NARRATIVE BY ACTIVITY

FOODS

(Dollars in Thousands)	FY 2018 Enacted	FY 2018 Actual	FY 2019 Annualized CR	FY 2020 President's Budget	FY 2020 +/- FY 2019
Foods	**1,070,187**	**1,059,291**	**1,070,187**	**1,122,047**	**51,860**
Budget Authority	***1,059,316***	***1,059,291***	***1,059,316***	***1,084,636***	***25,320***
User Fees	***10,871***	---	***10,871***	***37,411***	***26,540***
Center	327,044	326,210	327,044	361,678	34,634
Budget Authority	326,212	326,210	326,212	334,712	8,500
User Fees	832	---	832	26,966	26,134
Food And Feed Recall	*243*	---	*243*	*253*	*10*
Voluntary Qualified Importer Program	*243*	---	*243*	*253*	*10*
Third Party Auditor Program	*346*	---	*346*	*360*	*14*
Innovative Food Products	---	---	---	*26,100*	*26,100*
Field	743,143	733,081	743,143	760,369	17,226
Budget Authority	733,104	733,081	733,104	749,924	16,820
User Fees	10,039	---	10,039	10,445	406
Food And Feed Recall	*1,000*	---	*1,000*	*1,040*	*40*
Food Reinspection	*4,575*	---	*4,575*	*4,760*	*185*
Voluntary Qualified Importer Program	*4,320*	---	*4,320*	*4,495*	*175*
Third Party Auditor Program	*144*	---	*144*	*150*	*6*
FTE	**3,861**	**3,861**	**3,905**	**4,008**	**103**

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.

In collaboration with the Office of Regulatory Affairs (ORA), the Center for Food Safety and Applied Nutrition (CFSAN) administers the Foods Programs. 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 Office of Food Policy and Response (OFPR) provides executive leadership, management, and strategic direction for FDA's foods initiatives. OFPR also directs efforts to integrate the programs, policies, and budgets of CFSAN, the Center for Veterinary Medicine (CVM), and ORA and thereby ensure the optimal use of all available FDA resources.

The following accomplishments demonstrate the Foods Program's delivery of its regulatory and public health responsibilities and progress towards reaching the goals outlined in the FDA Commissioner's FY 2019 Priorities.

Strengthen Science and Efficient Risk-Based Decision Making

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

- An estimated 48 million foodborne illnesses occur every year[8]
- An estimated 128,000 hospitalizations and 3,000 deaths result[9]
- Foodborne illnesses cost an average of $3,630 per case[10]
- More than $36 billion per year in medical costs, lost productivity, and other burdens to society.[11]

The Foods Program prioritizes the prevention of foodborne and feed-borne illness of both known and unknown origins through the implementation of the FDA Food Safety Modernization Act (FSMA) and other legislative authorities. 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.

Nutrition-related priorities are another focus area 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 2018,

[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 Zorn, 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 Zorn, 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

90 percent of the nation's health care expenditures were for people with one or more chronic medical conditions.[12]

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 listed above, the Foods Program conducts other important activities related to food safety, nutrition, and cosmetics. These activities 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

The FDA Food Safety Modernization Act (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.

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.[13] 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 heralded a new era of enhanced collaboration between FDA and its counterparts in state governments across the country. To date, FDA has awarded 46 states and 1 territory a total of $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. FDA also issued a cooperative agreement with the National Association of State Departments of Agriculture (NASDA) to develop a national consortium of state and federal regulators to further states' implementation of their produce safety programs. FDA also worked with NASDA in 2018 to finalize resource materials and to

[12] 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.

[13] https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm

train states to implement the On-Farm Readiness Review (OFRR) program, which allows farms to request a review by regulators of the readiness of their operations for produce safety rule (PSR) implementation.

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

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.
Jan 2017	FDA 2011-N-0146	FSMA Final Rule: Amendments to Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits	Amends regulations on accreditation of third-party certification bodies to conduct food safety audits and to issue certifications to provide for a reimbursement (user fee) program to assess fees for the work FDA performs to establish and administer the third-party certification program under the FSMA.

Sanitary Transport of Food and Feed

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.

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 software tool for food facility owners and operators to use to create facility-specific food safety plans. 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.

Updated Guidance for Foreign Supplier Verification Programs (FSVP) Rule

FSVP is another one of the seven foundational FSMA rules. A central tenet of FSVP 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.

Selected Guidances Issued in 2018

Below are selected non-FSMA guidances issued by the Foods Program this calendar year. These guidances help address various issues. This list does not represent any degree of importance or priority ranking among the published guidances**.** [14]

Date	#	Title	Description
Jun 2018	FDA 2018-D-1323	Guidance for Industry: Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels	Permits manufacturers to move forward in updating labels regarding dietary fiber and implement the new Nutrition Facts and Supplement Facts label. The updated labels will better equip consumers with nutritional information on dietary fiber.
May 2018	FDA-2012-N-1210	Guidance for Industry: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes	Provides questions and answers on topics related primarily to two final rules: (1) "Food Labeling: Serving Sizes of Foods and (2) "Food Labeling: Revision of the Nutrition and Supplement Facts Labels."
May 2018	FDA 2011-F-0172	Guidance for Industry: Menu Labeling Supplemental Guidance	Addresses stakeholder's' concerns about the implementation of nutrition labeling required for foods sold in covered

[14] http://www.fda.gov/Food/GuidanceRegulation/

Date	#	Title	Description
			establishments. It also clarifies the additional options for complying with the labeling requirements and explains where FDA intends to be more flexible.
Apr 2018	FDA 2018-D-1189	Guidance for Industry: Highly Concentrated Caffeine in Dietary Supplements	Provides guidance to firms that manufacture, market, or distribute dietary supplement products that contain pure or highly concentrated caffeine, or are considering doing so.
Feb 2018	FDA 2006-P-0207	Guidance for Industry: Proper Labeling of Honey and Honey Products	Advise the regulated industry on the proper labeling of honey and honey products in accordance with sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342 and 343) and its implementing regulations.

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 *E. coli* outbreak associated Romaine lettuce
- 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 20176, a total of 293 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 sixth year and has collected more than 280,000 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 better protect public health by:

- investigating outbreaks faster and more efficiently
- adding 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 2018, FDA collected sequences as a regular part of foodborne outbreak investigations and compliance actions. To date, WGS has supported more than 370 cases of product adulteration and contaminated 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. Using WGS, likely prevented additional consumers from failing ill and conserved resources by limiting the scope of the FDA investigation to the specific facility producing the 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. Using WGS permitted source tracking back to specific overseas agricultural regions and allowed for the rapid identification of different serological variants of Salmonella as they emerged from contaminated papaya samples.[15]

FDA Finalizes Guidance on Mandatory Recall Authority

In November 2018, FDA released a final guidance regarding the agency's mandatory recall authority under FSMA.[16] The 2011 food safety law gave FDA mandatory recall authority for foods if there is a reasonable probability that the food is adulterated or misbranded under certain FDA authorities, and that the food could cause serious illnesses or death. FDA must give the responsible party an opportunity to conduct a voluntary recall before ordering a mandatory recall. Prior to the enactment of FSMA, FDA could only rely on manufacturers to voluntarily recall certain potentially harmful food products.

This final guidance follows a draft which was made available for public comment in 2015, and provides additional clarity including some modifications based on comments received. The guidance provides questions and answers on FDA's mandatory recall process, explains what FDA considers when moving forward with a mandatory recall, and more.

FDA has issued a mandatory recall order of a food product only once. In April 2018, FDA issued a mandatory recall order for all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals LLC, after several products were found to contain Salmonella. In two other instances, FDA started down the path of using its mandatory recall authority under FSMA until the companies ultimately chose to voluntarily recall their product.

While FDA's mandatory recall authority plays an important role in ensuring that potentially dangerous food products are removed from the marketplace, the agency remains committed to working with firms to facilitate the orderly and prompt voluntary removal of potentially

[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] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm445428.htm

dangerous products from the food supply. FDA Recall Coordinators are available to assist firms during the recall process.

Provided Resources for Food Producers in Flooded Areas Due To Hurricane Michael

FDA has provided several resources to aid farmers whose crops may have been impacted by the flooding and severe weather associated with Hurricane Michael. The FDA's Guidance for Industry: "Evaluating the Safety of Flood-affected Food Crops for Human Consumption," provides information that producers can use while assessing potential damage to their food crops.[17] This guidance is an important tool used in assuring the safety of flood-affected food crops for human consumption.

FDA reminds harvesters that generally, if the edible portion of a crop is exposed to contaminated flood waters, it is considered "adulterated" under the Federal, Food, Drug and Cosmetic Act and should not enter the human food supply. This applies to all food crops including underground crops such as peanuts and potatoes. For crops such as pecans that were in or near flooded areas but where flood waters did NOT contact the edible portions of the crops, the growers should evaluate the safety of the crops for human consumption on a case-by-case basis for possible food safety concerns.

Issued New Export Certificates for Certain Foods

In August 2018, FDA announced its new export certification program for certain FDA-regulated food products and the fees it will assess for issuing new export certifications to U.S.-based exporters of these products. The new export certification and fees were authorized by FSMA amendments to the FD&C Act and allow allowing the agency to collect up to $175 for the first export certification for food, which covers up to 25 products.

FDA issues different types of export certification for different food products. The "Certificate to a Foreign Government" and "Certificate of Exportability" are now available for food for human consumption, except for dietary supplements, medical foods, and foods for special dietary use.

The "Certificate to a Foreign Government" is available for conventional foods, food additives, food contact substances, and infant formula that meet the applicable requirements of the FD&C Act. This certificate certifies that a product (or products) may be marketed in and legally exported from the United States.

The "Certificate of Exportability" is available for export-only conventional foods, food additives, food contact substances, and infant formula. This certificate certifies that a product (or products) meet(s) the requirements of section 801(e)(1) of the FD&C Act and may be legally exported.

FDA anticipates that the new certificates will help facilitate exports by assisting industry in fulfilling importing country requirements for certification by FDA of FDA-regulated food products. Additionally, the electronic form for the new certificates responds to numerous industry requests for additional flexibility on regarding the information that is printed on export certificates.

FDA Recognizes New Accreditation Bodies under Accredited Third-Party Certification Program; Launches Voluntary Qualified Importer Program

[17] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm287808.htm

FDA has recognized four accreditation bodies under the voluntary Accredited Third-Party Certification Program, this voluntary program was developed as per Section 307 of the FDA Food Safety Modernization (FSMA).[18] The four entities recognized so far are: ANSI-ASQ National Accreditation Board (ANAB); American National Standards Institute (ANSI);

National Bureau of Agricultural Commodity and Food Standards (ACFS); and International Accreditation Services, Inc. (IAS). FDA has recognized all four entities for a five- year term of recognition.

Accreditation bodies recognized by FDA have the authority to accredit third-party certification bodies, also known as third-party auditors. These certification bodies, once accredited, can conduct food safety audits and issue certifications of foreign food facilities (including farms) and the foods – both human and animal – that they produce. As of November 13, 2018, one of the recognized accreditation bodies (ANSI) has accredited one certification body: Perry Johnson Registrars Food Safety, Inc. This certification body has been accredited for a two-year period. The FDA maintains public registries with information on recognized accreditation bodies and accredited certification bodies under the voluntary program: Recognized Accreditation Bodies Public Registry; Accredited Certification Bodies Public Registry.

FDA has also launched the Voluntary Qualified Importer Program (VQIP), a voluntary fee-based program which offers expedited review and entry of human and animal food into the United States. Importers interested in participating in VQIP will be required to meet a number of eligibility requirements, which include ensuring the facilities of their foreign supplier are certified under the Accredited Third-Party Certification Program.

In addition to being used to establish VQIP eligibility, FDA can also require, in certain circumstances, that imported products, or the facilities that produce them, be certified by an accredited certification body under the FDA's Accredited Third-Party Certification Program or by a foreign government agency before they enter the United States. While FDA does not generally require certification as a condition of entry into the United States, this is new tool granted by Section 303 of FSMA that will allow FDA to ensure that serious, ongoing food safety problems are corrected at their source.

These programs are additional tools FDA is using to help ensure that foods imported into the United States are produced in accordance with the same safety standards required of food produced domestically.

Issued Draft Guidance to Help Produce Farmers and Fresh-Cut Produce Processors

In October 2018, FDA issued two draft guidance documents to help farmers and fresh-cut produce processors comply with FSMA requirements.

The first draft guidance is a compliance and implementation guide to assist growers in meeting requirements of the Produce Safety Rule under FSMA.[19] The rule requires domestic and foreign farms to put preventative measures in place during growing, harvesting, packing and holding of their fruits and vegetables to protect against contamination. Flexibility was built into this rule to

[18] https://www.fda.gov/downloads/Food/GuidanceRegulation/ImportsExports/Importing/UCM564000.pdf

[19] https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM623178.pdf

accommodate regional and commodity-specific growing practices—which is reflected in this guidance through examples to demonstrate how farmers can implement the rule's requirements.

The second draft guidance, "Guide to Minimize Food Safety Hazards of Fresh-cut Produce," explains the FDA's current thinking on how fresh-cut produce processors may comply with the requirements found in the Preventative Controls for Human Food Rule under FSMA.[20] This rule requires food processors have a food safety plan that includes an analysis of hazards and preventive controls to minimize the likelihood that those hazards will contaminate the food.

Both guidance documents were opened for public comment for the 180-day period following their release and serve as an important supplemental educational tool in increasing consistent FSMA compliance.

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 in an effort to learn more about potential contamination in sprouts and how to protect consumers from disease-causing bacteria. Sprouts are especially vulnerable to pathogens given the plants' warm, moist and nutrient-rich growing conditions. This study was completed 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.

FDA's testing program was designed to estimate the prevalence of Salmonella, Listeria monocytogenes, and 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 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 learn more about 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 large scale surveillance sampling assignments, one focusing on fresh herbs and the other on processed avocados/guacamole. The assignments will be carried out were completed over the next 18 plus months to accomplish the following: The objectives of these assignments are to:

- determine the prevalence of select pathogens in the respective commodities
- identify common factors associated with positive findings (such as origin or variety)
- take regulatory action as warranted to protect consumers.

In May 2018, FDA published an update on traceback efforts related to recent E. coli outbreaks from Romaine lettuce – the largest outbreak in the U.S. in more than ten years. Tracebacks confirmed there is not a simple or obvious explanation for how this outbreak occurred within the

[20] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm623716.htm

supply chain. This particular outbreak illustrates the importance of moving forward with FSMA's Produce Safety Rule.

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. These herbs 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 before consumption. Both fresh herbs and processed avocados/guacamole have been associated with recalls and outbreaks of foodborne illness in recent years.

This 2018 sampling of fresh herbs also revealed two samples with the Cyclospora cayetanensis parasite from cilantro growers in Mexico and one sample in the United States. Though no known illness has been reported in relation to these products, the finding of the parasite through sampling highlights the importance of FDA surveillance activities to better define risks. These findings also highlight the importance of implementing the provisions of FSMA's Produce Safety Rule at home and abroad to reduce risk and prevent illnesses from occurring.

The Produce Safety Rule is designed to put science-based measures in place to prevent microbial contamination from occurring. State and foreign partners have an important role in working with FDA to implement the rule. These partnerships and others enhance FDA's ability to act swiftly to detain and remove any contaminated product from commerce to protect U.S. consumers, as happened after these findings in domestic and imported produce.

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 Newport contaminated vegetables grown on the Delaware/Maryland/Virginia (Delmarva) peninsula.[21]The 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 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, detects the factors involved in survival differences among pathogens living in identical environments. Pilot studies with the technology have begun to

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

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.

Other Foods Program accomplishments included:

- 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 developing portable and rapid lab-in-a-backpack tools that integrate rapid sampling and diagnostic technologies such as 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. FDA's continued development aims to make existing tools more portable for FDA scientists using nanopore-based whole genome sequencing and smart-phone mediated qPCR devices.

FDA Expanded Outreach of Recall Information Through Social Media

FDA uses social media to successfully communicate important public health information out to a wide range of consumers. In June 2018, FDA used Twitter to announce a multi-state Salmonella outbreak associated with Kellogg's Honey Smacks cereal. FDA also announced via Twitter that Kellogg's had decided to recalled the Honey Smacks due to which had the potential of Salmonella presence. FDA's initial tweet received 109,713 impressions, which is the highest engagement and retweets of anything FDA has ever posted on Twitter. Facebook engagement on this recall was also was higher than previous high-profile recalls., indicating that social media is proving to be an increasingly effective and beneficial way to get important information out to a wider range of consumers.

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 helps to ensure proper labeling of seafood products by:

- listing the laws, regulations, guidance documents, and other materials relevant to the proper labeling of seafood
- helping stakeholders understand FDA's role in ensuring the proper labeling of seafood.
- providing tips for identifying mislabeled seafood in the wholesale distribution chain or at the point of retail.

FDA uses DNA barcoding to identify seafood, instead of protein profiles. Barcoding provides a DNA sequence that allows analysts to identify different seafood products. These sequences are accessible online in a curated FDA library. This online access helps FDA field staff to 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.

Exercised Science-Based Compliance Actions

FDA 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 2018, FDA issued eight injunctions and two seizures related to adulterated or misbranded food. 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.

This is especially true in cases where food, dietary supplement or cosmetic products have been linked with outbreaks. The Agency works with Federal, state and local partners to identify the products causing problems and take efficient and effective compliance actions. In one such case, the FDA pursued a permanent injunction against a raw milk cheese company after it was responsible for a Listeria monocytogenes (Lm) outbreak that sickened eight people and caused 2 deaths. This action required the firm to get expert assistance to eliminate unsanitary conditions and develop a program to control the Lm before resuming operations.

FDA also issues import controls when non-compliant food products are discovered or when food companies manufacture or ship non-compliant products. In FY 2018, FDA issued 946 import alert notices (of which 306 were reviewed by CFSAN). Additionally, CFSAN worked with the FDA field offices to assist in 623 cases where the district needed CFSAN's technical expertise to determine import admissibility.

FDA monitors the recalls of human food, cosmetic, and dietary supplement products and ensures the removal of violative products from commerce. In FY 2018, FDA classified 197 Class I (most serious), 332 Class II, and 60 Class III recall events for human food, cosmetic, and dietary supplement products. This included the Agency's first issuance of a final order using mandatory recall authority to require the removal of certain salmonella-contaminated Kratom products from the market.

FDA also 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 high lead levels in additional spices and spice products potentially rendering them injurious to health. Infants, small children, pregnant women, and people with underlying kidney disorders are particularly vulnerable to lead poisoning.

Published Timely Food Additive, Color Additive, Generally Recognized as Safe (GRAS), and Food Contact Substance Reviews

The Foods Program has statutory responsibility for the following premarket review activities that help to foster competition and innovation

- 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.

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 obtain regulatory approval, either by petition for a food additive or a color additive, or through notification programs for food contact substances and GRAS food ingredients. The petition and notification processes are unique to FDA's regulatory mission. In FY 2018, FDA ensured safe access to the food supply by reviewing10 Food Additive or Color Additive Petitions, 73 GRAS notifications, and 94 premarket notifications for Food Contact Substances.

Launched New Inventory of Substances Added to Food

In June 2018, FDA launched the new Substances Added to Food inventory, an upgraded version of the original Everything Added to Food in the U. S. (EAFUS) inventory.[22] The searchable inventory contains approximately 4,000 substances, and includes information on food additives, color additives, Generally Recognized As Safe (GRAS) and prior-sanctioned substances. Additional features include:

[22] FDA's New Substances Added to Food Inventory; http://FDA.gov/Food/Ingredients

- a new search function that allows users to search multiple related food ingredient and packaging inventories;
- direct links to any applicable regulations for a substance
- additional information such as other known names, common uses, and information by other entities when available.

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 and food contact substances
- ingredients 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.

Empower Consumers and Patients

The Foods Program is responsible for ensuring that foods sold in the United States are safe, wholesome, and properly labeled so that consumers and patients are empowered to make well-informed food choices. 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. FDA, 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.

Encouraged the Safe Production of Dietary Supplements

In FY 2018, 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:

- 75 warning letters
- 3 untitled letters
- 180 detentions
- 4 injunctions (filed).

Additionally, FDA initiated several regulatory actions aimed at protecting consumers from fraudulent and/or products that were marketed as dietary supplements. These include products marketed as dietary supplements that made unlawful claims about treating opioid use disorder

and other products that made unproven claims about protecting consumers from the harms that come from sun exposure without meeting the FDA's standards for safety and effectiveness.

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 2018, FDA responded to 38 NDI notifications. Of the notifications submitted, 10 were deemed incomplete or determined to not pertain to an ingredient intended to be used in a dietary supplement. Of the remaining 28 notifications, FDA acknowledged 17 with no objection and raised safety or identity concerns with 11.

In FY 2017, FDA received more than 2,700 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.

FDA Steps Up Efforts to Stop Illegal Sale of Highly Concentrated Caffeine

Products consisting of or containing pure or highly concentrated caffeine have been linked to at least two deaths in the United States in the last few years and continue to present a significant public health threat. Many products that consist of primarily or highly concentrated caffeine are sold as dietary supplements.

In April 2018, FDA issued guidance to industry on highly concentrated caffeine in dietary supplements. This document is intended to provide guidance to firms that manufacture, market, or distribute dietary supplement products that contain pure or highly concentrated caffeine, or are considering doing so.

In June 2018, FDA issued warning letters to parties illegally selling certain highly concentrated caffeine products. These letters build on our efforts to stop illegal sale of highly concentrated forms of life-threatening dose.

Provide Outreach and Education on FDA Regulated Products

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 launch this work, FDA hosted public meetings in Charlotte, NC, and San Francisco, CA as part of its Agricultural Biotechnology Education and Outreach Initiative. These meetings provided the public with an opportunity to share information, experiences, and suggestions to inform the development of this education and outreach initiative. An additional $1.5 million was invested in this effort in FY 2018 to further the education and outreach capacity.

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FDA Released Final Guidance on Menu Labeling Compliance

In May 2018, FDA released final menu labeling guidance that provides flexibility on how covered establishments can provide calorie information in ways that meet various business models. For the first time, these new standards create a national and uniform method for the disclosure of calorie information on menus at chain restaurants.

The guidance includes many graphical depictions that convey FDA's thinking on various topics. For example, the guidance covers:

- calorie disclosure signage for self-service food
- various methods for providing calorie disclosure information
- criteria for distinguishing between menus and marketing material
- compliance, and enforcement, and; reasonable basis
- criteria for covered establishments; and standard menu items.

Completing work on menu labeling is an important part of a comprehensive, multi-year Nutrition Innovation Strategy announced in March of 2018 by FDA Commissioner Scott Gottlieb aimed at providing consumers with easier access to nutritious, affordable foods by empowering them with information and facilitating industry innovation toward healthier foods that consumers want.[23]

The menu labeling rule applies to restaurants and similar retail food establishments if they are part of a chain of 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items. Covered establishments have to disclose the number of calories contained in standard items on menus and menu boards, or for self-service foods and foods on display, in a manner in close proximity and clearly associated with the standard menu item. Businesses must also provide, upon request, nutrition information, such as total fat, saturated fat, trans fat, cholesterol, and sodium.

[23] https://www.fda.gov/Food/LabelingNutrition/ucm602651.htm

Many establishments are already displaying menu labeling information. By May 7, 2018, covered establishments nationwide are were expected to comply with the rule. During the first year of implementation, the FDA will work cooperatively with covered establishments to achieve high levels of compliance with the menu labeling requirements.

FDA Extended Compliance Dates for Nutrition Facts Label Final Rules

In May 2018, FDA issued a final rule 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. The agency published a proposed rule to extend the compliance date in September 2017, and this rule finalizes that extension.[24]

After considering a range of stakeholder comments, the FDA recognizes the need for manufacturers to have additional time to make required changes. The approximately 18-month extension accomplishes this goal and will provide sufficient time to transition to the new version of the Nutrition Facts label.

FDA also is committed to ensuring that all manufacturers have guidance to help implement the required label changes by the upcoming compliance dates. A full list of Nutrition Facts-related guidance documents is available on the FDA website.[25]

FDA Published Final Guidance on Dietary Fiber

In June 2018, FDA published final guidance on dietary fiber. This guidance permits manufacturers to update their labels regarding dietary fiber and to implement the new Nutrition Facts and Supplement Facts label. The updated labels will better equip consumers with nutritional information about dietary fiber.

Fiber-containing fruits, vegetables and grain products, particularly soluble fiber, may reduce the risk of coronary heart disease and can help lower cholesterol levels. Certain dietary fibers also can increase calcium absorption in the intestinal tract, improve laxation, or reduce calorie intake.

After manufacturers update their labels, consumers will be able to trust that if a food label states that a product contains dietary fiber, the source of that fiber is scientifically shown to have a beneficial health effect.

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."

[24] https://www. federalregister. gov/documents/2017/10/02/2017-21019/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels-and-serving-sizes-of-foods-that

[25] FDA Nutrition Facts-related guidance,https://www. fda. gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default. htm

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 FDA 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 FDA has ever received within the category of cosmetic hair cleansing products. The FDA 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[26]

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2016 Actual	$998,230,000	$998,230,000	---
FY 2017 Actual	$1,025,503,000	$1,025,503,000	---
FY 2018 Actual	$1,059,291,000	$1,059,291,000	---
FY 2019 Annualized CR	$1,070,187,000	$1,059,316,000	$10,871,000
FY 2020 President's Budget	$1,122,047,000	$1,084,636,000	$37,411,000

[26] Numbers reflect comparability adjustments for FY 2018, FY 2019, and FY 2020 consistent with budget figures.

BUDGET REQUEST

The FY 2020 Budget Request for the Foods Program is $1,122,047,000 of which $1,084,636,000 is budget authority and $37,411,000 is user fees. Budget authority increases by $25,320,000 compared to the FY 2019 Annualized Continuing Resolution level and user fees increase by $26,540,000.[27] The Center for Food Safety and Applied Nutrition (CFSAN) amount in this request is $361,678,000. The Office of Regulatory Affairs amount is $760,369,000.

In FY 2020, 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 food system. 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.

Food Safety (+$51.8 million / 103 FTE)

Strengthening Response Capabilities for Foodborne Outbreaks (+$13.3 million / 40 FTE)

Center: +$6.8 million / 17 FTE

Additional resources are urgently required to ensure that contaminated food is detected and removed from the marketplace as quickly as possible. The increased number of detected outbreaks and subsequent investigations resulting from the success of Whole Genome Sequencing (WGS) has greatly increased FDA's workload to identify and mitigate potential food safety concerns. WGS has made it possible to more easily determine the source of contaminated food associated with human illness, and to better identify foodborne outbreaks that previously would have gone undetected. By reassigning staff to address the surge in detection and response needs, recall classification time has decreased from 79 days to less than 14 days, on average, while the number of outbreak responses has increased 44 percent from 18 in 2015 to 26 in 2018. However, CFSAN has reached maximum capacity to reassign staff to address these surge needs.

Just as WGS has greatly altered our ability to identify food products contaminated with bacteria and viruses, newly developed methods are now changing the landscape of food products contaminated with parasitic organisms. Outbreaks of human illness associated with contamination of produce with the parasite Cyclospora cayetanensis have been on the rise since first reported in the mid-1990's. The CFSAN parasitology team developed and subsequently validated a novel method to recover, detect (using PCR or Polymerase Chain Reaction), and characterize C. cayetanensis oocysts in produce. This method is being implemented in regional ORA laboratories for use in outbreak investigations and has now been used successfully to identify C. cayetanensis in a 2018 outbreak investigation involving McDonald's salads. The new method is currently being used to assess the contamination of a number of other implicated foods. This technological achievement advances FDA's ability to protect consumers against

[27] The net increase to the Foods program is $25.3m. The overall increase to the Foods Program funding reflects -$1.8m of base funding based on the proposals laid out in the House report for FY 2019. This includes increasing FDA's biotechnology education and outreach efforts by $1.5m from FY 2018's levels and decreasing spending on fish decomposition research and dietary supplement research by $2.8m and $500k from the FY 2018 levels, respectively.

foodborne parasitic infections, and it will add to the workload involved in identifying and responding to C. cayetanensis in produce.

In 2017, despite limited staffing resources, CFSAN responded to 794 recall events and oversaw the recall of 3,609 products, more than any other FDA Center. Other parts of FDA that oversaw comparable numbers of recalls did so with more than double the staffing resources. This initiative's additional FTE will facilitate more effective and efficient oversight of recall initiations and make faster determinations of recall final classification(s). The initiative will also lead to more thoroughly collecting recalled product information, distributing it to the retail level, and posting information for consumers. Additional FTE will facilitate the deployment of personnel to work on outbreaks involving imported food products and to hold foreign firms to the same standards as domestic producers.

Additional resources also will increase FDA's ability to leverage new technologies that make it easier to track and trace products throughout the product lifecycle, from the time that they are grown or manufactured, until they are used by a consumer. Efficiently tracking and tracing FDA-regulated products will enable FDA to work with stakeholders, including industry producers, to quickly remove harmful products or ingredients from the supply chain. Examples of "track and trace" technologies include blockchain technology, which uses a decentralized, secure, ledger shared by all parties in the supply chain to provide transparency on a product's origins. Increasing FDA's ability to track and trace will also lessen costs imposed on industry by minimizing the number of products implicated in outbreaks of foodbourne illness and other product problems. These costs can be considerable where the lack of transparency in supply chains delays the identification of contamination sources and the root causes of product problems.

Field: +$6.5 million / 23 FTE

In recent years FDA has refined its traceback methods to increase speed and efficiency during outbreaks and recalls. Additional resources are required to ensure that, as soon as possible, contaminated food is detected and removed from the marketplace and that consumers are alerted.

FDA is requesting additional resources to hire FTE and support new procedures for collecting, reviewing, and posting retail consignees for certain Class I and Class II recalls. To ensure we have complete information in these recall situations, FDA will expend significant resources collecting consignee lists throughout the distribution chain (recalling firm, distributors, etc.) and then reviewing them to identify retailers that may have sold the recalled product. The list of retailers will be consolidated into one master list and posted onto FDA's website. This will better protect public health by allowing consumers to recognize whether they have purchased recalled products.

Advancing FSMA (+$10.6 million / 1 FTE)

Center: +$0.280 million / 1 FTE

FDA provides state regulatory programs with contract and cooperative agreement funding to conduct more than half of the domestic food and feed facility inspections required by FSMA. The increases proposed in the FY 2020 Budget will enhance compliance with the preventive control rules by funding cooperative agreements with state food regulatory programs. In addition, CFSAN will hire an additional FTE to provide technical support to the administration of the cooperative agreements.

Field Foods: +$10.3 million

FDA provides state regulatory programs with contract and cooperative agreement funding to conduct domestic food and feed facility inspections required by FSMA. With the increases proposed in the FY 2020 Budget, ORA will enhance its oversight of industry's compliance with the human food preventive control rules by expanding funding of cooperative agreements with state food regulatory programs.

To ensure effectiveness and efficiency, FDA expects states to continue or increase their number of inspections as FDA transitions to prevention-oriented inspections and determines industry compliance with the new FSMA standards and rules. NASDA and AFDO also have requested funds for FDA to provide to states to conduct Preventive Control (PC) inspections.

Promoting Innovation and Emerging Technology While Maintaining Product Safety (Budget Authority: $3.2 million / 10 FTE; Proposed User Fee Program: Innovative Food Products User Fee: $26.1 million / 52 FTE)

Center: $3.2 million / 10 FTE

FDA carries out its public health protection mission by assisting industry to meet its statutory responsibilities as it develops and implements new technologies in food, including cosmetics and biotechnology products. This includes modernizing our regulatory oversight of innovative biotechnology products to reflect advances in scientific understanding and technology, by improving transparency, coordination, and predictability of the system, consistent with the administration's Agriculture and Rural Prosperity Task Force Report.

This initiative also will support public confidence in new and emerging food production technologies, such as food from cultured animal cells or production of macro- and micro-ingredients through innovative plant-based and microbial-based technologies. This initiative will enable FDA to assess product safety in a timely, predictable, science-based process centered on safety and risk reduction. Consumer confidence in the safety of innovative technologies is a key component of consumer's acceptance and the commercial success of these technologies and their application in food production.

In the past five years, FDA's food ingredient safety program has reviewed a steady number of industry submissions for new ingredients (Food Additive and Color Additive Petitions ca. 8/year, GRAS notices ca. 60/year) and food contact substances (ca.121). Due to advances in food technology and innovation, FDA anticipates that the number of industry submissions will increase as new innovative products seek FDA's safety evaluation prior to market entry to meet consumer expectations. A newly proposed user fee program will provide the additional resources needed to increase expertise and scientific review capacity and grow with the need to support novel emerging products. Examples include new proteins, new ingredients, and synthetic foods, all of which can help foster new products and ingredients coming to the market in a timely manner.

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 2019 Target	FY 2020 Target	FY 2020 +/- FY 2019
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. *(Output)*	FY 2018: 100% Target: 80% (Target Exceeded)	80%	80%	Maintain
214101: 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. *(Outcome)*	FY 2018: 838 enrolled Target: 827 enrolled (Target Exceeded)	853	868	+15
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Campylobacter species. *(Outcome)*	CY 2017: 19.1 cases/100,000 Target: 10.2 cases/100,000 (Target Not Met)	9.2 cases/ 100,000	8.6 cases/ 100,000	-0.6
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli (STEC)* O157:H7. *(Outcome)*	CY 2015[28]: 0.95 cases/100,000 Target: 0.95 cases/100,000 (Target Met)	0.68 cases/ 100,000	0.60 cases/ 100,000	-0.08
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella species*. *(Outcome)*	CY 2017: 16.0 cases/100,000 Target: 12.8 cases/100,000 (Target Not Met)	11.9 cases/ 100,000	11.4 cases/ 100,000	-0.5
214306: The average number of working days to serotype priority pathogens in food (Screening Only) *(Output)*	FY 2018: 3 working days Target: 3 working days (Target Met)	3 working days	3 working days	Maintain

[28] For STEC, all serogroups were combined and individual CY 2017 data is not available for this measure in the CDC Morbidity and Mortality Weekly Report (MMWR) https://www.cdc.gov/mmwr/volumes/67/wr/mm6711a3.htm?s_cid=mm6711a3_w#T2_down

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 +/- FY 2019
214221: Percentage of Human and Animal[29] Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	Baseline: 90% (New Measure)	80%	80%	Maintain
214222: Percentage of Human and Animal[30] Food follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	Baseline: 78% (New Measure)	65%	65%	Maintain
214206: Maintain accreditation for ORA labs. (Outcome)	FY 2018: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2018: 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 2018 target of 80% by reviewing and completing 100% of the petitions received within 360 days of receipt, a result consistent with the FY 2017 performance of 100% completed within the same timeframe.

[29] Due to Program Realignment, ORA's Workplan now combines Human and Animal food inspection activities together, so this combination performance goal is repeated in both the Foods and Animal Drugs and Feed program narratives.

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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 2018 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 2019 and FY 2020 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 2018, 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 2019 and FY 2020 are three days, maintaining the critically important progress in analytical return times achieved in FY 2018.

New ORA Field Performance Measures

ORA is embarking on an initiative to move from output focused performance goals such as inspection counts to public health outcome-based performance goals. This initiative seeks to provide more meaningful performance goals for internal and external stakeholders, and to showcase more direct public health impacts for ORA. The new performance goals introduced for FY 2019 measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention, and allows for a more robust analysis.

FSMA High Risk Domestic Inspection Coverage

PROGRAM ACTIVITY DATA

Foods Program Activity Data (PAD)

Foods Program Activity Data			
CFSAN Workload and Outputs	**FY 2018 Estimate**	**FY 2019 Estimate**	**FY 2020 Estimate**
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	98	98	98
Notifications Reviewed [3]	98	98	98
Infant Formula Notifications			
Notifications Received [4]	28	28	28
Notifications Reviewed [5]	16	16	16
FDA Review Time	90 days	90 days	90 days
New Dietary Ingredient Notifications			
Notifications Received [6]	50	50	50
Notifications Reviewed [7]	50	50	50
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	FY18 Actuals	FY2019 Estimate	FY2020 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***8,629***	***8,000***	***8,000***
Domestic Food Safety Program Inspections	5,876	**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	162		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	234		
Domestic Fish & Fishery Products (HACCP) Inspections	809		
Import (Seafood Program Including HACCP) Inspections	191		
Juice HACCP Inspection Program (HACCP)	149		
Interstate Travel Sanitation (ITS) Inspections	1,046		
Domestic Field Exams/Tests	3,059	2,500	2,500
Domestic Laboratory Samples Analyzed	15,470	13,000	13,000
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***1,638***	***1,400***	***1,400***
All Foreign Inspections	1,638	1,400	1,400
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***10,267***	***9,400***	***9,400***
IMPORTS			
Import Field Exams/Tests	185,761	168,200	168,200
Import Laboratory Samples Analyzed	20,895	35,300	35,300
Import Physical Exam Subtotal	**206,656**	**203,500**	**203,500**
Import Line Decisions	16,859,790	17,702,780	18,587,918
Percent of Import Lines Physically Examined	1.23%	1.15%	1.09%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	84,113	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***8,073***	***9,062***	***9,062***
State Contract Food Safety (Non HACCP) Inspections	7,210	8,000	8,000
State Contract Domestic Seafood HACCP Inspections	788	1,000	1,000
State Contract Juice HACCP	57	100	100
State Contract LACF	117	100	100
State Contract Foods Funding	$13,620,000	$13,756,200	$13,893,762
Number of FERN State Laboratories	33	33	33
Annual FERN State Cooperative Agreements/Operations Funding	$15,865,891	$15,865,891	$15,865,891
Total State & Annual FERN Funding	**$29,485,891**	**$29,622,091**	**$29,759,653**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,340***	***18,462***	***18,462***

[1] The FY 2018 actual unique count of foreign inspections includes 171 OIP inspections (120 for China, 38 for India, & 13 for Latin America).

[2] ORA is currently evaluating the calculations for future estimates.

3 State partnership inspections have been removed from the PAD as they have been phased out. All state inspections are now accounted for under the "state contract" inspection category.

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Activity Data (PAD)			
Field Cosmetics Program Workload and Outputs	**FY 2018 Actuals**	**FY 2019 Estimate**	**FY 2020 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***71***	***100***	***100***
Domestic Inspections	71	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***6***	***0***	***0***
Foreign Inspections	6	0	0
IMPORTS			
Import Field Exams/Tests	6,195	1,600	1,600
Import Laboratory Samples Analyzed	335	400	400
Import Physical Exam Subtotal	**6,530**	**2,000**	**2,000**
Import Line Decisions	2,729,584	2,866,063	3,009,366
Percent of Import Lines Physically Examined	0.24%	0.07%	0.07%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***77***	***100***	***100***

1 ORA is currently evaluating the calculations for future estimates.