct better and more real-time root cause analysis to prevent similar reoccurrences.

Finally, our enhanced use of state food safety resources can also help our work securing the safety of imported foods, allowing the FDA to focus more resources on import oversight. Planned resources in the 2020 Budget request will also advance our import program goal of ensuring that domestic and imported foods receive parity of oversight by investing in additional resources to increase compliance with [Foreign Supplier Verification Programs](#) (FSVP) as well as assessing the agency's [Import Alert program](#).

## **Advancing Food Innovation**

Just as consumer demands have changed how we respond to problems with food, the FDA supports industry as it develops and implements new technologies in food and veterinary products. This includes biotechnology products. Although neither traditional human nor animal food products require pre-market approval, new foods and new ingredients such as food and color additives must be reviewed to determine that they will be safe for the ways in which they'll be used. We want to improve the timeliness of these reviews and eliminate unnecessary burdens to industry related to the premarket safety reviews of these food ingredients. We've requested additional resources to help us meet these important objectives.

Biotechnologies are enabling the development of many promising, innovative food products, such as genome-edited animals and plants. At the same time, we are seeing increased interest in the development of new protein sources, such as cell-culture technology. Part of our public health mission is to advance these promising innovations and to ensure they're safe, and that they don't have any unintended consequences.

Last fall, the FDA announced a new [Plant and Animal Biotechnology Innovation Action Plan](#). Our plan is focused on advancing policy priorities the FDA will pursue to clarify our science-and-risk-based approach for product developers; avoiding unnecessary barriers to future innovation in plant and animal biotechnology; and securing their safety and our public health mission. In the 2020 Budget, we've requested additional resources to ensure that the FDA continues to keep pace with the increasing requests for review of new products.

We're dedicated to making sure the FDA continues building a modern, prevention-based food safety system. We believe that the additional resources requested from Congress will help our program better protect our nation's food supply and lay the foundation for efforts to create a new era of smarter food safety in which new technologies can provide innovative products, help us better detect outbreaks, and better track and trace foods in the supply chain to prevent contaminated foods from reaching consumers.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.