

NARRATIVE BY ACTIVITY**FOODS**

(Dollars in Thousands)	FY 2017 Final	FY 2017 Actual	FY 2018 Annualized CR	FY 2019	
				President's Budget	+/- FY 2018
Foods.....	1,040,761	1,025,503	1,033,082	1,040,734	7,652
<i>Budget Authority.....</i>	<i>1,029,175</i>	<i>1,025,503</i>	<i>1,022,211</i>	<i>1,029,863</i>	<i>7,652</i>
<i>User Fees.....</i>	<i>11,586</i>	<i>---</i>	<i>10,871</i>	<i>10,871</i>	<i>---</i>
Center.....	315,356	310,994	313,526	316,326	2,800
Budget Authority.....	314,806	310,994	312,694	315,494	2,800
User Fees.....	550	---	832	832	---
Food And Feed Recall.....	243	---	243	243	---
Voluntary Qualified Importer Program.....	243	---	243	243	---
Third Party Auditor Program.....	64	---	346	346	---
Field.....	725,405	714,509	719,556	724,408	4,852
Budget Authority.....	714,369	714,509	709,517	714,369	4,852
User Fees.....	11,036	---	10,039	10,039	---
Food And Feed Recall.....	1,000	---	1,000	1,000	---
Food Reinspection.....	4,575	---	4,575	4,575	---
Voluntary Qualified Importer Program.....	4,320	---	4,320	4,320	---
Third Party Auditor Program.....	1,141	---	144	144	---
FTE.....	3,935	3,905	3,939	3,939	---

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Food Additives Amendment of 1958; Color Additives Amendments of 1960; The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Nutrition Labeling and Education Act of 1990; Dietary Supplement Health and Education Act of 1994; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Food Allergen Labeling and Consumer Protection Act of 2004; Sanitary Food Transportation Act of 2005; Food and Drug Administration Amendments Act of 2007; Food and Drug Administration Food Safety Modernization Act of 2011 (Public Law 111-353); Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C. 379aa-1)

Allocation Methods: Direct Federal/intramural; Contract; Competitive grant

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The purpose of the Foods Program is to protect and promote human health by ensuring the safety of the American food supply, dietary supplements, and cosmetics, as well as the proper labeling of food and cosmetics. The Foods Program began with the passage of the 1906 Pure Food and Drugs Act.

FDA's Foods Program is part of the Foods and Veterinary Medicine (FVM) Program. The FVM Program includes the Foods and the Animal Drugs and Feeds Programs and field activities in the

Office of Regulatory Affairs (ORA). In collaboration with ORA, the Center for Food Safety and Applied Nutrition (CFSAN) administers the Foods Programs and the Center for Veterinary Medicine (CVM) administers the Animal Drugs and Feeds Programs.⁷

CFSAN ensures the safety of the human food supply, dietary supplements, and cosmetics as well as the proper labeling of foods and cosmetics. The Foods Program ensures that the nation's food supply is wholesome and honestly labeled, and that nutrition labeling is informative and accurate. The Foods Program also promotes a nutritionally healthy food supply.

The Center for Veterinary Medicine protects human and animal health by approving safe and effective drugs for animals, and ensuring the safety of feed and devices for animals.

The Office of Foods and Veterinary Medicine (OFVM) provides leadership and strategic direction to Foods and Veterinary Medicine programs and oversees all CFSAN and CVM activities. OFVM also manages the crosscutting outbreak response and evaluation team, leads all external communications and stakeholder engagement, and coordinates FVM wide resource planning.

The following accomplishments demonstrate the Foods Program's delivery of its regulatory and public health responsibilities and progress towards reaching FVM Strategic Plan goals.

Enhance Oversight

Outbreaks of foodborne illness and contamination events have a substantial impact on public health:

- An estimated 48 million foodborne illnesses occur every year⁸
- An estimated 128,000 hospitalizations and 3,000 deaths result⁹
- Foodborne illnesses cost an average of \$3,630 per case¹⁰
- More than \$36 billion per year in medical costs, lost productivity, and other burdens to society.¹¹

The FVM Strategic Plan¹² provides a framework for implementing the Food Safety Modernization Act (FSMA) and other legislative authorities. The Plan prioritizes the prevention of foodborne and feed-borne illness of both known and unknown origins. The Foods Program addresses food safety risks at multiple points of the food supply chain. The program accomplishes this through regulations, guidance, technical assistance, training, outreach, consumer information, and model codes for food service establishments.

⁷ The Center for Veterinary Medicine does not implement the Foods Program, and the Center for Food Safety and Applied Nutrition does not implement the Animal Drugs and Feeds Program.

⁸ CDC. 2011. Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

⁹ CDC. 2011. Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

¹⁰ Minor, T., Lasher, A., Klontz, K., Brown, B., Nardinelli, C. and Zom, D. (2015), The Per Case and Total Annual Costs of Foodborne Illness in the United States. *Risk Analysis*, 35: 1125–1139. doi:10.1111/risa.12316

¹¹ Minor, T., Lasher, A., Klontz, K., Brown, B., Nardinelli, C. and Zom, D. (2015), The Per Case and Total Annual Costs of Foodborne Illness in the United States. *Risk Analysis*, 35: 1125–1139. doi:10.1111/risa.12316

¹² <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM507379.pdf>

The FVM Strategic Plan also emphasizes nutrition-related priorities of the Foods Program. Poor diet is a key risk factor for chronic diseases – the leading cause of death and disability in the United States. Chronic diseases and conditions – such as heart disease, stroke, cancer, diabetes, obesity, and arthritis – are among the most common, costly, and preventable of all health problems. In 2010, 86 percent of all health care spending was for people with one or more chronic medical conditions.¹³

The Foods Program ensures that nutrition labeling is informative and accurate. The Program promotes a nutritionally healthy food supply to reduce the hundreds of thousands of deaths each year attributable to poor diet.

In addition to the high-priority initiatives identified in the FVM Strategic Plan, the Foods Program conducts other important activities related to food safety, nutrition, and cosmetics. These include:

- review of infant formula notifications from manufacturers before marketing a new formula
- premarket regulation of ingredients and packaging, such as review of food additive and color additive petitions
- postmarket monitoring for chemical contaminants
- authorization of nutrient content and health claims
- regulation of dietary supplements
- cosmetics safety and labeling.

The FDA Food Safety Modernization Act

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law, significantly reforming food safety laws. FSMA is transforming the nation's food safety system from reactive to proactive by allowing FDA to focus on preventing food safety problems before they occur rather than reacting to problems after the fact. FSMA guides the food safety system in implementing effective measures to prevent contamination. FSMA engages all domestic and foreign participants in the food system to do their part to minimize the likelihood of harmful contamination. For example, FSMA requires food importers to ensure that their suppliers meet U.S. safety standards.

FDA faces unique food safety challenges in the 21st century. FSMA enables FDA to better protect the public health by:

- shifting the food safety paradigm from reactive to preventive
- strengthening FDA's technical expertise and capacity to support industry in implementing the new prevention standards
- furthering federal, state, local and territorial partnerships and investing in training and capacity to ensure efficient, high quality, and consistent oversight nationwide
- broadening interaction with foreign partners and increasing oversight of importers by placing more responsibility for the safety of imported foods on them.

¹³ Centers for Disease Control and Prevention. "Chronic Disease Prevention and Health Promotion: Chronic Disease Overview." <http://www.cdc.gov/chronicdisease/overview/>. Accessed October 23, 2015.

FSMA gives FDA new enforcement authorities to achieve high rates of industry compliance with prevention- and risk-based food and feed safety standards and to better respond to and contain food safety problems when they occur.

FDA finalized seven foundational FSMA rules in 2015 and 2016, and is conducting extensive outreach to industry to ensure that stakeholders understand the new requirements. These seven foundational FSMA rules provide a framework for the food industry to implement effective measures to prevent contamination.¹⁴ In 2017, FDA launched a new web page on fda.gov which compiles compliance dates for all of the foundational FSMA rules into a single graphic.

FSMA recognizes that FDA had previously-established regulations that are specific to seafood, juice, and Low-Acid Canned Foods (LACF) and, therefore, some exemptions were made in the FSMA rules for these products. However, there are still some requirements in the FSMA regulations that apply to processors of these products. To help producers of low-acid canned foods, juice, and seafood products understand which parts of the FSMA rules apply to them and how the FSMA rules may affect their operations, in 2017 FDA published three guidance documents: Low-Acid Canned Foods and FSMA, Juice HACCP and FSMA, and Seafood HACCP and FSMA.

FSMA heralded a new era of enhanced collaboration between FDA and its counterparts in state governments across the country. State officials were instrumental in providing comments to help FDA create regulations that take into account the complexities of food production and are designed to be flexible and practical while meeting the agency's public health goals.

In September 2017, FDA awarded 43 states a total of \$30.85 million in cooperative agreements to develop produce safety programs that will enable them to deliver education and technical assistance to farmers and create infrastructure to provide inspection, compliance, and oversight.

Since the inception of FSMA, leaders of FDA's Foods Program have made stakeholder engagement a top priority. This robust commitment to engagement was particularly evident as the foundational rules implementing the FSMA took shape. FDA was involved in more than 600 engagements between FSMA's enactment in 2011 and the finalization of the rules in 2015-16.

Selected Rules Published in 2017

Below is the FSMA-related rule published by the Foods Program in the last calendar year.

Date	#	Title	Description
Sep 2017	FDA-2011-N-0921	FSMA Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E	Proposes to extend, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule.

In July 2017, FDA released a proposed rule to extend, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule (FSMA Produce

¹⁴ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm>

rule). FDA is proposing to extend the compliance dates to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration's policies. The FSMA Produce rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

In 2017, FDA released an online food safety training module for carriers engaged in the transportation of food by rail or motor vehicle in the United States. FDA is offering this training free of charge to help carriers meet the requirements of the FDA's Sanitary Transportation of Human and Animal Food Rule (Sanitary Transportation Rule). The Sanitary Transportation Rule requires rail and motor vehicle carriers covered by the rule to provide food safety training to their personnel engaged in transportation operations. The training must provide personnel with an awareness of 1) potential food safety problems, 2) basic sanitary practices, and 3) carrier responsibilities. The carrier training requirement applies when the shipper and carrier have agreed, in a written contract, that the carrier is responsible, in whole or part, for sanitary conditions during transportation operations. A carrier may wish to offer this FDA module to their operations personnel as a means of satisfying the training requirements of the Sanitary Transportation Rule or to complement other training offered by the carrier.

In August 2017, FDA announced the availability of a Small Entity Compliance Guide (SECG) to help small businesses comply with the Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration (or Intentional Adulteration Rule), one of the seven foundational rules mandated by FSMA. It provides nonbinding recommendations on such topics as developing a food defense plan and records management. The compliance date for small businesses under the Intentional Adulteration Rule is July 27, 2020. Very small businesses are exempt from the rule, except for a documentation requirement described in the SECG, which has a compliance date of July 26, 2020.

Launched Food Safety Plan Builder

In August 2017, to help businesses meet the requirements of the FSMA Final Rule for Preventive Controls for Human Food, FDA released a new software tool for owners and operators of food facilities to use to create a food safety plan specific to their facilities. The Food Safety Plan Builder (FSPB) is a free software application developed by FDA that businesses can download from the FDA's website to guide them, step-by-step, through the creation of a food safety plan, as required by FSMA. The user is taken through a series of sections (tabs) in the application that prompt the user to answer questions and/or fill in information specific to their business and facility. Once all the tabs have been completed, the file may be saved or printed, and the firm will have a food safety plan to use in its operations and to provide when FDA conducts an inspection. While the Food Safety Plan Builder was primarily designed for use by small manufacturers which may have limited resources, any size manufacturer can opt to use it. To assist users, FDA has also developed an overview video about the application, as well as individual videos that demonstrate how to navigate the various tabs.

Updated Guidance for Foreign Supplier Verification Programs (FSVP) Rule

In FY 2017, FDA updated FDA.gov to include revised fact sheets and new guidance as a resource for importers subject to the FSVP rule. The first major compliance date for importers covered by the FSVP rule was May 30, 2017. FSVP is another one of the seven foundational

FSMA rules. A central tenet of that law is that the same preventive food safety standards apply to food consumed in the U.S., regardless of where the food is produced. FSVP achieves this by requiring importers to verify that their foreign suppliers of food for human and animal consumption meet applicable FDA safety standards.

Launched Accredited Third-Party Certification Site

The Accredited Third-Party Certification program is a voluntary program established by FSMA to expand FDA's oversight of imported foods. In FY 2017, FDA launched the website through which organizations can apply to be recognized as a Third-Party accreditation body.

Accreditation bodies recognized by FDA will have the ability to accredit third-party certification bodies, also known as third-party auditors. These accredited certification bodies will conduct food safety audits of foreign food entities and, based on their audit findings, may issue certifications of those entities and the foods for humans and animals that they produce. Such certifications may be used to help establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP), which was also established by FSMA. VQIP offers expedited review and entry of food for eligible participants. In addition, FDA can require that an imported product be certified in specific circumstances to prevent a potentially harmful food from entering the U.S.

Foreign governments and agencies or private third-parties may apply to be recognized as an accreditation body. The process includes a web-based application and a user fee.

Hurricane Response

The recent hurricanes (Harvey, Irma, and Maria), have resulted in numerous challenges for the residents of affected regions, for farmers, and for manufacturers of FDA-regulated products. CFSAN has provided technical assistance and support in the following areas:

- the safety of crops and other foods potentially exposed to flood-waters (these three hurricanes struck a large number of states/territories with agricultural activities)
- food safety issues involving products that may not have been stored safely due to factors such as limited power/refrigeration
- the procurement and safety of food and bottled water to meet the needs of the residents of Puerto Rico
- doing our part to support the dairy industry in Puerto Rico, which was experiencing challenges in purchasing and distributing feed to herds.

FDA performs extensive preliminary work in advance of storms to help prepare for the potential impacts. For example, FDA uses storm protection data, Geographic Information Systems (GIS), and firm registration databases to prepare maps to identify FDA-regulated firms, including those that manufacture critical products that could be damaged by the storms.

Often the most significant role that FDA plays comes after the storm, as facilities come back on line and may need remediation, and farmers seek to put crops or farmland that were damaged back into commercial use. For example, since Hurricane Harvey devastated the rice fields around Houston, FDA has been working with local producers and states to help determine which crops can be used commercially. FDA has been supporting farmers and food producers impacted by these storms, and disseminating information about the proper handling of crops exposed to floodwaters, and when these products can be safely diverted into animal feed uses.

The direct discussions FDA is having with state officials and with farmers are aimed at providing our most up-to-date, science-based information on which crops can enter commerce without creating risks to consumers or animals. FDA has experts in the affected regions who can help provide direct assistance and we are taking additional steps to support recovery efforts. FDA incident management group (IMG) continues to work through the numerous challenges posed, in concert with our state, local, and other federal partners.

Improved Outbreak Response

The Foods Program and the Coordinated Outbreak Response and Evaluation (CORE) team rapidly detect and respond to major foodborne illness outbreaks. This team coordinates activities across FDA field and compliance offices, state investigative and laboratory resources, and local city and county resources. The CORE team works cooperatively with other federal agencies such as CDC and USDA to ensure timely and effective resolution of foodborne illness outbreaks. Examples include:

- the *E. coli* outbreak associated with flour
- the *Hepatitis A* outbreaks associated with frozen strawberries from Egypt
- the *Listeria monocytogenes* outbreak associated with frozen vegetables.

To prepare for outbreak responses, FDA field offices support and provide technical assistance to laboratories awarded International Organization for Standardization (ISO) Cooperative Agreement Program (CAP) grants and to laboratories seeking or maintaining their accreditation.

This program continues to add national food/feed testing laboratories. By 2016, a total of 23 laboratories joined the program and several are working towards ISO accreditation.

Improved Pathogen Detection and Traceability



Figure 1 GenomeTrakr

FDA operates the national network of whole genome sequencers (WGS) – GenomeTrakr, the first integrated network of State and Federal laboratories to use whole genome sequencing to track foodborne pathogens to improve outbreak response and effective monitoring of preventive controls. Whole genome

sequencing reveals the complete DNA make-up of an organism. This technology points investigators to specific food products potentially related to an outbreak, and provides insight into the origin of the contaminated food. This capability is particularly important considering the global nature of the food supply.

The Network is now in its fifth year and has collected more than 170,000 whole bacterial genome sequences from the FDA Network and collaborating sites. These genome sequences are stored in a publicly accessible database at the National Institutes of Health. FDA developed outbreak traceback methodology based on whole bacterial genomes that can determine the source of certain outbreaks down to the farm level with great precision.

Applying WGS helps the Foods Program to:

- investigate outbreaks faster and more efficiently

- add innovative technology protocols for testing and surveillance, enhancing confidence in regulatory actions
- identify emerging antimicrobial resistance threats in the food supply.

Implementing WGS reduces the time needed to conduct outbreak investigations and improves FDA's ability to pinpoint the source of contamination events. Sample collection and sequence cataloging from food production sites can help monitor compliance with FDA's rules on safe food-handling practices, enhancing preventive controls for food safety.

The FDA Foods Program applies WGS regularly to trace foodborne outbreaks for *Salmonella* and *Listeria monocytogenes*. By generating about two whole genomes per hour, GenomeTrakr is rapidly increasing the number of *Salmonella* and *Listeria monocytogenes* genomes in the database. The network includes more than 40 state, international, FDA, and federal partner (CDC and USDA-FSIS) laboratories.

In 2017, FDA collected sequences as a regular part of foodborne outbreak investigations and compliance actions. WGS was used to support more than 165 cases of product adulteration and insanitary conditions investigated by the FDA.

For example, in 2017, FDA used the GenomeTrakr to link *Listeria monocytogenes* to an artisanal cheese manufacturer and creamery that had manufactured soft raw milk cheeses contaminated with this pathogen. The soft cheese was the source of an outbreak that included 6 illnesses and 2 deaths. As in previous cases, the low level and sporadic nature of *Listeria* contamination associated with this product would have been difficult to identify and associate with clinical cases of illness without WGS, which likely prevented additional consumers falling ill and limited the scope of the FDA investigation to the specific facility producing contaminated product.

The combination of real-time clinical and food/environmental surveillance using WGS has reduced the average number of illnesses in *Listeria* outbreaks from 9 to 3 over the past two years and has increased the number of illnesses that could be linked to specific food sources.

In the summer of 2017, FDA also used WGS to augment investigation of a large and widespread *Salmonella* outbreak associated with imported papaya. The outbreak, caused by several strains of *Salmonella* extended to more than 26 states and included more than 250 illnesses and two deaths. The application of WGS permitted source tracking back to specific overseas agricultural regions and also allowed for the rapid identification of different serological variants of *Salmonella* as they emerged from contaminated papaya samples.¹⁵

Developed and Applied Novel Technologies to Improve Food Safety

Addressing emerging safety concerns as food science technology advances remains a priority for the Foods Program. In FY 2017, FDA scientists further extended its environmental studies of foodborne illness outbreaks associated with *Salmonella* Newport¹⁶ contaminated vegetables grown on the Delaware/Maryland/Virginia (Delmarva) peninsula. FDA helped to address several important scientific questions raised by the Delmarva Food Safety Taskforce by examining the prevalence of *Salmonella* in growing regions in Delaware and documenting infiltration and

¹⁵ *Listeria monocytogenes* are a bacterium that can cause Listeriosis, a serious infection usually caused by eating contaminated food. The disease primarily affects older adults, pregnant women, newborns, and adults with weakened immune systems. Rarely, persons without these risk factors can also be affected. The risk may be reduced by following recommendations for safe food preparation, consumption, and storage.

¹⁶ *Salmonella* is a bacteria that can cause diarrhea, fever, and abdominal cramps. For more information, see <http://www.cdc.gov/salmonella/general/index.html>

persistence of *Salmonella* through the blossoms of tomatoes, cucumbers, and cantaloupes – all high-risk crops cultivated on the Delmarva. Taken together, these data have further strengthened FDA’s guidance for safe produce production on the Delmarva and have provided additional important *Salmonella* isolates to the GenomeTrakr database. It is important to note that we have not had any significant outbreak events associated with Delmarva produce since the Taskforce rolled out its science and communications efforts in 2015.

In another study aimed at understanding foodborne illness, Foods program scientists applied a new genomic tool known as RNASEQ technology for the first time. This technology, borne out of whole genome sequencing, actually detects the factors involved in providing survival differences among pathogens living in identical environments. Pilot studies with the technology have begun to reveal the adaptive traits that allow *Salmonella* Newport to persist within tomatoes and other produce. These adaptive traits provide potential targets for preventive controls against *Salmonella* known to invade produce production.¹⁷

Other Foods Program accomplishments include:

- Analyzed foods that list live microbes as an ingredient (such as probiotics) to conduct genomic characterization and identify bacteria that may be a safety concern
- Implemented rapid detection methods to improve detection of adulterated food products such as oil and honey
- Developed advanced methods for detecting allergens and gluten in foods, improving FDA’s capabilities to inform and protect sensitive individuals from severe adverse effects.

Finally, with the goal of placing cutting edge technologies directly in the hands of frontline food and environmental field inspectors, FDA microbiologists made significant strides in the development of portable and rapid lab-in-a-backpack tools that integrate rapid sampling and diagnostic technologies (i.e., qPCR) with detailed pathogen characterization tools such as whole-genome sequencing. Field tests in environmental regions prone to *Salmonella* in the wild were highly successful using current mobile technology configurations. Continued development will aim to make existing tools more portable using nanopore-based whole genome sequencing and smart-phone mediated qPCR devices.

Conducted Major Sampling of Produce

In response to recent foodborne illness outbreaks linked to various types of sprouts, FDA conducted a large-scale sampling study as part of its efforts to learn more about potential contamination in these products and how to protect consumers from disease-causing bacteria in sprouts. Sprouts are especially vulnerable to pathogens given the warm, moist, and nutrient-rich conditions needed to grow them. This study was concluded in August 2017. From 1996 to July 2016, there were 46 reported outbreaks of foodborne illness in the United States linked to sprouts. These outbreaks accounted for 2,474 illnesses, 187 hospitalizations, and three deaths. The agency’s testing program was designed to estimate the prevalences of *Salmonella*, *Listeria monocytogenes*, and *Escherichia coli* (E. coli) O157:H7 in sprouts, and to identify patterns in hopes of preventing these pathogens from contaminating sprouts. FDA collected 825 samples from 37 states, Puerto Rico, and the District of Columbia, and found that most of the positive samples came from a small number of sprouting operations: A total of 14 positive

¹⁷ *Salmonella* is a bacteria that can cause diarrhea, fever, and abdominal cramps. For more information, see <http://www.cdc.gov/salmonella/general/index.html>

samples were found at eight of the 94 growers, and ten of these samples came from just four growers. FDA tested samples collected at three points in the production process (seeds, finished product, and spent irrigation water) to gain insights into the sources of contamination in sprouts. The agency found:

- *Salmonella* on 2.35 percent of seed samples
- *Listeria monocytogenes* on 1.28 percent of finished sprouts
- None of the finished sprout or spent irrigation water samples tested positive for *E. coli* O157:H7.

In September 2017, CFSAN issued two largescale surveillance sampling assignments, one focusing on fresh herbs and the other on processed avocados/guacamole. The assignments will be carried out over approximately the next 18 months. The objectives of these assignments are to determine the prevalence of select pathogens in the respective commodities, to identify common factors associated with positive findings (such as origin or variety), and to take regulatory action as warranted to protect consumers. The fresh herbs assignment targets *Salmonella* and Shiga toxin-producing *E. coli* on fresh cilantro, parsley, and basil. These herbs are grown low to the ground and are thus susceptible to contamination, such as from irrigation water splashing off the ground. Additionally, they are often eaten without a “kill step,” and consumers may be unaware that they are eating fresh herbs when they are included in multi-ingredient dishes. Similarly, processed avocado/guacamole products, including avocado that is fresh cut, refrigerated or frozen, can be packaged and consumed without a “kill-step” applied prior to consumption. Both fresh herbs and processed avocados/guacamole have been associated with recalls and outbreaks of foodborne illness in recent years.

FDA Recognizes Australia as Having a Comparable Food Safety System to the U.S.

In FY 2017, FDA signed an arrangement with the Australian Department of Agriculture and Water Resources recognizing each other’s food safety systems as comparable. This is the third time that FDA has recognized a foreign food safety system as comparable, the first being New Zealand in 2012 and Canada in 2016.

By recognizing each other’s systems as comparable, FDA and the Australian Department of Agriculture and Water Resources have confidence that they can leverage each other’s science-based regulatory systems to help ensure food safety. For example, each partner intends to consider the oversight of the other when prioritizing inspection activities. The benefits go beyond inspection and admissibility. Systems recognition establishes a framework for regulatory cooperation in a variety of areas that range from scientific collaboration to outbreak response.

Systems recognition is voluntary and not required for a country to export foods to the U.S. FDA continues to have inspection authority over food imported from any country with which it has an arrangement and can exercise this authority as needed. Imports from Australia must continue to comply with U.S. statutory and regulatory requirements to ensure safety and proper labeling, including the new standards adopted under FSMA.

Evaluating ‘Organ-on-Chips’ Technology

FDA has a leading role in advancing revolutionary new testing technology that creates human organ systems in miniature on micro-engineered chips about the size of a AA battery.

On April 11, 2017, FDA announced a multi-year research and development agreement with a company called Emulate Inc. to test the company's "Organs-on-Chips" technology in laboratories at the agency's Center for Food Safety and Applied Nutrition.

Beginning with a liver-chip, FDA scientists will be evaluating the effectiveness of the technology, designed to give researchers a better understanding of the effects of disease-causing bacteria in foods, chemicals, and other potentially harmful materials on the human body.

Developed Seafood Product Labeling Online Learning Module

To ensure the proper labeling of seafood products sold in the U.S., FDA developed an online learning module for seafood producers, retailers, state regulators, and others involved in the processing, distribution, sale, or regulation of seafood.

The module explains federal identity labeling requirements for seafood and lists the laws, regulations, guidance documents, and other materials relevant to the proper labeling of seafood. The module helps stakeholders better understand FDA's role in ensuring the proper labeling of seafood. The module also provides tips for identifying mislabeled seafood in the wholesale distribution chain or at the point of retail.



Figure 2 Seafood Labeling

Instead of protein profiles, FDA uses DNA barcoding to identify seafood. Barcoding provides a DNA sequence that allows analysts to identify different seafood products. These sequences are accessible online in a curated FDA library. This allows FDA field staff to better identify potentially toxic species of imported puffer fish currently restricted to a single species from Japan.

Enhanced Food Emergency Response Network Capacity

To prepare for food-related emergencies and high-profile events, FDA directly oversees the Food Emergency Response Network (FERN) in addition to using FDA's field, Center, and FERN laboratories. FERN grants provide state-of-the-art equipment, analytical platforms, methodology, training, and proficiency testing. These resources support surge capacity, outbreak sampling, and large surveillance assignments. FERN grants also support the FERN training program that provides courses for both federal and state laboratory analysts. FDA maintains the FERN Storeroom that provides reagents and supplies to federal and state laboratories to support analytical activities. This program increases the FERN capacity and analytical capability for chemical, microbiological, and radiological testing that enhances the response to food emergency events—including food safety and food defense.

Encouraged the Safe Production of Dietary Supplements

In FY 2017, FDA field investigators completed inspections of both domestic and foreign firms to enforce dietary supplement regulations, including current Good Manufacturing Practices (cGMPs) and labeling requirements. These inspections resulted in:

- 70 warning letters
- 3 untitled letters
- 69 detentions

- 3 injunctions.

Additionally, FDA initiated several regulatory actions aimed at protecting consumers from fraudulent products that were, in some cases, marketed as dietary supplements. These include products making fraudulent claims about cancer as well as bodybuilding products containing steroids.

Premarket notification of new dietary ingredients (NDIs) is FDA's only opportunity to identify potentially unsafe supplements before they are available to consumers. In FY 2017, FDA received a record number of 101 NDI notifications. Of the notifications submitted, 68 were deemed incomplete or determined to not pertain to an ingredient intended to be used in a dietary supplement. Of the remaining 33 notifications, FDA acknowledged 13 with no objection and raised safety or identity concerns with 20.

FDA emphasizes education and outreach regarding NDI notifications and regularly engages with submitters before and during the notification review process. FDA continues to review stakeholder comments submitted in response to the revised draft NDI guidance issued in August 2016 and engages with stakeholders on issues related to the revised draft guidance. In 2017, FDA also announced and planned a public meeting to discuss development of an authoritative list of pre-DSHEA dietary ingredients, an idea raised in the revised draft guidance on which a number of stakeholders commented favorably.

In FY 2017, FDA received more than 3,500 adverse event reports (AERs) related to dietary supplements. The reports are evaluated by clinical reviewers in the Center for Food Safety and Applied Nutrition (CFSAN) to monitor the safety of consumer products. FDA is undergoing a modernization of the CFSAN Adverse Event Reporting System (CAERS) to track when and how an AER is evaluated. In addition, FDA is working on a solution for linking AER data to data on compliance and other FDA actions through the use of a high-end analytics platform tailored for big data. This platform will merge and link multiple internal and external data sets and will be able to track products and adverse events throughout the signal's lifecycle, including regulatory actions recommended or taken.

Implemented New Procedures to Address Food Recalls

In 2016, FDA created a senior leadership team to direct FDA's actions to address challenging recall situations. The team, Strategic Coordinated Oversight of Recall Execution (SCORE), supports FDA's field staff and district offices by evaluating the range of FDA's compliance and enforcement authorities. SCORE quickly decides the best action to take to protect consumers.

For example, in September 2016 SCORE suspended a company's facility registration because a food product from the company was contaminated with *Listeria monocytogenes*. At the FDA's request, the company agreed to a recall and briefly stopped operations to improve its cleaning and sanitation procedures. In follow-up inspections FDA identified contaminated food using environmental sampling, and FDA suspended the firm's food facility registration.

Exercised Science-Based Compliance Actions

When firms violate FDA requirements, FDA monitors firms and encourages prompt voluntary corrective action to obtain full compliance. When firms do not comply with FDA regulations, or FDA identifies a safety risk, FDA pursues regulatory action to prevent unsafe or improperly labeled products from reaching U.S. consumers.

FDA monitors the recalls of human food, cosmetic, and dietary supplement products and ensures the removal of violative products from commerce. In FY 2017, FDA classified 367 Class I (most serious), 380 Class II, and 47 Class III recall events for human food, cosmetic, and dietary supplement products.

FDA issues import controls when non-compliant food products are discovered or when food companies manufacture or ship non-compliant products. In FY 2017, FDA issued 1,191 import alert notices (of which 548 were reviewed by CFSAN).

FDA expanded Import Alert # 28-13 covering lead in turmeric to cover all spices because in 2017 sampling by FDA and State Departments of Health revealed additional types of spices and spice products having high levels of lead that may render the products injurious to health. Particularly vulnerable populations susceptible to lead poisoning include infants, small children, pregnant women, and people with underlying kidney disorders.

Additionally, CFSAN worked with the FDA field offices to assist in 769 cases where the district needed CFSAN's technical expertise to determine import admissibility.

FDA also protects the public from impure, adulterated, and misbranded food and acts as an industry-wide deterrent for regulated entities and criminal enterprises through its authority to initiate criminal cases. In FY 2017, FDA issued five (5) injunctions, one (1) seizure and one (1) suspension related to adulterated or misbranded food.

Selected Guidances Issued in 2016 and 2017

Below are non-FSMA guidances issued by the Foods Program in the last calendar year. These guidances help address various issues. This list does not represent any degree of importance or priority ranking among the published guidances.¹⁸

Date	#	Title	Description
Nov 2017	FDA-2011-F-0172	Draft Guidance for Industry: Menu Labeling Supplemental Guidance	Addresses concerns raised by stakeholders regarding the implementation of nutrition labeling required for foods sold in covered establishments, including expanded and new interpretations of policy.
Jan 2017	FDA-2016-D-4414	Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals	Provides information related to compliance with FDA's final rule: "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" and discusses labeling of added sugars

¹⁸ For more information on guidance please visit <http://www.fda.gov/Food/GuidanceRegulation/>

Nov 2016	FDA-2016-D-3401	Draft Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition	Explains current thinking on information needed when submitting a citizen petition and the scientific review approach we plan to use for evaluating scientific evidence
Sep 2016	FDA-2016-D-2241	Draft Guidance for Industry: Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling	Helps infant formula manufacturers and distributors comply with certain labeling requirements for infant formula products.
Sep 2016	FDA-2016-D-2335	Guidance for Industry: Use of the Term “Healthy” in the Labeling of Human Food Products	Advises manufacturers who wish to use the implied nutrient content claim “healthy” to label their food products as provided by our regulations.

Published Infant Formula Rule and Guidances

Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.

In September 2016, FDA issued guidance for industry to help infant formula manufacturers and distributors comply with certain labeling requirements for infant formula products. In this guidance,¹⁹ FDA clarifies the following infant formula labeling requirements.

Issued Draft Guidance on Structure and Function Claims Made in Infant Formula Labels and Labeling

In September 2016, FDA’s Foods Program issued draft guidance for industry to help infant formula manufacturers who make structure and function claims comply with the requirement that all claims in infant formula labels and labeling be truthful and not misleading. “Structure and function” claims are statements made about the effects of a product or its constituent on the normal structure or function of the body. An example of a structure and function claim in infant formula labeling is a statement that the formula “supports digestion.”

In the draft guidance²⁰ FDA describes its recommendations for the type and quality of scientific evidence that is appropriate to support structure and function claims made about an infant formula by the product’s manufacturers or distributors. The draft guidance provides recommendations for all infant formulas, including formulas marketed for use by infants who

¹⁹ Guidance for Industry: Labeling of Infant Formula, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517113.htm>

²⁰ Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm514640.htm>

have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

Created Internet Resource for Sampling Programs for Food Safety

FDA developed a public website to share microbiological surveillance information to help predict and prevent bacterial contamination. In FY 2016, FDA sampled and tested cucumbers and hot peppers under this program and published the test results on the website.²¹ This resource helps FDA shift to a prevention-based model by providing information needed to identify hazards. This resource also will help determine if contamination occurs due to factors such as season, region, or import status (domestic vs import).

Improve and Safeguard Access

The Foods Program has statutory responsibility for the following premarket review activities that fall within the FDA goal of improving and safeguarding access:

- review and approval of all petitions for direct food additives
- review and approval of all new food contact substances, food contact materials, packaging, antimicrobials, and other indirect food additives
- review of Generally Recognized as Safe (GRAS) ingredients and products of biotechnology related to food.

Published Timely Food and Color Additive and Food Contact Substance Reviews

FDA has the primary legal responsibility for determining the safe use of food additives and color additives. To market a new food additive, color additive or food contact substance – or before using an additive already approved for one use in another manner not yet approved – a manufacturer or other sponsor must first petition FDA for its approval. This petition process is unique to FDA's regulatory mission. In FY 2017, FDA ensured safe access to the food supply by reviewing 9 Food and Color Additive Petitions, 54 GRAS notifications, and 107 premarket notifications for Food Contact Substances.

Updated Risk Assessment Capabilities

FDA Centers, led by CFSAN, continue to update FDA's Toxicological Principles for the Safety Assessment of Food Ingredients – also called the “Redbook” – so that it reflects the most recent science. FDA's overarching goal in this effort is to develop a framework that incorporates the assessment of ingredients in various products such as:

- food additives
- food contact substances
- ingredients that are generally regarded as safe (GRAS)
- new plant varieties
- dietary supplements and new dietary ingredients
- cosmetic ingredients.

The Centers plan to jointly develop a process to ensure use of consistent methodologies for safety and risk assessments throughout CFSAN, and between CFSAN and CVM.

²¹ Source: Microbiological Surveillance Sampling: FY16 Cucumbers and Hot Peppers, <http://www.fda.gov/Food/ComplianceEnforcement/Sampling/ucm473115.htm>

Promote Informed Decisions

The Foods Program is responsible for ensuring that foods sold in the United States are safe, wholesome, and properly labeled. The Nutrition Labeling and Education Act (NLEA) requires most packaged foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements.

The Foods Program also serves as FDA's primary organization for directing, developing, and coordinating web communications, outreach, and consumer education. FDA has statutory responsibility for food safety, and has jurisdiction over all domestic and imported food except meat, poultry, and processed egg products that fall under the authority of the U.S. Department of Agriculture. Outreach is essential to ensure that consumers and food safety partners have the information needed to make informed decisions.

Provide Outreach and Education on FDA Regulated Products

FDA strives to provide consumers with material about healthy choices using the most up-to-date science. CFSAN's social scientists use scientific methods to learn about and understand human behavior to help FDA fulfill its public health mission. In FY 2016, CFSAN conducted consumer studies using a variety of methods such as focus groups, surveys, and eye tracking studies. In one study FDA surveyed 4,169 Americans ages 18 and older to learn more about consumers' attitudes, behaviors, and knowledge of food safety. Survey results inform FDA's efforts to improve consumer food safety behaviors through targeted education outreach. Results are also used in the Healthy People 2020 initiative.²²

In 2016, FDA released findings from its 2014 Health and Diet Survey. This survey helps FDA make informed regulatory, educational, and other decisions with a better understanding of consumer knowledge, attitudes, and practices about current and emerging nutrition and labeling issues.²³

In FY 2017, Congress appropriated \$3 million to fund FDA to work with USDA to provide education and outreach to the public on agricultural biotechnology and food and animal feed ingredients derived from biotechnology. To kick off this work, FDA hosted public meetings in Charlotte, NC, and San Francisco, CA regarding its Agricultural Biotechnology Education and Outreach Initiative. The purpose of these meetings was to provide the public with an opportunity to share information, experiences, and suggestions to help inform the development of this education and outreach initiative.

FDA Proposes to Extend Compliance Dates for Nutrition Facts Label Final Rules

In FY 2017, FDA proposed to extend the compliance dates for the Nutrition Facts and Supplement Facts label final rule and the Serving Size final rule from July 26, 2018, to Jan. 1, 2020, for manufacturers with \$10 million or more in annual food sales. Manufacturers with less than \$10 million in annual food sales would receive an extra year to comply—until Jan. 1, 2021.

FDA is committed to making sure that consumers have the facts they need to make informed decisions about their diet and the foods they feed their families. The proposed rule only

²² Food Safety Survey Shows Consumer Knowledge Up, Still Room to Grow, <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm529604.htm>

²³ FDA Releases 2014 Health and Diet Survey Findings, <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm499141.htm>

addresses the compliance dates. FDA is not proposing any other changes to the Nutrition Facts Label and Serving Size final rules.

The agency is proposing to extend the compliance dates in response to the continued concern that companies and trade associations have shared with us regarding the time needed for implementation of the final rules. These stakeholders expressed concerns about their ability to update all products by the original compliance dates and the importance of obtaining clarification from the FDA on a number of technical issues relating to the final rules.

Pending completion of this rulemaking, FDA intends to exercise enforcement discretion with respect to the current July 26, 2018, and July 26, 2019, compliance dates.

Issued Requests for Information and Draft Guidance on Fiber and Use of the term “Healthy” in Food Labeling

In November 2016, FDA’s Foods Program issued a Request for Information (RFI) and Draft Guidance on Fiber on the Nutrition Facts Label. The request for information, along with the accompanying draft guidance, will help industry understand how FDA reviews the scientific evidence to determine whether other fibers beyond the seven identified in the rule should be added to the regulations. It also provides an opportunity for stakeholders to add to or comment on FDA’s review of the science with respect to whether any of 26 additional types of fiber are beneficial to human health and therefore should be included in the fiber definition.

In September 2016, the Foods Program published a RFI and Guidance for Industry on the Use of the term “Healthy” in the Labeling of Human Food Products. The guidance advises manufacturers who wish to use the implied nutrient content claim “healthy” to label their food products in accordance with FDA’s regulations.

More specifically, this guidance is intended to advise food manufacturers of FDA’s intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim “healthy” on their labels which:

- Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats
- Contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

FDA Developed Improved Method for Attributing Foodborne Illness (in Collaboration with Federal Partners)

FDA, working with the Centers for Disease Control and Prevention (CDC) and USDA’s Food Safety Inspection Service, developed an improved method for analyzing outbreak data to determine which foods are responsible for illnesses related to four major foodborne bacteria.

The three agencies, operating as a partnership known as the Interagency Food Safety Analytics Collaboration (IFSAC), released a paper titled “Comparing Characteristics of Sporadic and Outbreak-Associated Foodborne Illnesses, United States, 2004-2011.”

The results of this study provide evidence that *Campylobacter*, *Listeria monocytogenes*, and *E. coli* O157 outbreak illnesses are not significantly different from sporadic illnesses with respect to patients’ illness severity, gender, and age. The study also provides evidence that *Salmonella* outbreak illnesses are not significantly different from sporadic illnesses with respect to illness severity and gender. Analyses, such as this study, help us better understand the

relationship between sporadic foodborne illnesses and those that are identified as a part of an outbreak. Such analyses are essential to advancing scientific progress in this field.

Investigated Adverse Event Reports Related to the Use of Cosmetic Products

In an effort to protect consumers from potentially dangerous cosmetics products, FDA initiated an investigation on reports of hair loss, hair breakage, balding, itching, and rash associated with the use of WEN by Chaz Dean Cleansing Conditioner products. As of November 15, 2016, FDA received 1,386 adverse event reports directly from consumers with some reports occurring after general outreach to consumers and health care professionals. Of note, FDA was made aware, during inspections of manufacturing and distribution facilities, of more than 21,000 complaints reported directly to Chaz Dean, Inc. and Guthy Renker, LLC. This is the largest number of adverse event reports within the category of cosmetic hair cleansing products. The FDA also has reached out to physicians and other health care providers asking them to notify their patients of hair loss and other complaints associated with the use of these products and to report adverse events to the agency. FDA encourages consumers to stop using these products if they have a reaction, contact their health care provider, and report the incident to FDA.

Developed Additional Education Materials Related to Risks Associated with Tattoo Inks

State and local authorities oversee the practice of tattooing. However, ink and color additives (such as pigments) used in tattoos are subject to FDA oversight. The CFSAN Adverse Event Reporting System (CAERS) database continues to receive adverse event reports associated with tattoo inks. These reports include infections from tattoo inks contaminated with microorganisms, and allergic reactions to ingredients in the inks.

FDA developed educational materials to alert consumers to potential problems from tattooing and difficulties with tattoo removals. FDA is continuing research projects on the safety and quality of tattoo inks and pigments.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2015 Actual	\$903,340,000	\$903,340,000	---
FY 2016 Actual	\$998,230,000	\$998,230,000	---
FY 2017 Actual	\$1,025,503,000	\$1,025,503,000	---
FY 2018 Annualized CR	\$1,033,082,000	\$1,022,211,000	\$10,871,000
FY 2019 President's Budget	\$1,040,734,000	\$1,029,863,000	\$10,871,000

BUDGET REQUEST

The FY 2019 Budget Request for the Foods Program is \$1,040,734,000 of which \$1,029,863,000 is budget authority and \$10,871,000 is user fees. Budget authority increases by \$7,652,000 compared to the FY 2018 Annualized CR level and user fees remain nearly flat. The Center for Food Safety and Applied Nutrition (CFSAN) amount in this request is \$316,326,000. The Office of Regulatory Affairs amount is \$724,408,000.

The FY 2019 funding level restores the Foods Program to maintain FY 2017 funded activities. In FY 2019, the Foods Program will continue its statutory mission of promoting and protecting

public health by ensuring that the nation's food supply is safe, sanitary, wholesome, and properly labeled, and that cosmetic products are safe and properly labeled. This mission becomes more challenging every year as globalization, advances in science and technology, and shifts in consumer expectations drive change throughout the human and animal food systems. In response to these increasing demands, the Foods Program conducts a variety of activities aimed at providing American consumers with food and cosmetics products that are safe and properly labeled.

One ongoing priority is the implementation of the FDA Food Safety Modernization Act (FSMA), a sweeping modernization of FDA's food safety program based on science and risk-based prevention of food safety problems for both domestic and imported food. FSMA requires:

- comprehensive prevention-oriented food safety standards across the food system
- mandated domestic inspection frequency, based on risk, to ensure high rates of compliance
- a national integrated food safety system based on full partnership with states
- a new import safety system based on food safety accountability for importers, increased foreign presence, and more collaboration with foreign governments.

The Budget also supports the development of state produce safety infrastructure as states prepare for their increased role in conducting inspections on larger farms and continuing outreach and education to small farms as they prepare for their upcoming compliance dates.

In addition to implementing FSMA and promoting a safe and nutritious food supply, other examples of Foods Program priorities funded within base include:

- Enhancing the safety of dietary supplements and food additives
- Improving quick and accurate detection and response to foodborne outbreaks by advancing the use of a new technology known as 'whole genome sequencing' to track outbreaks and contamination through the "GenomeTrakr" network of state and federal laboratories
- Providing consumers with information that is useful and accurate for safe handling of food products.

In FY 2019, FDA will continue work to develop analytical methods to detect and measure:

- food allergens
- naturally-occurring toxins
- industrial chemicals
- food additives
- food adulterants,
- food pathogens.

These analytical methods enhance compliance and surveillance and enable FDA to ensure the safety of the food supply and reduce foodborne sickness. Further, FDA will continue to research, develop, and deploy the most effective methods for identifying, containing, and eliminating hazards in foods, dietary supplements, and cosmetics.

Activities to improve nutritional quality of packaged and restaurant foods will continue in FY 2019 by promoting industry compliance with the updated Nutrition Facts Label and requirements for calorie labeling for menus and vending machines, and educating consumers on how to best

use this information. These labeling rules reflect the latest public health and scientific evidence, including the link between diet and chronic disease such as obesity and heart disease. The new labels will replace out-of-date serving sizes to better align with how much people really eat, and will feature a modern design to highlight key parts of the label such as calories and serving sizes.

The Foods Program will maintain current levels of operational activities to inspect regulated products and manufacturers, conduct sample analyses of regulated products, and review imported products offered for entry into the United States. FDA will continue to work with its state, local, tribal, territorial, and foreign counterparts to make the best use of all available public resources and improve program efficiency and effectiveness.

PERFORMANCE

The Foods Program's performance measures focus on premarket application review, incidence of foodborne pathogens, regulatory science activities, and postmarket inspection and import screening activities in order to ensure the safety and proper labeling of the American food supply and cosmetics, as detailed in the following table.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 +/- FY 2018
<u>213301</u> : Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (<i>Output</i>)	FY 2017: 100% Target: 80% (Target Exceeded)	80%	80%	Maintain
<u>214101</u> : Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. (<i>Outcome</i>)	FY 2017: 812 enrolled Target: 697 enrolled (Target Exceeded)	827	842	+15
<u>212404</u> : Reduce the incidence of infection caused by key pathogens commonly transmitted by food: <i>Campylobacter</i> species. (<i>Outcome</i>)	CY 2016: 11.79 cases/100,000 Target: 10.6 cases/100,000 (Target Not Met)	9.7 cases/100,000	9.2 cases/100,000	- 0.5
<u>212405</u> : Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing <i>Escherichia coli</i> (STEC) O157:H7. (<i>Outcome</i>)	CY 2015 ²⁴ : 0.95 cases/100,000 Target: 0.95 cases/100,000 (Target Met)	0.76 cases/100,000	0.68 cases/100,000	- 0.08
<u>212407</u> : Reduce the incidence of infection caused by key pathogens commonly transmitted by food: <i>Salmonella</i> species. (<i>Outcome</i>)	CY 2016: 15.4 cases/100,000 Target: 13.2 cases/100,000 (Target Not Met)	12.4 cases/100,000	11.9 cases/100,000	- 0.5

²⁴ 2016 data is not yet available for this specific serotype of STEC O157:H7 in the CDC Morbidity and Mortality Weekly Report (MMWR) <https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6615.pdf>

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2018 Target	FY 2019 Target	FY 2019 +/- FY 2018
<u>214306</u> : The average number of working days to serotype priority pathogens in food (Screening Only) (Output)	FY 2017: 3 working days Target: 3 working days (Target Met)	3 working days	3 working days	Maintain
214212: Percentage of planned import food field exams. (Output)	FY 2017: 94% Target: 99% (Target Not Met)	95%	95%	Maintain
<u>214206</u> : Maintain accreditation for ORA labs. (Outcome)	FY 2017: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain
214209: As required by the FSMA Legislation, cover all of the High Risk domestic inventory every three years. (Output)	FY 2017: 34.8% Target: 33% (Target Exceeded)	66%	99%	+33%
<u>214305</u> : Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). (Outcome)	FY 2017: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

The following selected items highlight notable results and trends detailed in the performance table.

Food Additive and Color Additive Petition Review

The Foods Program conducts an extensive review as part of its Food Additive and Color Additive Petition review process, which includes a Chemistry, Toxicology, and Environmental evaluation. The current measure requires FDA to complete review and action on the safety evaluation of direct and indirect food and color additive petitions within 360 days of receipt. FDA exceeded the FY 2017 target of 80% by reviewing and completing 100% of the petitions received within 360 days of receipt, a result consistent with the FY 2016 performance of 100% completed within the same timeframe.

Voluntary National Retail Food Regulatory Program Standards

Strong and effective regulatory programs at the state, local, and tribal level are needed to prevent food borne illness and reduce the occurrence of food borne illness risk factors in retail and foodservice operations. The voluntary use of the Retail Program Standards by a food inspection program reflects a commitment toward continuous improvement and the application of effective risk-based strategies for reducing food borne illness. The FY 2017 target for enrollment of State, local, and tribal agencies in the Retail Program Standards was far exceeded. Awareness of the value of the using the Retail Program Standards to drive program improvement continues to grow, particularly among local health departments. In addition, more retail food regulatory programs are recognizing that FDA cooperative agreement funds are available to jurisdictions that enroll in the Retail Program Standards and commit to achieving key milestones. The FY 2018 and FY 2019 targets reflect increases in the number of enrollees by 15 above the previous year's actual number of enrollees or target.

Pathogen Detection

FDA microbiologists are evaluating and integrating commercially available instrumentation into its microbiological testing workflow that is vastly improving the ability of FDA to more quickly and effectively detect and characterize foodborne pathogens such as Salmonella directly from the food supply. Improvements in sample throughput, along with the high degree of sensitivity and specificity built into new pathogen detection technologies, will dramatically improve FDA's foodborne response and traceback capabilities. When fully deployed, technologies such as next-generation whole-genome sequencing (WGS) and others will reduce the time required to conduct these analyses from 14 days to just a few days. One updated technology which provides highly accurate and rapid Salmonella serotype results for FDA, known as the flow cytometry/fluorescence platform, has been validated extensively and is now deployed in nearly all FDA field laboratories, as well as in CFSAN and CVM laboratories. In FY 2017, FDA met the target of reducing the average number of days to serotype priority pathogens in foods to three days. The proposed targets for FY 2018 and FY 2019 are three days, maintaining the critically important downward progress in analytical return times achieved in FY 2017.

New ORA Field Performance Measures

ORA has been working to improve the field performance measures to better align with ORA's Program Alignment initiative. In this submission, ORA has completed the process of adjusting the performance goals, so that the FY 2018 and FY 2019 targets now complete a certain percentage of the planned inspections in ORA's annual Workplan. The ORA Workplan is the necessary mechanism that takes into account all the complex variables (geography, commodity, risk, availability, efficiency, etc.) that allows ORA to plan which inspections to do. With these newly formulated performance goals, ORA is committing to complete a certain percentage of the initially planned inspections. This revision strengthens the importance of the Workplan, and allows the flexibility to respond dynamically to changing circumstances during the year to better handle emerging risks and evolving public health priorities such as the heavy hurricane damage this past year. This is a significant departure from the previous performance goals, so FY 2018 will be an important year in resetting the new baselines. Also, since the targets are now based on a planned number of inspections, it is possible to inspect more than what was planned and thus have an actual inspection rate over 100%.

FSMA High Risk Domestic Inspection Coverage

FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world. ORA plays a critical role in the implementation of FSMA, and recognizes the importance of complying with high-risk domestic inspections mandated by FSMA legislation. FSMA legislation requires inspecting the entire high-risk domestic inventory every three years. This goal serves to cumulatively track the progress over the three-year period as the coverage of the high-risk domestic inventory approaches the FSMA-driven goal of 100 percent. The new three-year cycle began again in FY 2017 during which 34.8 percent of the identified inventory was inspected. The FY 2018 and FY 2019 targets are 66% and 99% respectively.

Import Food Field Exams

During FY 2017, ORA accomplished 150,955 out of 160,189 planned import food field label exams. Although this is a high level performance, it falls short of the 99 percent target. Import resource constraints had a significant impact on the ability to meet this target. Additional resources for entry review and shifting the focus in FY 2018 to work plan targets for food exams will help streamline this work, and improve the field's ability to meet this work plan target in FY 2018.

PROGRAM ACTIVITY DATA**Foods Program Activity Data (PAD)**

CFSAN Workload and Outputs	FY 2017 Actual	FY 2018 Annualized CR	FY 2019 President's Budget
Food and Color Additive Petitions			
Petitions Filed ¹	10	10	10
Petitions Reviewed ²	10	10	10
Premarket Notifications for Food Contact Substances			
Notifications Received	107	130	130
Notifications Reviewed ³	107	128	128
Infant Formula Notifications			
Notifications Received ⁴	15	15	15
Notifications Reviewed ⁵	8	11	11
FDA Review Time	90 days	90 days	90 days
New Dietary Ingredient Notifications			
Notifications Received ⁶	101	85	85
Notifications Reviewed ⁷	101	85	85
FDA Review Time	75 days	75 days	75 days

¹ This number is for the cohort of petitions filed in the FY.

² Number reviewed includes petitions approved, withdrawn, or placed in abeyance due to deficiencies during the FY.

³ Number reviewed includes notifications that became effective or were withdrawn.

⁴ A notification may include more than 1 infant formula.

⁵ Number of submissions reviewed includes some submissions that were received in the previous FY.

⁶ Number of submissions received in current FY includes some received late in the FY that are expected to be completed in the next FY when the due date occurs.

⁷ Number of submissions reviewed in the current FY includes some submissions that were received in the previous FY when the due date occurred in the current FY.

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2017 Actual	FY 2018 Annualized CR	FY 2019 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	8,484	8,000	8,000
Domestic Food Safety Program Inspections	6,145	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.
Imported and Domestic Cheese Program Inspections	195		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	321		
Domestic Fish & Fishery Products (HACCP) Inspections	763		
Import (Seafood Program Including HACCP) Inspections	253		
Juice HACCP Inspection Program (HACCP)	167		
Interstate Travel Sanitation (ITS) Inspections	909		
Domestic Field Exams/Tests	3,541	2,500	2,500
Domestic Laboratory Samples Analyzed	13,548	13,000	13,000
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS¹	1,548	1,400	1,400
All Foreign Inspections	1,548	1,400	1,400
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	10,032	9,400	9,400
IMPORTS			
Import Field Exams/Tests	229,129	168,200	168,200
Import Laboratory Samples Analyzed	23,774	35,300	35,300
Import Physical Exam Subtotal	252,903	203,500	203,500
Import Line Decisions	15,251,687	16,014,271	16,814,985
Percent of Import Lines Physically Examined	1.66%	1.27%	1.21%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	81,035	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	8,460	9,062	9,062
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	110	100	100
State Contract Food Safety (Non HACCP) Inspections	7,497	8,000	8,000
State Contract Domestic Seafood HACCP Inspections	902	1,000	1,000
State Contract Juice HACCP	61	100	100
State Contract LACF	129	100	100
State Partnership Inspections	110	100	100
State Contract Foods Funding	\$12,465,850	\$12,839,826	\$13,225,020
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	\$16,436,868	\$16,929,974	\$17,437,873
Total State & Annual FERN Funding	\$28,902,718	\$29,769,800	\$30,662,894
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	18,602	18,562	18,562

¹ The FY 2017 actual unique count of foreign inspections includes 161 OIP inspections (118 for China, 39 for India, & 4 for Latin America).

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2017 Actuals	FY 2018 Estimate	FY 2019 Estimate
<i>FDA WORK</i>			
DOMESTIC INSPECTIONS			
<i>UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS</i>	<i>95</i>	<i>100</i>	<i>100</i>
Domestic Inspections	95	100	100
FOREIGN INSPECTIONS			
<i>UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS</i>	<i>5</i>	<i>0</i>	<i>0</i>
Foreign Inspections	5	0	0
IMPORTS			
Import Field Exams/Tests	10,118	1,600	1,600
Import Laboratory Samples Analyzed	423	400	400
Import Physical Exam Subtotal	10,541	2,000	2,000
Import Line Decisions	2,625,555	2,756,833	2,894,674
Percent of Import Lines Physically Examined	0.40%	0.07%	0.07%
<i>GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS</i>	<i>100</i>	<i>100</i>	<i>100</i>