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FOOD SAFETY AND NUTRITION

FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities

GAO-18-174

GAO Highlights

Highlights of GAO-18-174, a report to congressional requesters

January 2018

FOOD SAFETY AND NUTRITION

FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities

Why GAO Did This Study

FDA is responsible for overseeing the safety of about 80 percent of the nation's food supply and for promoting good nutrition. Federal oversight of food safety has been on GAO's high-risk list since 2007. According to FDA, FSMA aims to improve food safety by shifting FDA's focus toward preventing food contamination, rather than responding to foodborne illnesses.

GAO was asked to review FDA's food safety- and nutrition-related activities and resources. This report examines (1) FDA's key food safety- and nutrition-related activities since FSMA's enactment in 2011 and how FDA determined its priorities for those activities, (2) the resources FDA dedicated to those activities in fiscal years 2011 through 2016, (3) the extent to which FDA set goals for those activities in fiscal years 2011 through 2017 and is assessing progress toward those goals, and (4) FDA's planned food safety- and nutrition-related activities and associated time frames. GAO analyzed FDA documents and data for fiscal years 2011 through 2018 and interviewed FDA officials.

What GAO Recommends

GAO is making three recommendations, including that FDA (1) develop performance measures with associated targets and time frames for all eight of its food safety- and nutrition-related objectives and (2) complete a plan that includes specific actions, priorities, and milestones for implementing the FVM Program's strategic plan. The agency agreed with GAO's recommendations and identified actions to implement them.

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What GAO Found

From the enactment of the FDA Food Safety Modernization Act (FSMA) in January 2011 through September 2017, the Food and Drug Administration (FDA) has conducted numerous food safety- and nutrition-related activities, determining its priorities for those activities based on statutes and its strategic goals. More specifically, FDA published 33 proposed or final key regulations and 111 draft or final key guidance documents, focused mainly on food safety. FDA also conducted other key activities related to food safety and nutrition, such as conducting inspections and developing risk-assessment tools, responding to foodborne illness outbreaks, and providing outreach and education.

FDA dedicated at least $1 billion annually, including salaries for at least 4,300 full-time equivalent (FTE) staff, to food safety and nutrition activities in fiscal years 2011 through 2016. About 98 percent of those resources were dedicated to food safety each fiscal year, and about 2 percent were dedicated to nutrition.

Since fiscal year 2011, FDA has set goals for its food safety- and nutrition-related activities but has not fully developed the necessary framework to assess progress toward those goals. Most recently, for fiscal years 2016 through 2025, the agency's Foods and Veterinary Medicine (FVM) Program, which is primarily responsible for carrying out these activities, has set a food safety goal to protect American consumers from foreseeable hazards and a nutrition goal to foster an environment that promotes healthy and safe food choices. These goals are supported by eight strategic objectives. The program has developed performance measures to assess progress toward five of these objectives but not for the other three. For each developed performance measure, FDA reports both targets set and measurements taken for specific time frames. For one such measure related to FDA's evaluation of food safety hazards, FDA targeted the completion of 50 percent of evaluations by their due dates in the first quarter of fiscal year 2017 and achieved 89 percent. Leading practices in performance management state that federal programs should use performance information to achieve program goals, and each objective should be tracked through performance measures that have targets and time frames. According to agency officials, the program is developing additional measures for its food safety- and nutrition-related objectives, but it had not finalized them as of January 2018. Until the program develops measures with associated targets and time frames for all eight objectives, FDA cannot fully assess progress toward achieving its goals.

FDA has identified food safety- and nutrition-related activities that it plans to undertake in fiscal year 2018, but its time frames for such activities in the longer term are unclear. According to FDA officials, the agency plans to pursue the food safety and nutrition strategies identified in the FVM Program's 10-year strategic plan. However, the specific time frames for the activities that would support those strategies are unclear because FDA has not developed a plan that includes actions, priorities, and milestones to implement the strategic plan. The strategic plan states that the FVM Program will develop such an implementation plan, and FDA officials told GAO that they expected to complete one, but as of January 2018, they had not done so. Until the program completes such an implementation plan, it will be difficult for FDA to ensure it is prioritizing and sequencing the necessary actions to achieve the program's objectives.

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Abbreviations

congressional budget justification	*Justification of Estimates for Appropriations Committees*
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FSMA	FDA Food Safety Modernization Act
FTE	full-time equivalent
FVM	Foods and Veterinary Medicine
GPRA	Government Performance and Results Act
GPRAMA	GPRA Modernization Act of 2010
OMB	Office of Management and Budget
Unified Agenda	*Unified Agenda of Federal Regulatory and Deregulatory Actions*
USDA	U.S. Department of Agriculture

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January 31, 2018

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Pat Roberts
United States Senate

In January 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law,[1] representing the largest expansion and overhaul of U.S. food safety authorities since the 1930s, according to Department of Health and Human Services' Food and Drug Administration (FDA) documents. FSMA aims to improve food safety by shifting FDA's focus toward preventing food contamination, rather than responding to foodborne illnesses after they have occurred, FDA documents state. The U.S. food supply is generally considered safe, but foodborne illness is still a common and costly—yet largely preventable—public health problem. The Centers for Disease Control and Prevention estimates that every year, as a result of foodborne illness, roughly 1 in 6 Americans (48 million people) gets sick, 128,000 are hospitalized, and 3,000 die.[2] According to a May 2015 estimate by the U.S. Department of Agriculture (USDA), the 15 most common foodborne pathogens in the United States together impose an annual economic burden of over $15.5 billion based on illnesses, hospitalizations, and deaths.[3]

[1]Pub. L. No. 111-353, 124 Stat. 3885 (2011).

[2]Elaine Scallan, Robert M. Hoekstra, Frederick J. Angulo, et al., "Foodborne Illness Acquired in the United States—Major Pathogens," *Emerging Infectious Diseases*, vol. 17, no. 1 (2011).

[3]Sandra Hoffmann, Bryan Maculloch, and Michael Batz, "Economic Burden of Major Foodborne Illnesses Acquired in the United States" (Washington, D.C.: Economic Research Service, U.S. Department of Agriculture, May 2015). The economic burden is stated in 2013 dollars. Pathogens are disease-causing organisms, including bacteria such as *Salmonella*, that can be transferred from food animals to the human population; some pathogens can cause foodborne illness.

FDA is responsible for overseeing the safety of about 80 percent of the nation's food supply,[4] including animal food.[5] FSMA provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur—such as through mandatory recalls of food products that will cause serious adverse health consequences or death. According to a 2016 Congressional Research Service report, FSMA also requires FDA to develop more than 50 regulations,[6] guidelines, and studies to improve food safety.[7] For example, the act requires FDA to develop new, prevention-oriented regulations for the production of foods consumed by humans or animals.

FDA, in addition to being responsible for ensuring the safety of most foods, is responsible for ensuring that those foods are properly labeled. According to FDA officials, the agency conducts a range of activities to improve nutritional status in humans and animals and to reduce the prevalence of diet-related risk factors for chronic disease. These activities include ensuring that food labels for most foods under its jurisdiction contain required nutrition information.[8] As part of its nutrition activities, FDA maintains educational information, databases, and disclosures related to food ingredients.

[4]USDA's Food Safety and Inspection Service is responsible for the safety of meat, poultry, processed egg products, and catfish. FDA is responsible for virtually all other food.

[5]Animal food is made for a variety of species, including livestock from which humans obtain food, pet animals, and laboratory animals. We have previously reported that the safety of animal food is important not only for the health of animals but also for the health of humans. For example, contaminated food for livestock can cause harm both to the livestock and to humans that consume the livestock. See GAO, *Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed*, GAO-16-425 (Washington, D.C.: May 19, 2016).

[6]We use the terms regulations and rules interchangeably in this report.

[7]Congressional Research Service, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*, R43724 (Washington, D.C.: Dec. 16, 2016).

[8]Nutrition labeling for raw fruits and vegetables, as well as raw fish, is voluntary.

In fiscal year 2016, FDA centers and offices obligated about $1.3 billion for food safety- and nutrition-related activities.[9] According to the agency, FDA will need additional funding increases to maintain momentum toward full implementation of FSMA. More specifically, FDA has stated that additional funding would assist the agency, its state partners, and the food industry in fully implementing FSMA.[10] In the first years after FSMA's enactment, FDA was focused on developing key regulations, conducting stakeholder outreach, planning for the implementation of associated rules, investing in state partnerships, and increasing inspection oversight for both domestic and foreign-produced food. FDA estimates that it has received a total net increase of approximately $266 million in additional funding for FSMA implementation in fiscal years 2011 through 2017.

Federal oversight of food safety has been on our list of areas at high risk in the federal government since 2007, when we added it because of risks to the economy, public health, and safety; we have reported that the fragmented federal food safety system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources among the 16 agencies that collectively administer it.[11] In addition, we have found shortcomings in FDA's oversight of seafood, dietary supplements, and

[9]This $1.3 billion includes obligations for some activities not related to food safety or nutrition, such as those related to FDA's oversight of cosmetics. An obligation is a definite commitment that creates a legal liability of the government to make payment for goods and services received or a legal duty that could mature into a legal liability by virtue of actions beyond the control of the federal government. FDA obligates funds, for example, when it awards a grant, signs a contract, purchases a service, or takes other actions that require the government to make payments. Other federal agencies with food safety and nutrition oversight responsibilities, including USDA, also obligate funds to implement these responsibilities.

[10]Food and Drug Administration, "The Context and History of FSMA Funding" (Washington, D.C.: Feb. 22, 2016), https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM436591.pdf, accessed November 20, 2017.

[11]Our high-risk program has focused attention on government operations with greater vulnerabilities to fraud, waste, abuse, and mismanagement or that are in need of transformation to address economy, efficiency, or effectiveness challenges. See GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007), and *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, GAO-17-317 (Washington, D.C.: Feb. 15, 2017).

other matters.[12] We have made numerous recommendations to improve FDA's oversight, and the agency has implemented some of them. We have also previously found that FDA faced performance management challenges,[13] but the agency has made progress in addressing some of those challenges in recent years. For example, FDA implemented our recommendations to more clearly demonstrate the alignment of activities to strategic goals and to expand its capacity to collect and analyze performance information.

In January 2011, the statutory framework for performance management in the federal government, established by the Government Performance and Results Act (GPRA), was updated by the GPRA Modernization Act of 2010 (GPRAMA).[14] As part of our previous work, we examined strategic plans, which are required by GPRAMA. Specifically, the act requires agencies to complete strategic plans in which the agencies define their missions, establish results-oriented goals, and identify objectives and strategies needed to achieve those goals. GPRAMA also requires agencies to use performance information to assess their progress toward strategic goals. GPRAMA requirements apply at the departmental or agency level, not to organizational components. We have previously reported, however, that the requirements can serve as leading practices at other organizational levels within federal agencies, such as component agencies, offices, programs, and projects.[15]

You asked us to examine FDA's food safety- and nutrition-related activities and resources since FSMA's enactment in fiscal year 2011. This report examines (1) key food safety- and nutrition-related activities that

[12]For example, see GAO, *Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues*, GAO-17-443 (Washington, D.C.: Sept. 15, 2017); *Dietary Supplements: FDA May Have Opportunities to Expand Its Use of Reported Health Problems to Oversee Products*, GAO-13-244 (Washington, D.C.: Mar. 18, 2013); and *Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible*, GAO-16-399 (Washington, D.C.: May 26, 2016).

[13]GAO, *Food and Drug Administration: Opportunities Exist to Better Address Management Challenges*, GAO-10-279 (Washington, D.C.: Feb. 19, 2010).

[14]Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRAMA amends provisions of GPRA, Pub. L. No. 103-62, 107 Stat. 285.

[15]See GAO, *Motor Carriers: Better Information Needed to Assess Effectiveness and Efficiency of Safety Interventions*, GAO-17-49 (Washington, D.C.: Oct. 27, 2016) and *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct 6, 2011).

FDA has conducted since FSMA's enactment and how FDA determined its priorities for those activities; (2) the resources, including personnel, that FDA dedicated to food safety- and nutrition-related activities in fiscal years 2011 through 2016; (3) the extent to which FDA set goals for food safety- and nutrition-related activities in fiscal years 2011 through 2017 and is assessing progress toward those goals; and (4) FDA's planned activities related to food safety and nutrition and the time frames for those activities.

For all objectives, we reviewed documents from FDA and other sources, and we interviewed knowledgeable FDA officials. We generally focused on FDA activities related to food for humans and feed for livestock animals (animal feed), and we generally excluded activities concerning veterinary medicine or related substances, such as growth hormones or antibiotics.[16]

To describe key food safety- and nutrition-related activities that FDA has conducted since FSMA's enactment, we reviewed FDA documentation describing actions the agency has undertaken since FSMA's enactment in January 2011 through September 2017. These documents include FDA's *Justification of Estimates for Appropriations Committees* (congressional budget justifications) for fiscal years 2012 through 2018, as well as FDA food safety- and nutrition-related regulations and guidance published from January 2011 through September 2017. To compile and verify lists of key regulations and guidance, we analyzed several sources, including (1) the *Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda)*, (2) the *Federal Register*,[17] and (3) various FDA websites.[18] In addition, we evaluated FDA's written

[16]We included activities and resources related to animal drug products and antimicrobial resistance to the extent that they are related to food safety and are included as a subset of the Center for Veterinary Medicine's food safety resources. For example, the use of antimicrobial drugs in feed or water of food-producing animals may affect public health and the risk of antimicrobial resistance development.

[17]The *Unified Agenda*, published biannually by the Office of Management and Budget (OMB), is a compilation of information about federal agencies' planned rulemaking actions. To identify FDA's planned food safety- and nutrition-related rulemaking actions since FSMA's enactment, we reviewed each *Unified Agenda* published from January 2011 through August 2017. To verify the actions taken by FDA, we then compared these planned actions with the draft and final food safety- and nutrition-related regulations published in the *Federal Register*.

[18]The FDA websites include "FSMA Rules & Guidance for Industry," "Food Guidance Documents," and "Search for FDA Guidance Documents."

responses to our questions on this topic, and we updated our lists of key food safety- and nutrition-related regulations and guidance, as appropriate. Using FDA's descriptions of food safety and nutrition—for example, those from FDA's strategic plans and interviews with agency officials—we took several steps to categorize the regulations and guidance as being related to food safety, nutrition, or both. (App. I contains a detailed discussion of the methodology used to compile our lists of key regulations and guidance.)

To assess how FDA determined its priorities for the food safety- and nutrition-related activities it conducted since FSMA's enactment, we interviewed agency officials about their processes for determining food safety- and nutrition-related priorities, including their decisions to issue regulations and guidance. We then reviewed relevant statutes and regulations, strategic plans, and documentation describing FDA's decision-making processes to verify what agency officials told us. We also compared FDA's processes for determining priorities with commitments that FDA has made as part of an agency initiative to promote transparency and with federal standards for internal controls.[19]

To describe the resources, including personnel, that FDA dedicated to food safety- and nutrition-related activities in fiscal years 2011 through 2016, we collected and analyzed FDA's data on its obligations and full-time equivalent (FTE) staff for these activities during these fiscal years.[20] To assess the reliability of FDA's data, we reviewed FDA's methodology for producing the data, interviewed knowledgeable agency officials, and conducted tests to identify obvious errors, outliers, and missing information. We determined that the data were sufficiently reliable for the purposes of our reporting objectives. Appendix II contains a detailed discussion of the methodology used to compile these data.

[19]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

[20]FTEs reflect the total number of regular, straight-time hours (i.e., hours that exclude overtime and holiday hours) worked by employees, divided by the number of compensable hours applicable to each fiscal year. One FTE is equivalent to about 2,080 hours of work. Budget authority is authority provided by federal law for an agency to enter into financial obligations that will result in immediate or future outlays involving federal government funds. During our review, the most recent data available on FDA's budget authority, obligations, and FTEs for food safety and nutrition were for fiscal year 2016.

To determine the extent to which FDA has set goals for food safety- and nutrition-related activities since fiscal year 2011, we reviewed relevant strategic planning documents, such as those for FDA's Foods and Veterinary Medicine (FVM) Program, which is primarily responsible for carrying out FDA's food safety- and nutrition-related activities. To determine how FDA is assessing its progress toward goals for these activities, we collected and analyzed information on performance measures for which FDA established targets in fiscal year 2017. We also interviewed agency officials about their performance management practices, including the FVM Program's efforts to assess progress, and reviewed leading practices in performance management.[21] Appendix III contains a detailed discussion of the methodology used in our analysis.

To describe FDA's planned activities related to food safety and nutrition and to examine the time frames for those activities, we reviewed documents such as FDA's congressional budget justification for fiscal year 2018,[22] the FVM Program's 10-year strategic plan, and written testimonies by FDA officials. We also compared the extent to which FDA established time frames for activities and goals with leading practices in strategic planning.[23] To identify FDA's planned food safety- and nutrition-related regulations, we reviewed the *Unified Agenda* published in August 2017, and to identify the agency's planned guidance, we analyzed draft guidance that FDA had published since January 2011 that agency officials indicated would be finalized in the future. In addition, we reviewed relevant executive orders and interviewed knowledgeable agency officials to describe the extent to which FDA anticipated that the agency's planned priorities for food safety- and nutrition-related activities might change.

[21]See GAO, *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers*, GAO/GGD/AIMD-99-69 (Washington, D.C.: Feb. 26, 1999).

[22]*Department of Health and Human Services, Fiscal Year 2018: Food and Drug Administration, Justification of Estimates for Appropriations Committees*.

[23]See, for example, GAO, *Defense Health Care Reform: Actions Needed to Help Ensure Defense Health Agency Maintains Implementation Progress*, GAO-15-759 (Washington, D.C.: Sept. 10, 2015); *Streamlining Government: Key Practices from Select Efficiency Initiatives Should Be Shared Governmentwide*, GAO-11-908 (Washington, D.C.: Sept. 30, 2011); *Biobased Products: Improved USDA Management Would Help Agencies Comply with Farm Bill Purchasing Requirements*, GAO-04-437 (Washington, D.C.: Apr. 7, 2004); and *Results-Oriented Cultures: Implementation Steps to Assist Mergers and Organizational Transformations*, GAO-03-669 (Washington, D.C.: July 2, 2003).

We conducted this performance audit from October 2016 to January 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

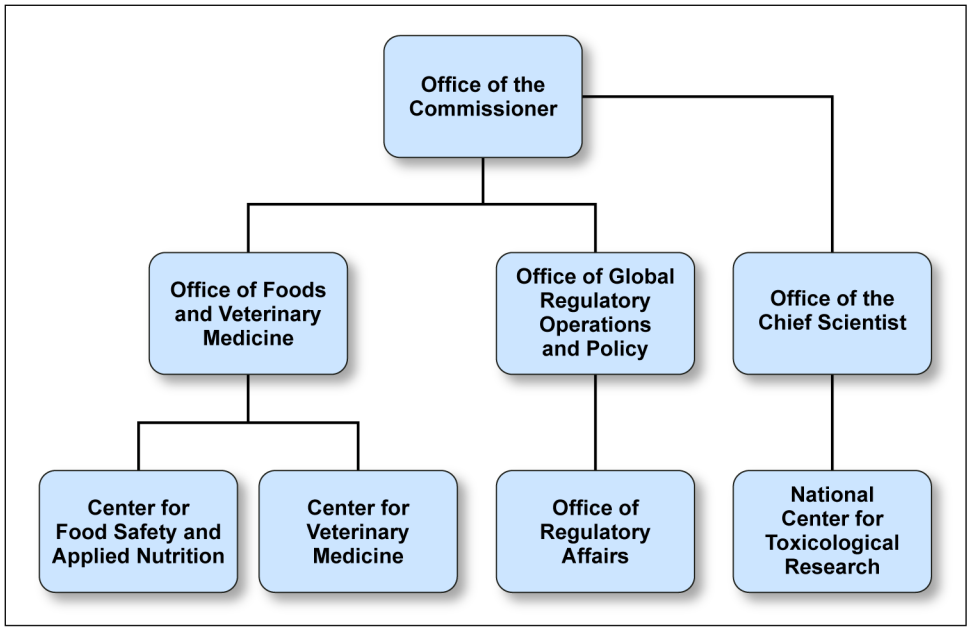
Background

This section provides information on FDA's organizational structure for food safety and nutrition, relevant federal statutes, and processes for developing federal regulations and guidance.

FDA Organizational Structure for Food Safety and Nutrition

FDA is responsible for protecting and promoting public health by (1) ensuring the safety of food and animal feed, cosmetics, and radiation-emitting products; (2) ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; and (3) regulating tobacco products. Regarding food safety and nutrition specifically, the mission of the agency's FVM Program—overseen by FDA's Office of Foods and Veterinary Medicine—is to promote human health by preventing foodborne illness and fostering good nutrition. The FVM Program contains two components—the Foods Program and the Animal Drugs and Feeds Program—which are managed by the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, respectively. In addition, the Office of Regulatory Affairs is responsible for food safety- and nutrition-related regulatory actions, and the National Center for Toxicological Research conducts research, in part, to improve FDA's ability to assess the safety of regulated products, including food. (See fig. 1 for an excerpt of FDA's organizational chart showing the offices and centers that are responsible for food safety- and nutrition-related activities.)

Figure 1: FDA Offices and Centers Responsible for Food Safety- and Nutrition-Related Activities



Source: GAO excerpt of Food and Drug Adminstration (FDA) organizational chart. | GAO-18-174

The FDA offices and centers responsible for carrying out food safety- and nutrition-related activities, according to agency documents, are as follows:

- The Office of Foods and Veterinary Medicine is responsible for providing leadership and strategic direction to the FVM Program and for overseeing all Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine activities. In addition, to rapidly detect and respond to major foodborne illness outbreaks, the office is to coordinate activities across FDA field and compliance offices; other federal agencies, such as USDA and the Centers for Disease Control and Prevention; state investigative and laboratory resources; and local resources. The office also is responsible for leading external communications and stakeholder engagement and for coordinating FVM Program-wide resource planning.
- Within the Center for Food Safety and Applied Nutrition, the Foods Program's food safety responsibilities include (1) conducting and supporting food safety research, (2) developing and overseeing enforcement of food safety and quality regulations, (3) coordinating and evaluating FDA's food surveillance and compliance programs, (4) coordinating and evaluating states' food safety activities, and (5)

developing and disseminating food safety and regulatory information to consumers and industry. In addition to improving food safety, the Foods Program carries out nutrition-related activities, such as regulating food labeling and promoting a healthy food supply to reduce the hundreds of thousands of deaths each year attributable to poor diet.

- The Center for Veterinary Medicine administers the Animal Drugs and Feeds Program, whose purposes include (1) protecting the safety of feed and devices for animals and (2) ensuring the safety and effectiveness of animal drugs.
- The Office of Regulatory Affairs carries out field activities—including inspections, sample collections, and import exams—in collaboration with the Center for Food Safety and Applied Nutrition's Foods Program and with the Center for Veterinary Medicine's Animal Drugs and Feeds Program. The Office of Regulatory Affairs is overseen by the Office of Global Regulatory Operations and Policy and is not part of the Office of Foods and Veterinary Medicine.
- The National Center for Toxicological Research conducts peer-reviewed research to advance scientific approaches and tools required to support public health and to improve FDA's ability to assess the safety of regulated products. The center's purpose is to enhance the agency's basis for science-based regulatory decisions by conducting collaborative research to help reduce and rapidly detect contaminants in food products, among other things. The center is overseen by the Office of the Chief Scientist.

Key Food-Related Laws

FDA is responsible for implementing several statutes that have food safety- or nutrition-related elements, including the following:

- **Federal Food, Drug, and Cosmetic Act (FFDCA)**.[24] Under this act and its implementing regulations, FDA oversees the safety of most of the U.S. food supply.[25] Among other things, FDA has the authority under the act to seek an order to remove any food from the market if the food is unsafe. The agency can also pursue enforcement action against those marketing such a food.

[24]21 U.S.C. §§ 301-399g.

[25]USDA, under its authority, is responsible for the safety of meat, poultry, processed egg products, and catfish.

- **FSMA**.[26] This law amended the FFDCA by expanding FDA's food safety authorities and responsibilities in five major areas: (1) requiring the development of prevention-oriented standards for food processing facilities and farms; (2) establishing mandatory inspection frequencies for domestic and foreign food facilities, based on risk; (3) implementing programs to improve oversight of imported products; (4) granting FDA additional enforcement tools, such as mandatory recalls and suspension of registration of food facilities; and (5) mandating that FDA take steps that, when taken, would better integrate its food safety oversight with that of states, localities, tribes, and territories.
- **National Nutrition Monitoring and Related Research Act of 1990**.[27] Under this act, the Department of Health and Human Services and USDA are required to review and update a report entitled *Dietary Guidelines for Americans*, containing nutritional and dietary information and guidelines for the general public, at least every 5 years. These guidelines, which were most recently issued in December 2015, serve as the basis for federal nutrition policies—such as policies pertaining to updating and expanding food labels. The act requires the guidelines to be based on current scientific and medical knowledge.
- **Nutrition Labeling and Education Act of 1990**.[28] This act requires nutrition labeling of most foods and dietary supplements. The act excludes labeling of food sold in restaurants.
- **Patient Protection and Affordable Care Act**.[29] This 2010 act, among other things, amended the FFDCA in a number of ways, including by mandating that FDA require disclosure of calorie and other nutrition information for standard menu items in certain restaurants and retail food establishments.

Federal Regulation and Guidance Development Processes

Federal regulatory agencies, such as FDA, have authority and responsibility for developing and issuing regulations. Regulations are legally binding and are one of the principal tools that the federal government uses to implement public policy. Agencies' rulemaking processes generally share three basic steps or phases: initiation of

[26]Pub. L. No. 111-353.

[27]Pub. L. No. 101-445, 104 Stat. 1034.

[28]Pub. L. No. 101-535, 104 Stat. 2353.

[29]Pub. L. No. 111-148 § 4205, 124 Stat. 119, 573 (2010).

rulemaking actions, development of proposed rules, and development of final rules.[30] The Administrative Procedure Act, among other things, establishes the basic process by which all federal agencies develop and issue regulations.[31] The act generally requires agencies to first publish a notice of proposed rulemaking in the *Federal Register*. After giving interested persons an opportunity to comment on the proposed rule, the agency may then publish the final rule. Regulatory actions can be categorized as significant—which includes actions that are economically significant—or non-significant under Executive Order 12866.[32] According to the Office of Management and Budget (OMB), the majority of rules issued every year by executive agencies are not significant regulatory actions.

Guidance is not legally binding and is often used by agencies for clarifying or interpreting a statute or regulations.[33] Agencies produce and issue the bulk of guidance—guidance that is considered non-significant—without government-wide standards for those processes. An OMB Bulletin establishes policies and procedures for the development, issuance, and use of "significant" guidance,[34] but most guidance does not fit into this

[30]See GAO, *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews*, GAO-09-205 (Washington, D.C.: Apr. 20, 2009).

[31]5 U.S.C.§ 553. Originally enacted in 1946, the Administrative Procedure Act, ch. 324, 60 Stat. 237 (1946), was repealed and codified in scattered sections of title 5 of the U.S. Code as part of the 1966 revision of title 5. In addition to the requirements under the Administrative Procedure Act, an agency may also need to comply with requirements imposed by other statutes.

[32]Exec. Order No. 12866, *Regulatory Planning and Review* (Washington, D.C.: Sept. 30, 1993).

[33]See GAO, *Regulatory Guidance Processes: Selected Departments Could Strengthen Internal Control and Dissemination Practices*, GAO-15-368 (Washington, D.C.: Apr. 16, 2015).

[34]See Office of Management and Budget, *Final Bulletin for Agency Good Guidance Practices*, 72 Fed. Reg. 3432 (Jan. 25, 2007), and GAO-15-368. The OMB Bulletin directs each agency to develop written procedures for the approval of "significant" guidance, establishes standard elements that must be included in significant guidance, and requires agencies to maintain a website to assist the public in locating significant guidance. Non-significant guidance is not subject to the OMB Bulletin, and guidance procedures are left to agency discretion.

category.[35] Additionally, FDA's Good Guidance Practices regulations differentiate between "Level 1" and "Level 2" guidance and require that, for Level 1 guidance, FDA solicit public comments through a notice in the *Federal Register* and by posting the draft guidance online prior to issuance of the final guidance. The regulations do not require that FDA solicit public comments for Level 2 guidance.[36] For the purposes of this report, "key" guidance includes Level 1 guidance and excludes Level 2 guidance.

During our review, FDA officials noted that regulations and guidance can differ greatly in terms of complexity, detail, and documentation. For example, the officials stated that one final rule took up 258 pages in the *Federal Register* and listed 276 references; as part of this rulemaking, FDA reviewed approximately 300,000 comments.[37] In contrast, the officials stated, another final rule took up fewer than 11 pages in the *Federal Register* and contained 4 references; FDA reviewed 19 comments on this rule.[38]

[35]The OMB Bulletin defines "significant" guidance as guidance disseminated to regulated entities or the general public that may reasonably be anticipated to (1) lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.

[36]21 C.F.R. § 10.115 (2014). These regulations define "Level 1" documents as those that set initial interpretations or more-than-minor changes to interpretations, are scientifically complex, or are likely to be highly controversial; and "Level 2" documents as those that set forth existing practices or minor changes in interpretations. See also GAO-15-368.

[37]Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742 (May 27, 2016).

[38]Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids, 79 Fed. Reg. 23,262 (Apr. 28, 2014).

FDA Has Conducted Numerous Key Food Safety- and Nutrition-Related Activities, Determining Its Priorities Based on Statutes and Strategic Goals

Since FSMA's enactment in January 2011, FDA has conducted numerous key food safety- and nutrition-related activities, determining its priorities for these activities based on statutes and strategic goals. More specifically, FDA issued regulations and guidance,[39] focused mainly on food safety, and conducted other key activities related to food safety and nutrition, such as inspections. FDA prioritized these activities based on statutes—such as FSMA—and its strategic goals, according to agency officials, but how the agency decided between issuing regulations and guidance in support of these priorities is unclear because it did not consistently document those decisions.

[39]We limited our review to key food safety- and nutrition-related regulations and guidance, which refer to regulations and guidance that are most relevant and important to this review. For the purposes of this report, proposed or draft, and subsequent final, versions of the regulations and guidance that were published during the relevant time period were counted only once. See app. I for more information about how we compiled these regulations and guidance documents.

FDA Published Key Regulations and Guidance, Focused Mainly on Food Safety, and Conducted Other Food Safety- and Nutrition-Related Activities

From January 2011 through September 2017, FDA published key regulations and guidance, focused mainly on food safety, and conducted other food safety- and nutrition-related activities. More specifically, FDA published 33 key proposed or final regulations[40] and 111 key draft or final guidance documents that were related to food safety or nutrition.[41] Of the 33 proposed and final regulations that FDA published, 21 were food safety-related, 7 were nutrition-related, and 5 were related to both.[42] In addition, of the 33 published regulations, 30 regulations were final and 3 were proposed.[43] These 33 regulations included the 7 foundational rules required by FSMA.[44] Of the 111 guidance documents that FDA published on its website during the same time frame, 82 were food safety-related, 12 were nutrition-related, and 17 were related to both food safety and nutrition. Furthermore, 80 of those guidance documents were issued in final form, and 31 were published in draft form from January 2011 through September 2017. (See app. I for a list of FDA's key food safety- and nutrition-related regulations and guidance published from January 2011

[40]The number of regulations is based on GAO's analysis of the *Unified Agenda*, verified against the *Federal Register* and FDA officials' written and oral responses.

[41]The number of guidance documents is based on GAO's analysis of FDA websites, verified against *Federal Register* publications and FDA officials' written and oral responses. In addition, FDA withdrew certain food safety- or nutrition-related regulations and guidance documents during this time frame. FDA officials told us that the agency withdrew these regulations and guidance documents for various reasons, such as the need for a planned regulation becoming obsolete with the publication of a different rule.

[42]While we could not find an applicable statutory definition for food safety- and nutrition-related activities, FDA officials told us that the agency's food safety activities encompass a range of activities to prevent or mitigate contamination of food for humans and animals. They noted that FDA's nutrition activities also encompass a range of activities to improve nutritional status in humans and to reduce the prevalence of diet-related risk factors for chronic disease. Some of the agency's activities, however, cut across these two categorizations and, therefore, are related to both food safety and nutrition. FDA officials added that the Center for Veterinary Medicine is not engaged in activities related to the nutritional status of animals and does not receive funding for nutrition activities.

[43]For the purposes of this report, "final" includes "interim final" and "final" rules, as indicated in the corresponding *Federal Register* notice (for regulations); for guidance documents, "final" includes documents that are not indicated as being in "draft" form.

[44]To implement FSMA, FDA published seven critical rules to establish preventive and risk-based standards for the growing, harvesting, packing, processing and distribution of domestic and imported food for people and animals, from farm through transportation to retail. The seven foundational rules are as follows: (1) Preventive Controls for Human Food, (2) Preventive Controls for Animal Food, (3) Produce Safety, (4) Foreign Supplier Verification Program, (5) Accredited Third-Party Certification, (6) Sanitary Transportation, and (7) Intentional Adulteration.

through September 2017, as well as additional information, including publication dates.)

In addition, among the food safety- and nutrition-related activities that FDA conducted, according to its congressional budget justifications for fiscal years 2012 through 2018, are activities such as conducting compliance inspections and developing risk assessment tools, responding to foodborne illness outbreaks, and providing outreach and education on food safety and nutrition matters.[45] For example, since FSMA's enactment in January 2011, which provided FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards, FDA reported conducting risk-based inspections of high-risk and non-high risk food facilities based on the facilities' known safety risks, compliance histories, and years since last inspection.[46] The agency has also reported developing risk assessment tools—such as FDA-iRISK[47] and the Virtual Deli Risk-Tool[48]—to predict the interventions most effective at preventing

[45]Each year, as part of the annual appropriations process, federal agencies, including FDA, develop and submit to Congress supporting information for their funding requests in congressional budget justifications. FDA's congressional budget justification notes past accomplishments; reflects how FDA proposes to meet its mission, goals, and objectives in the future; and assists Congress in determining how much funding to appropriate for FDA in the upcoming fiscal year.

[46]FDA reported that in fiscal year 2012, it developed a new framework for selecting food facilities for inspection, based on known safety risks, compliance history, and years since the last inspection. Based on these factors, FDA categorized facilities as high-risk and non-high-risk. For example, a facility that manufactures food associated with foodborne outbreaks and class I recalls may be placed in the high-risk category. Likewise, if a facility's inspection results for the previous 5 fiscal years indicate that it has a history of non-compliance with food safety requirements and has food safety violations of regulatory significance, it may be categorized as high-risk. Alternatively, a facility may be categorized as non-high-risk if it neither manufactures a food associated with outbreaks or class I recalls, nor has a compliance history in the previous 5 fiscal years indicating that it has a history of non-compliance with food safety requirements or food safety violations of regulatory significance.

[47]According to FDA's congressional budget justifications for fiscal years 2014 and 2017, in October 2012, FDA released FDA-iRISK—a web-based tool that automates the process of developing mathematical models to simulate risk and intervention in food production chains. This tool also predicts the number of cases of illness prevented by various interventions applied against specific contaminants in specific foods. More recently, FDA released an enhanced version of the tool, with advanced modeling and reporting methods.

[48]According to FDA's congressional budget justification for fiscal year 2016, the Virtual Deli Risk-Tool simulates pathways of *Listeria* cross-contamination in ready-to-eat foods such as those sold in delicatessens.

foodborne illness. Outbreaks of foodborne illness that the agency reported responding to included outbreaks of *Cyclospora*, *Hepatitis A*, *Listeria monocytogenes*, and *Salmonella*. With respect to outreach and education activities, FDA reported, among other things, conducting consumer studies to learn about attitudes, behaviors, and knowledge of food safety; maintaining a Nutrition Label education program with a television network specializing in cartoons to build awareness of such labels among children; conducting activities to help consumers improve heart health through reduced sodium intake; and partnering with USDA to manage a program for food safety training, education, and outreach to small farm owners and food processors.

Agency Officials Said FDA Based Its Priorities on Statutes and Strategic Goals, but How It Decided between Issuing Regulations and Guidance Was Not Always Clear

Since FSMA's enactment in January 2011 through fiscal year 2017, FDA based its food safety- and nutrition-related priorities on statutes and strategic goals, according to agency officials. However, how the agency decided between issuing regulations and guidance in support of these priorities is unclear because FDA did not consistently document those decisions.[49]

Agency Officials Said FDA Based Priorities on Statutes and Strategic Goals

FDA officials told us that the FVM Governance Board, consisting of FDA senior executives, and an executive council,[50] consisting of the deputies for relevant FDA offices and centers, are the internal governing bodies that have been responsible, respectively, for establishing and implementing FVM Program priorities since FSMA's enactment. FDA officials said that the governance board determined top priorities for each fiscal year based, in part, on statutes—including FSMA, FFDCA, and the Patient Protection and Affordable Care Act.[51] (See app. I for the statutory authorities FDA cited in developing the regulations.)

[49]Although we examined the period since FSMA's enactment in January 2011 through September 2017, FDA officials told us that they had a decision-making process in place prior to FSMA's enactment to determine food safety- and nutrition-related priorities.

[50]The full name of this executive council is the Food and Veterinary Medicine and the Office of Regulatory Affairs Food and Veterinary Medicine Program Executive Council.

[51]FDA officials informed us that the governance board and executive council were formed in March 2014. The charter for the governance board was signed in March 2014, and the charter for the executive council was signed on various dates in March and April 2014.

In determining priorities, FDA officials stated, the board also considered strategic goals, identified in the FVM Program's strategic plan, which the governance board reviewed and approved.[52] For example, one of the goals in the strategic plan—which provides a framework for implementing FSMA and other legislative authorities—is to protect consumers and animals from foreseeable hazards. A related objective, in support of this goal, is to improve the prevention, detection, and response to foodborne illness outbreaks. Another strategic goal is to foster an environment that promotes healthy and safe food choices, with a related objective to provide and support accurate and useful information and education so consumers can choose healthier diets. FDA officials stated that once the FVM Program top priorities were established for a given fiscal year, the executive council oversaw the implementation of those priorities.

The Bases for FDA's Decisions for Issuing Regulations or Guidance Were Not Always Clear

How FDA decided between issuing regulations or guidance in support of food safety- and nutrition-related priorities was not always clear because the agency did not consistently document those decisions. Since January 2011,[53] FDA's decisions to develop either regulations or guidance generally went through a review process whereby FDA considered multiple factors, according to agency officials, on a case-by-case basis. Specifically, FVM Program officials told us that the decision to develop regulations or guidance was often made by individual offices with the necessary expertise—for example, the Office of Food Safety within the Center for Food Safety and Applied Nutrition or the Office of Surveillance and Compliance within the Center for Veterinary Medicine.[54] This decision was then reviewed by FDA's Office of Policy and, where appropriate, FDA's Office of Chief Counsel. FDA officials told us that among the factors the agency considered were (1) statutory requirements and

[52]To achieve the program's mission over a 10-year time frame, the FVM Program's strategic plan outlines goals, outcomes, objectives, and strategies, taking into account the program's responsibility to implement FSMA and other congressional mandates, and to ensure that FDA regulations and guidance provide clear and reliable direction to industry. See Food and Drug Administration, *FDA Foods and Veterinary Medicine Program Strategic Plan Fiscal Years 2016-2025* (Washington, D.C.: July 14, 2016).

[53]As previously noted, we examined the period since FSMA's enactment in January 2011 through September 2017; however, FDA officials told us that the process described here was in place prior to FSMA's enactment.

[54]FDA officials also told us that this decision-making process may differ for broader program initiatives, such as those addressing FSMA and antimicrobial resistance. In those cases, FDA officials told us that cross-cutting groups are formed to develop and review work products. For example, the decision-making and documentation for a specific FSMA regulation would be included in the process of the broader FSMA initiative.

authorities, (2) the agency's intention to either create a requirement or provide advice, (3) public health and the urgency of a particular communication, and (4) agency resources.[55] In particular, FDA officials told us that in cases where an underlying statute did not prescribe either issuance of regulations or guidance, the agency developed regulations when it intended for a policy to be legally binding, and it developed guidance when it intended to provide advice to industry or other stakeholders. FDA officials said that more agency resources are needed to develop regulations, compared with guidance; therefore, if the agency believes it can address an issue successfully with guidance, it will do so.

However, FDA's bases for deciding whether to address certain FVM Program priorities through regulations or guidance were not always clear because FDA did not uniformly document its decision-making process—including whether it considered alternative approaches (i.e., developing regulations rather than guidance, or vice versa). According to agency officials, FDA generally had tools in place—such as "concept papers,"[56] and "guidance initiation sheets"[57]—for staff to prepare and present to

[55]See GAO-15-368 for additional information on what we previously found regarding the factors that the Department of Health and Human Services and other agencies (and agency components) considered before deciding whether to issue guidance or undertake rulemaking. Note that FDA was not one of the audited agency components in that GAO report.

[56]For example, the Center for Veterinary Medicine's "Concept or Issue Resolution Paper" template provides instructions on how staff proposing to address an issue through rulemaking should prepare a two- to three-page document describing relevant factors such as why the issue should be addressed through regulation, the agency's legal authority, as well as other options that were considered and why they were rejected. According to agency officials, the Center for Food Safety and Applied Nutrition also uses concept papers on occasion.

[57]For example, the Center for Veterinary Medicine makes available a "Guidance Information Sheet"—a form consisting of a one-page questionnaire, and one page of instructions. This tool is intended to encourage staff to consider important factors as they develop guidance. This sheet includes instructions for selecting the reason guidance is needed—whether it is to interpret existing regulation or statute, is mandated by a statute, or for another reason.

senior management.[58] These tools were intended, FDA officials told us, to document the reasons for developing a regulation or guidance—and, in some cases, consideration of alternatives—and to ensure agreement with the proposed path forward. However, FDA officials stated that these concept papers and guidance initiation sheets were not uniformly used by Center for Veterinary Medicine or Center for Food Safety and Applied Nutrition staff—and that FDA does not require that the tools be used for every initiated regulation or guidance. These tools were available for staff to use, and FDA officials told us that they were occasionally used for complex decisions and for those they determined to be particularly substantive.

Under its transparency initiative, FDA has committed to improving transparency to regulated industry.[59] In its January 2011 transparency initiative report, FDA describes 19 steps the agency is taking to improve its transparency to regulated industry, including action items and draft proposals for improving transparency by topic area. Among the topic areas discussed is the development of guidance and regulations.

Furthermore, legal scholars and federal courts have noted that it is not always easy to determine whether an agency should address a concern by issuing a regulation—which is subject to public notice and comment requirements under the Administrative Procedure Act—or, instead, by

[58]FDA provided us with blank template forms used for Center for Veterinary Medicine regulations ("CVM Concept or Issue Resolution Paper") and guidance ("CVM Guidance Information Sheet (GIS)") development. The agency also provided us with an example of a completed form, used by the Office of Surveillance and Compliance within the Center for Veterinary Medicine, for developing a guidance related to anti-*Salmonella* food additives in food for animals. However, FDA did not provide us with an example of a completed concept paper, used within the Center for Veterinary Medicine, for developing a food safety- or nutrition-related regulation. Additionally, after multiple requests since June 2017 for documentation of similar forms used within the Center for Food Safety and Applied Nutrition, FDA provided us, in October 2017, with a "CFSAN Concept Paper" template and a completed "FSMA Concept Paper" for a FSMA-related interim final rule, used within the Center for Food Safety and Applied Nutrition. During interviews, FVM Program officials provided conflicting responses as to whether concept papers are used within the Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition.

[59]FDA launched its transparency initiative in response to the President's commitment to openness in government and the Department of Health and Human Services' making transparency a priority. 74 Fed. Reg. 4685 (Jan. 26, 2009), and Department of Health and Human Services, Transparency Task Force, *FDA Transparency Initiative: Improving Transparency to Regulated Industry* (January 2011).

issuing guidance, which is exempt from those requirements.[60] Consequently, agency guidance may be legally challenged based on procedural concerns that the agency inappropriately used guidance, rather than the rulemaking process, or concerns that the agency has issued guidance that goes beyond its authority.[61] For example, agencies have been sued for applying a new interpretation to an existing rule without going through notice and comment rulemaking. In 2015, the U.S. Supreme Court overturned prior federal court rulings that had held that an agency is precluded from substantively changing its interpretation of a rule without notice and comment.[62]

Under federal standards for internal control, management should design control activities to achieve objectives and respond to risks.[63] As an example of designing such control activities, management should clearly document internal control and all transactions and other significant events in a manner that allows the documentation to be readily available for examination.[64] The agency's bases for deciding whether to address certain FVM Program priorities through regulations or guidance would qualify as significant events. Without uniformly documenting the bases for its decisions for issuing either regulations or guidance related to food safety and nutrition—such as by using concept papers or guidance

[60]For additional discussion on Administrative Procedure Act requirements, differences between regulations and guidance, and requirements prior to issuance of final guidance, see GAO-15-368. FDA's Good Guidance Practices regulations also stipulate that FDA "may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time." FDA's Good Guidance Practices also set certain requirements for some guidance documents, including the requirement to solicit public comments through a notice in the *Federal Register* and by posting the draft guidance online prior to issuance of final guidance. 21 C.F.R. § 10.115.

[61]See GAO-15-368.

[62]On March 9, 2015, the Supreme Court held in Perez v. Mortgage Bankers Ass'n, No. 13-1041, slip. op (U.S. Mar.9, 2015), that an agency could make substantive changes to an interpretive rule without going through notice and comment under the Administrative Procedure Act. This decision overturned prior federal court rulings that had held that an agency is precluded from substantively changing its interpretation of a regulation through issuance of a new interpretive rule without notice and comment. See, e.g., Alaska Prof'l Hunters Ass'n v. FAA, 177 F.3d 1030 (D.C. Cir. 1999).

[63]GAO-14-704G; see also GAO-15-368.

[64]The use of "significant event" in the context of internal controls differs from the use of "significant" regulations and guidance previously discussed in this report.

initiation sheets—FDA cannot help ensure consistency and transparency in its decision-making process.

FDA Dedicated at Least $1 Billion per Year, Including Salaries for at Least 4,300 FTEs, to Food Safety- and Nutrition-Related Activities in 2011 through 2016

FDA has dedicated at least $1.0 billion annually—including salaries for at least 4,300 FTEs—to food safety- and nutrition-related activities in fiscal years 2011 through 2016, with food safety-related activities accounting for about 98 percent of these resources and nutrition-related activities accounting for about 2 percent.[65] For food safety-related activities for this period, FDA dedicated at least $1.0 billion annually, including salaries for at least 4,200 FTEs. In contrast, for nutrition-related activities during this time frame, the agency dedicated at least $20 million annually, including salaries for at least 97 FTEs.

For Fiscal Years 2011 through 2016, FDA Dedicated at Least $1 Billion and 4,200 FTEs Annually to Food Safety-Related Activities

FDA dedicated from $1.0 billion to $1.3 billion annually, including salaries for 4,200 to 4,800 FTEs, to food safety-related activities for fiscal years 2011 through 2016. These resources accounted for about 98 percent of FDA's obligations and FTEs dedicated to food safety- and nutrition-related activities during this time frame.[66] Table 1 shows food safety-related obligations and FTEs dedicated by FDA components in each fiscal year. (See app. II for more detailed information on FDA components' dedication of resources across specific food safety-related activities.)

[65]For the purposes of this report, "dedicated" is synonymous with "obligated." We excluded user fees from our analysis. Authorized obligations of user fee collections accounted for a small proportion of FDA's total obligations for food safety- and nutrition-related activities in each fiscal year from 2011 through 2016. User fees are assessed to users of goods and services provided by the federal government in conjunction with regulatory activities.

[66]As previously noted, an obligation is a definite commitment that creates a legal liability of the government to make payment for goods and services received or a legal duty that could mature into a legal liability by virtue of actions beyond the control of the federal government. FDA obligates funds, for example, when it awards a grant, signs a contract, purchases a service, or takes other actions that require the government to make payments. During our review, the most recent data available on FDA's obligations and FTEs for food safety and nutrition were for fiscal year 2016.

Table 1: FDA Obligations, Including Salaries for Full-Time Equivalent (FTE) Staff, for Food Safety-Related Activities, by Agency Component, for Fiscal Years 2011 through 2016

Dollars in millions

	2011		2012		2013		2014		2015		2016	
Component	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**
Center for Food Safety and Applied Nutrition	242.0	818	252.3	827	234.8	868	253.7	884	266.9	900	285.5	969
Center for Veterinary Medicine	57.9	285	58.4	299	53.0	287	61.5	292	61.5	294	63.5	322
Office of Regulatory Affairs	612.9	2,909	631.3	2,838	577.8	2,870	648.1	2,924	653.7	2,924	733.7	3,054
National Center for Toxicological Research	10.8	48	10.2	46	12.1	56	10.2	47	10.2	45	10.2	49
FDA Headquarters and Infrastructure[a]	154.2	237	159.0	256	162.6	263	181.8	328	187.6	313	196.4	32
Total	**1,077.7**	**4,297**	**1,111.2**	**4,266**	**1,040.3**	**4,344**	**1,155.4**	**4,475**	**1,180.0**	**4,476**	**1,289.0**	**4,718**

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

Note: Amounts are rounded and may not sum to totals.

[a]FDA Headquarters provides FDA-wide program direction and administrative services. The primary Headquarters components responsible for providing FDA-level oversight and advice are the Office of the Commissioner, the Office of Foods and Veterinary Medicine, the Office of Medical Products and Tobacco, the Office of Operations, and the Office of Global Regulatory Operations and Policy. Infrastructure refers to FDA's Infrastructure program, which provides office and laboratory space and consists of General Services Administration rental payments; other rent and rent-related activities; and the operations of FDA's White Oak campus, which replaces geographically disparate facilities with new, centralized facilities in Maryland.

The resources that these FDA components dedicated to food safety-related activities generally increased or remained the same over this time frame. More specifically:

- **Center for Food Safety and Applied Nutrition** resources for food safety-related activities generally increased from fiscal years 2011 through 2016. The center dedicated $285.5 million and 969 FTEs in fiscal year 2016 for these activities, compared with $242.0 million and 818 FTEs in fiscal year 2011. Because of data limitations, it is unclear how the center's resources for specific food safety-related activities

may have changed from fiscal years 2011 through 2016.[67] However, of the food safety-related activities it carried out in fiscal year 2016, the center obligated the most funding, $111.9 million, to regulatory science activities. According to FDA officials, the center's regulatory science activities included increasing FDA's bioinformatics capacity and developing enhanced screening methods to better detect contaminated food.

- **Center for Veterinary Medicine** resources for food safety-related activities generally increased from fiscal years 2011 through 2016. The center dedicated $63.5 million and 322 FTEs in fiscal year 2016, compared with $57.9 million and 285 FTEs in fiscal year 2011. FDA reported the center's food safety-related data across two activities: animal food safety and antimicrobial resistance. According to agency officials, the center increased funding for animal food safety activities to implement FSMA. The center's data show a decline in obligations dedicated to antimicrobial resistance activities from fiscal year 2012 to fiscal year 2013; however, center officials we interviewed stated that this decline was due to a change in the center's methodology for identifying antimicrobial resistance resources.
- **Office of Regulatory Affairs** resources for food safety-related activities generally increased from fiscal years 2011 through 2016. The office dedicated $733.7 million and 3,054 FTEs to food safety-related activities in fiscal year 2016, compared with $612.9 million and 2,909 FTEs in fiscal year 2011. Over this time frame, the office generally decreased annual resources dedicated to inspections, field examinations, and label reviews. The office increased obligations dedicated to other activities, such as implementing FSMA and conducting FSMA-related training. For example, in July 2017, FDA announced that the office would award $30.9 million to 43 states to implement a new FSMA rule for the safe growing, harvesting, packing, and holding of fruits and vegetables.[68] This followed a separate announcement of office funding to states in 2016. According to an agency website, funding will support states' efforts to formulate multi-year plans to implement a produce safety system and provide related education, outreach, and technical assistance.

[67]We did not analyze trends related to the Center for Food Safety and Applied Nutrition's obligations and FTEs for specific categories of food safety-related activities because data from fiscal years 2011 through 2013 are not comparable with data from fiscal years 2014 through 2016, as the center made changes to its data reporting systems in fiscal year 2014.

[68]80 Fed. Reg. 74354 (Nov. 27, 2015) (codified in 21 C.F.R. pt. 112).

- **National Center for Toxicological Research** resources for food safety-related activities generally remained constant from fiscal years 2011 through 2016. The center dedicated $10.2 million and 49 FTEs to food safety-related activities in fiscal year 2016, compared with $10.8 million and 48 FTEs in fiscal year 2011. FDA reported the center's food safety-related resources across three categories: food, antimicrobial resistance, and dietary supplements. According to FDA officials, the center increased or decreased resources dedicated to specific activities as it initiated or completed various research projects. For example, obligations for dietary supplement research increased from $1.0 million in fiscal year 2015 to $4.0 million in fiscal year 2016 as the center initiated a significant research project on over-the-counter dietary supplements. The center's obligations for other food safety research during this time frame decreased as the center ended multiple, other research projects related to food safety.
- **FDA Headquarters and Infrastructure** resources for food safety-related activities generally increased from fiscal years 2011 through 2016.This component dedicated $196.4 million and 324 FTEs to food safety-related activities in fiscal year 2016, compared with $154.2 million and 237 FTEs in fiscal year 2011.

In Fiscal Years 2011 through 2016, FDA Dedicated at Least $20 Million and 97 FTEs Annually to Nutrition-Related Activities

FDA dedicated from $20.3 million to $33.7 million annually, including salaries for 97 to 127 FTEs, to nutrition-related activities in fiscal years 2011 through 2016. These resources accounted for about 2 percent of FDA's total obligations and FTEs dedicated to food safety- and nutrition-related activities for this period. Table 2 shows the nutrition-related resources dedicated by each of these components each fiscal year. (See app. II for more detailed information on FDA components' dedication of resources across specific nutrition-related activities.)

Table 2: FDA Obligations, Including Salaries for Full-Time Equivalent (FTE) Staff, for Nutrition-Related Activities, by Agency Component, for Fiscal Years 2011 through 2016

Dollars in millions												
	2011		2012		2013		2014		2015		2016	
Component	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**
Center for Food Safety and Applied Nutrition	8.2	54	12.0	55	10.9	55	12.7	59	13.1	61	18.5	68
Office of Regulatory Affairs	11.8	54	11.5	50	9.6	40	10.5	42	10.7	42	14.8	57
FDA Headquarters and Infrastructure[a]	0.3	2	0.3	2	0.4	2	0.4	3	0.5	3	0.4	2
Total	**20.3**	**110**	**23.8**	**107**	**20.8**	**97**	**23.6**	**104**	**24.3**	**106**	**33.7**	**127**

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

Note: Amounts are rounded and may not sum to totals.

[a]FDA Headquarters provides FDA-wide program direction and administrative services. The primary Headquarters components responsible for providing FDA-level oversight and advice are the Office of the Commissioner, the Office of Foods and Veterinary Medicine, the Office of Medical Products and Tobacco, the Office of Operations, and the Office of Global Regulatory Operations and Policy. Infrastructure refers to FDA's Infrastructure program, which provides office and laboratory space and consists of General Services Administration rental payments; other rent and rent-related activities; and the operations of FDA's White Oak campus, which replaces geographically disparate facilities with new, centralized facilities in Maryland.

The resources that these FDA components dedicated to nutrition-related activities generally increased over this time frame, although resources dedicated by some components decreased or remained the same across some fiscal years. More specifically:

- **Center for Food Safety and Applied Nutrition r**esources for nutrition-related activities generally increased from fiscal years 2011 through 2016. The center dedicated $18.5 million and 68 FTEs in fiscal year 2016, compared with $8.2 million and 54 FTEs in fiscal year 2011. Because of data limitations, it is unclear how center resources for specific categories of nutrition-related activities may

have changed from fiscal years 2011 through 2016.[69] However, of the nutrition-related activities it carried out in fiscal year 2016, the center obligated the most funding, $7.8 million, to regulatory science activities. According to FDA officials, the center's regulatory science activities for nutrition include activities such as studies on consumer perception and evaluation of the intake of nutrients in the diet.

- **Office of Regulatory Affairs** resources for nutrition-related activities generally decreased from fiscal years 2011 through 2015 but increased from fiscal years 2015 to 2016. The office dedicated $14.8 million and 57 FTEs in fiscal year 2016, compared with $11.8 million and 54 FTEs in fiscal year 2011. FDA officials we interviewed stated that the office increased nutrition-related obligations in fiscal year 2016 to conduct increased field examinations in support of implementing the Food Allergen Labeling and Consumer Protection Act of 2004,[70] which requires food labels to list major allergens present in those foods.[71] In addition, officials stated that the office identified new food risks through these additional field examinations. In response to these risks, the office obligated additional funding in fiscal year 2016 for regulatory actions, such as monitoring class I recalls.[72]
- **FDA Headquarters and Infrastructure** resources for nutrition-related activities generally remained the same from fiscal years 2011 through 2016.The component dedicated $0.4 million and 2 FTEs to nutrition-related activities in fiscal year 2016 compared with $0.3 million and 2 FTEs in fiscal year 2011.

[69]We did not analyze trends related to the Center for Food Safety and Applied Nutrition's obligations and FTEs for specific categories of nutrition-related activities because data from fiscal years 2011 through 2013 are not comparable with data from fiscal years 2014 through 2016, as the center made changes to its data reporting systems in fiscal year 2014.

[70]FDA field examinations are on-site examinations of FDA-regulated imported or domestic products. According to FDA officials, the agency may conduct field exams of any commodity or at any location. In contrast, FDA conducts facility inspections ("inspections") at factories, warehouses, and establishments involved in food manufacturing, processing, packing, or holding.

[71]Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, tit. II, § 203, 118 Stat. 906, 906-908 (amending 21 U.S.C. 343(w)).

[72]FDA classifies a recall as class I when there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death. Examples include food found to contain toxins or undeclared allergens.

FDA Has Set Goals for Food Safety- and Nutrition-Related Activities Every Year since 2011 but Cannot Fully Assess Progress

Since fiscal year 2011, FDA has set goals for food safety- and nutrition-related activities but has not fully developed the necessary framework to assess progress toward those goals. Specifically, FDA cannot fully assess progress toward its food safety- and nutrition-related goals because the FVM Program has developed performance measures related to some, but not all, of the eight strategic objectives that support its goals. For developed performance measures, the program reports both targets set and measurements taken for specific time frames.

FDA Has Set Goals for All Agency Activities, and since 2012, the FVM Program Has Set Specific Goals for Food Safety- and Nutrition-Related Activities

Since fiscal year 2011, FDA has set strategic goals for all agency activities, including food safety- and nutrition-related activities. These goals provide direction to agency programs in their efforts to achieve FDA's public health mission. FDA's 2014-2018 strategic plan identifies four strategic goals: (1) enhance oversight of FDA-regulated products, (2) improve and safeguard access to FDA-regulated products to benefit health, (3) promote better informed decisions about the use of FDA-regulated products, and (4) strengthen organizational excellence and accountability. These goals encompass FDA's food safety- and nutrition-related activities, in addition to activities not related to food.[73]

Some FDA components have set their own strategic goals for specific product areas they manage in support of FDA's broader goals. For example, the FVM Program set more specific goals for food safety- and nutrition-related activities in fiscal year 2012 and later modified these goals under its current 2016-2025 strategic plan.[74] Under this plan, the FVM Program set two goals for its food safety- and nutrition-related activities: (1) protect American consumers and animals from foreseeable hazards and (2) foster an environment that promotes healthy and safe food choices. The FVM Program identified public health outcomes that it intends to achieve through these goals. It also set several strategic objectives for each goal. The FVM Program's strategic planning framework—including goals, outcomes, and objectives—for food safety- and nutrition-related activities is shown in table 3. The FVM Program did

[73]Food and Drug Administration, *FDA Strategic Priorities, 2014-2018* (Washington, D.C.: September 2014).

[74]Food and Drug Administration, *FDA Foods and Veterinary Medicine Program Strategic Plan, Fiscal Years 2016-2025* (Washington, D.C.: July 14, 2016).

not have a strategic plan in place in fiscal year 2011, the year of FSMA's enactment; agency officials stated that FDA was preparing to implement FSMA at that time.

Table 3: Foods and Veterinary Medicine Program Strategic Planning Framework for Food Safety- and Nutrition-Related Activities, from Fiscal Years 2016 through 2025 Strategic Plan

	Food safety	Nutrition
Goal	Protect America's consumers and animals from foreseeable hazards	Foster an environment to promote healthy and safe food choices
Outcome	Reduce the incidence of illnesses and deaths attributable to preventable contamination of FDA-regulated food and feed products	Reduce risk factors for and the incidence of nutrition-related chronic disease
Objectives	Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum Improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents Strengthen the ability of consumers to play a proactive role in minimizing food safety risks Enhance the safety of food and feed additives and dietary supplements Strengthen existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of FDA's food safety program for government and industry	Provide and support accurate and useful nutrition information and education, so consumers can choose healthier diets, consistent with the Dietary Guidelines for Americans and other evidence-based recommendations Monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional health status of Americans Encourage and facilitate new products and product reformulation to promote a healthier food supply

Source: GAO analysis of the Food and Drug Administration's FDA Foods and Veterinary Program Strategic Plan, Fiscal Years 2016-2025. | GAO-18-174

According to FVM Program officials, the program's 2016-2025 strategic plan set strategic goals, intended outcomes, and objectives for its food safety- and nutrition-related activities, to better demonstrate the program's work across its core functions, which include food safety and nutrition.[75] Under the older framework used in the 2012-2015 strategic plan, the FVM Program intended to make similar impacts through its food safety- and nutrition-related work, as demonstrated by similarities to the current strategic plan. However, the older framework did not organize the FVM Program's food safety- or nutrition-related activities under one strategic goal specific to either core function.

[75]According to its 2016-2025 strategic plan, the FVM Program intends to promote public health by preventing foodborne illness, fostering good nutrition, and improving the safety and efficacy of animal health products.

FDA Has Developed Performance Measures for Its Food Safety- and Nutrition-Related Goals but Cannot Fully Assess Progress toward These Goals

FDA has developed performance measures for its food safety- and nutrition-related goals, and these measures reflect some, but not all, of the FVM Program's food safety- and nutrition-related objectives supporting these goals. Specifically, FDA has developed performance measures for five of the FVM Program's eight objectives for food safety or nutrition. For example, FDA has developed performance measures for the food safety objective to establish and gain high rates of compliance with science-based preventive control standards; its food safety objective to enhance the safety of food and feed additives and dietary supplements; and its nutrition objective to provide and support accurate and useful nutrition information and education. An example of an FVM Program performance measure that supports the first food safety objective, and which includes targets and time frames, is the measure related to enhancing preventive controls for reducing pathogen contamination of high-risk produce such as tomatoes, cantaloupes, and leafy greens. FDA reports on each measure, either through FDA-TRACK, FDA's agency-wide performance management system, or through its congressional budget justifications.[76]

The FVM Program collects data for completed performance measures to assess progress toward its strategic goals. For developed performance measures, the program reports both targets set and measurements taken for specific time frames. For example, for the FDA-TRACK performance measure "Percentage of health hazard evaluations completed by due date," the program reports 50 percent as its target for the first quarter of fiscal year 2017 and measured 89 percent of health hazard evaluations completed by their due dates. The FVM Program conducts health hazard evaluations to evaluate the scope and severity of hazards posed by foods sourced from animals that may have received unsafe drugs or consumed unsafe feed. By setting targets and collecting data for this and other performance measures, the FVM Program is assessing progress toward its strategic goals.

FVM Program management reviews developed performance measures through a quarterly performance review process. The quarterly performance review work group includes officials from the Office of Foods and Veterinary Medicine, the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine. According to officials

[76]FDA launched FDA-TRACK in April 2011. According to FDA, performance measures in FDA-TRACK represent the foundational activities and outputs produced by FDA employees.

we interviewed, the group reviews all FDA-TRACK and congressional budget justification performance measures related to the FVM Program. The work group examines opportunities to revise these measures in an effort to make progress toward intended public health outcomes, which are reflected in the FVM Program's strategic goals. For example, the performance measure "Average number of working days to serotype priority pathogens in food" supports the FVM Program's strategic goal for food safety.[77] Agency officials we interviewed told us that the work group identified an opportunity to improve the serotyping process in 2010. From fiscal years 2011 through 2017, the work group lowered serotyping targets, collected relevant data, and assessed the program's progress toward improving the serotyping process. Program officials told us that, in addition to the program's quarterly performance review work group, another work group meets twice monthly to review the extent to which FDA performance measures support FSMA requirements and show progress toward FSMA-related public health outcomes.

However, FDA has not developed performance measures for three of its eight food safety- and nutrition-related objectives as of January 2018, and as a result, the FVM Program cannot fully assess progress toward its food safety- and nutrition-related goals. For one of these objectives—the food safety objective related to the consumers' role—FDA developed indicators but did not set targets with time frames.[78] OMB defines a performance measure (which it refers to as a performance indicator) as an indicator for which a target is set with a time frame, and which will be used to track progress.[79] Therefore, an indicator alone—without targets or time frames—is not a performance measure.[80] For two of the FVM Program's three nutrition objectives—(1) monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional health status of Americans, and

[77]According to FDA documentation, faster serotyping enables FDA to more quickly detect foodborne pathogens and effectively respond to foodborne illness outbreaks.

[78]For example, for "the number of Center for Food Safety and Applied Nutrition website page views" indicator, the FVM Program captured quarterly data but did not set a quarterly target for the number of page views it hoped to achieve.

[79]An indicator, according to OMB, is a measurable value that indicates the state or level of something whereas a target is a quantifiable or otherwise measurable characteristic that tells how well or at what level an agency aspires to perform.

[80]Office of Management and Budget, *Preparation, Submission and Execution of the Budget*, OMB Circular No. A-11 (Washington, D.C.: July 2017).

(2) encourage and facilitate new products and product reformulation to promote a healthier food supply—FDA has not developed an indicator with a target and time frame. (See tables 11 and 12 in app. III for FDA performance measures for food safety- and nutrition-related activities.)

FVM Program officials acknowledged the need to develop performance measures that align with those three objectives for which the program has not yet developed measures. Officials told us they expect to complete the development of performance measures for these three food safety- and nutrition-related objectives by the end of the first quarter of fiscal year 2018. Officials we interviewed told us that the program has not yet developed performance measures for nutrition-related activities because management has first focused on updating the food safety-related performance measures since releasing the program's new strategic plan in July 2016. The officials said that management has focused on updating food safety-related performance measures because of the importance of implementing FSMA.

Leading practices in performance management state that federal programs should use performance information to achieve the mission and goals of those programs.[81] As previously noted, the FVM Program's goals are supported by strategic objectives. Strategic objectives serve as the primary unit of analysis for assessment of how a program is achieving its goals,[82] and each objective should be tracked through a set of performance measures that have targets with time frames.[83] Until FDA develops performance measures with associated targets and time frames for all eight of the FVM Program's food safety- and nutrition-related objectives, FDA cannot fully and accurately assess progress toward achieving its food safety- and nutrition-related goals.

[81]GPRA Modernization Act of 2010 (GPRAMA), Pub. L. No. 111-352, §8, 124 Stat. 3866, 3878 (codified at 31 U.S.C. § 1123(b)(1). Although GPRAMA's requirements apply at the departmental level (e.g., the Department of Health and Human Services), we have previously stated that they can serve as leading practices at other organizational levels, such as component agencies, offices, programs (e.g., the FVM Program), and projects. See, for example, GAO-17-49.

[82]OMB Cir. A-11, p. 210-6.

[83]OMB Cir. A-11, p. 210-7.

FDA's Planned Food Safety- and Nutrition-Related Activities to Focus on FSMA Implementation in 2018, but Time Frames for Longer-Term Activities Are Unclear

FDA has identified food safety- and nutrition-related activities that the FVM Program plans to undertake in fiscal year 2018, but its time frames for such activities in the longer term are unclear. According to the *Unified Agenda* of August 2017 and FDA's congressional budget justification for fiscal year 2018, the FVM Program's planned activities for fiscal year 2018 include regulations to enhance food labeling and continued FSMA implementation. However, the specific time frames for activities planned over the longer term are unclear because the FVM Program has not developed an implementation plan that identifies specific actions, priorities, and milestones for its 10-year strategic plan.

FDA's Planned Activities in 2018 Include Enhanced Food Labeling and Continued FSMA Implementation

FDA's plans for the FVM Program in fiscal year 2018 include publishing regulations to enhance food labeling, continued implementation of FSMA, and other food safety- and nutrition-related activities. For example, the *Unified Agenda* published in August 2017[84] identified two food safety- and nutrition-related regulations that FDA planned to publish within 12 months: (1) a proposed labeling rule concerning the use of health claims related to soy protein and coronary heart disease[85] and (2) a final rule on gluten-free labeling of fermented, hydrolyzed, or distilled foods.[86] In addition, the August 2017 *Unified Agenda* identified four food safety- and

[84]A subsequent *Unified Agenda* published in December 2017 provided an update on FDA's planned food safety- and nutrition-related regulations. It is not reflected in our report because of timing constraints.

[85]In October 2017, FDA published a proposed rule to revoke its regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease on the label or in the labeling of foods. FDA stated that it is taking this action based on its review of the totality of publicly available scientific evidence currently available and its tentative conclusion that such evidence does not support its previous determination that there is significant scientific agreement among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease. FDA seeks public comments on the proposed rule by Jan. 16, 2018. See 82 Fed. Reg. 50,324 (Oct. 31, 2017).

[86]The August 2017 *Unified Agenda* also identified two "long-term" food safety-related regulations regarding tolerances for residues of new animal drugs in food consumed by humans. The *Unified Agenda* defines long-term actions as items that are under development but for which the agency (in this case, FDA) does not expect to have a regulatory action within 12 months of a given *Unified Agenda* publication.

nutrition-related "inactive rules" that were still being reviewed or considered by FDA at that time.[87]

Furthermore, in September 2017, FDA announced in the *Federal Register* that the agency and many of its components—including the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine—were seeking public comments and information from interested parties until December 7, 2017, "to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction," while allowing the agency to achieve its mission and fulfill statutory obligations. On December 6, 2017, FDA extended the comment period to February 5, 2018. Thus, FDA's past food safety- and nutrition-related regulations were undergoing review as of January 2018.[88]

FDA's planned food safety- and nutrition-related activities also include finalizing draft guidance documents published since FSMA. While considering agency priorities and resources, FDA officials told us they plan to finalize food safety-related guidance such as on (1) mandatory food recalls, (2) current good manufacturing practice requirements for animal food, (3) arsenic in apple juice, and (4) proper labeling of honey and honey products. Regarding nutrition-related guidance, FDA plans to finalize draft guidance such as (1) a list of products for each of the product categories included in the tables of "Reference Amounts Customarily Consumed" relevant to the nutrition facts label, (2) agency views on the scientific evidence needed and the approach to evaluating scientific evidence on the physiological effects of isolated or synthetic non-digestible carbohydrates, and (3) helping vending machine operators

[87]The August 2017 *Unified Agenda* identified four FDA food safety- and nutrition-related "inactive rules" that were identified in previous editions of the *Unified Agenda* as planned regulations. Those inactive rules were (1) a laboratory accreditation rule, required by FSMA, that would enable FDA to recognize accredited bodies to ensure that food laboratories have appropriate equipment, personnel, and procedures to conduct reliable analyses; (2) a mandate requiring labels on food that has been refused admission into the United States; (3) current good manufacturing practices in the manufacturing, packing, labeling, or holding operations for dietary supplements; and (4) general principles and modernization of food standards.

[88]For the Center for Food Safety and Applied Nutrition's announcement, see 82 Fed. Reg. 42,503 (Sept. 8, 2017) and for the Center for Veterinary Medicine's announcement, see 82 Fed. Reg. 42,497 (Sept. 8, 2017). For FDA's extension of the comment period to February 5, 2018, see 82 Fed. Reg. 57,560 (Dec. 6, 2017).

and industry better understand and comply with a regulation regarding calorie labeling of food in vending machines.[89]

Other near-term activities for the FVM Program, identified as priorities in FDA's congressional budget justification for fiscal year 2018, include the following activities to be conducted by the Center for Food Safety and Applied Nutrition:

- working with industry to implement FSMA regulations, such as the produce safety rule;[90]
- responding to foodborne illness outbreaks;
- reviewing infant formula notifications from manufacturers before marketing a new formula;
- helping to ensure the safety of dietary supplements;
- conducting reviews of food ingredients and packaging, such as reviews of food additives and color additives;
- ensuring that foods are safe and properly labeled, including nutrient content and health claims; and
- postmarket monitoring for chemical contaminants.

In addition, FDA's congressional budget justification for fiscal year 2018 states that the Office of Regulatory Affairs will (1) maintain food manufacturing inspections conducted through state contracts and (2) strengthen state, local, and tribal regulatory programs to prevent foodborne illness and to reduce the occurrence of risk factors in retail and

[89]In addition, in January 2018, FDA officials informed us that the agency intends to publish guidance in the near future related to FSMA and the nutrition facts label's recently added sugar provision. Regarding FSMA, these guidance documents refer to (1) produce safety implementation and compliance (for non-water provisions), (2) additional chapters of the preventive controls for human foods guidance, (3) preventive controls for animal foods, (4) the Foreign Supplier Verification Program, and (5) "same level of public health protection guidance" related to several FSMA rules. Agency officials also noted that in November 2017, FDA published (1) supplemental, draft guidance on menu labeling for industry and (2) a small entity compliance guide for sanitary transport, related to FSMA.

[90]For more information on FDA's Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption—also known as the produce safety rule or, simply, the produce rule—see GAO, *Food Safety: FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule*, GAO-18-85 (Washington, D.C.: Nov. 27, 2017) and *Food Safety: FDA's Efforts to Evaluate and Respond to Business Concerns Regarding the Produce Rule*, GAO-17-98R (Washington, D.C.: Nov. 28, 2016).

food service operations. The fiscal year 2018 document also states that FDA's National Center for Toxicological Research will continue to conduct projects to limit the emergence and spread of drug resistance in bacterial pathogens that compromise the ability to treat foodborne illnesses.

For the Animal Drugs and Feeds Program—another component of the FVM Program, administered by the Center for Veterinary Medicine—FDA's congressional budget justification for fiscal year 2018 states that the agency will continue to conduct, among other things, the following activities:

- advancing FSMA efforts by implementing a modern, prevention-focused, science- and risk-based food and feed safety system;
- surveillance efforts, such as monitoring antimicrobial resistance among intestinal bacteria via a national antimicrobial resistance monitoring system;
- response efforts, such as utilizing laboratory capacity to assist FDA with investigations into potential problems with animal feeds and animal drugs;
- field inspections, investigations, and enforcement activities to ensure the adherence to laws that protect and advance human and animal health;
- enhancing the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain animal health, and do not compromise human health;
- monitoring the safety and effectiveness of animal drugs on the market,
- reviewing "adverse drug experience" reports,
- enforcing compliance actions, and
- reducing the availability of illegally marketed unapproved animal drugs.

Time Frames for Activities Planned for the Longer Term Are Unclear Because the FVM Program's 10-Year Strategic Plan Does Not Have an Implementation Plan

In the longer term, according to FDA officials, the agency plans to pursue the food safety and nutrition strategies that are identified in the FVM Program's 10-year strategic plan.[91] The strategic plan states that FDA places high priority on the implementation of FSMA, which requires sustained focus and commitment over an extended period and focuses on how FDA plans to modernize its food safety work, including:

- an increased focus on obtaining compliance with preventive control standards, rather than finding and responding to violations after an illness or outbreak has occurred;
- strengthening FDA technical expertise and capacity to support FDA and 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; and
- broadening interaction with foreign partners and increasing oversight of importers, who will have more responsibility for the safety of imported foods.

Beyond FSMA, the FVM Program's strategic plan also asserts that it provides greater focus on the agency's public health goals and objectives in the areas of nutrition and chemical safety and that organizational excellence will remain a central strategic priority to make the best use of available resources and to continue investing in FDA's workforce.[92]

The strategic plan also identifies 19 food safety and 9 nutrition strategies that support its food safety- and nutrition-related goals and objectives, as shown in appendix IV. For example, to support the food safety objective of improving prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents, the FVM Program has four strategies: (1) improve data analysis and collaboration with food and feed safety partners, including industry, academia, and other domestic and foreign regulatory bodies; (2) improve risk prediction and prioritization to focus FVM Program resources and the efforts of

[91]Food and Drug Administration, *FDA Foods and Veterinary Medicine Program Strategic Plan, Fiscal Years 2016-2025* (Washington, D.C.: July 14, 2016).

[92]The strategic plan states that FDA conducts a wide range of standard-setting and premarket oversight activities involving chemical safety, encompassing food and feed additives, dietary supplements, food packaging, chemical contaminants in food, and cosmetics.

regulatory partners on high-risk commodities and firms; (3) utilize knowledge gained from previous outbreaks and other incidents to better inform risk modeling, identify best practices, and increase compliance through voluntary corrective actions; and (4) improve collaboration and communication within the agency and among external stakeholders in order to improve the efficiency and effectiveness of FVM Program compliance actions.

To support the nutrition objective of providing and supporting accurate and useful nutrition information and education so that consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations, the FVM Program has four strategies: (1) improve the availability and accuracy of nutrition information provided to consumers by modernizing nutrition and supplement fact labels, and by expanding nutrition labeling to menus in restaurants, other retail establishments, and vending machines; (2) promote collaboration to advance the science underlying dietary guidance statements, medical food disease claims, and nutrition-related claims; (3) enhance understanding of how consumers notice, understand, and act on labeling and nutrition information, including nutrition facts labels, nutrition product claims, front-of-package nutrition labels, and dietary recommendations; and (4) promote collaboration with stakeholders, including industry, consumer, and public health groups, to enhance consumer nutrition education directed toward age and demographic groups with specific needs.

However, the specific time frames for the activities that would support the strategies identified in its 10-year strategic plan are unclear because the FVM Program has not developed a plan that includes specific actions, priorities, and milestones to implement these strategies. The FVM Program's strategic plan states that an implementation plan will identify the specific actions it will implement over a shorter time frame to achieve the strategic plan's objectives. In addition, the strategic plan states that the implementation plan will prioritize and sequence these actions, based on anticipated resources and other practical constraints, and identify initial and intermediate outcomes and performance measures to monitor progress. FDA officials told us that they expected to complete this implementation plan by the end of fiscal year 2017, but as of January 2018, they had not done so.

Our previous work, consistent with GPRAMA, sets forth several key elements of strategies that can guide agencies in planning and implementing an effective government program.[93] As noted in our prior work, elements such as specific actions, priorities, and milestones are desirable for evaluating progress, achieving results in specific time frames, and ensuring effective oversight and accountability. These elements can also be used to gauge progress when implementing programs and to determine whether adjustments need to be made in order to maintain progress within given time frames.[94] Until FDA completes an implementation plan that includes specific actions, priorities, and milestones for the FVM Program's strategic plan, it will be difficult for the agency to ensure it is prioritizing and sequencing the necessary actions to achieve its objectives.

Conclusions

Since FSMA's enactment, FDA has conducted numerous key food safety- and nutrition-related activities. For example, it has issued a number of food safety- and nutrition-related regulations and guidance to implement statutes, such as FSMA, and its strategic goals. FDA considered multiple factors in deciding between developing regulations or guidance, and its decisions went through multiple reviews. However, the agency did not uniformly document the bases for those decisions. Without uniformly documenting the bases for its decisions for issuing either regulations or guidance related to food safety and nutrition—such as by using concept papers or guidance initiation sheets—FDA cannot help ensure consistency and transparency in the decision-making process.

The FVM Program has set two goals and eight objectives for its food safety- and nutrition-related activities. FDA has developed performance measures to assess progress for some, but not all, of these objectives. Until FDA develops performance measures with associated targets and time frames for all eight of the FVM Program's food safety-and nutrition-related objectives, FDA cannot fully and accurately assess progress toward achieving its food safety- and nutrition-related goals.

[93]GAO, *Electronic Health Records: HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones*, GAO-14-242 (Washington, D.C.: Mar. 24, 2014), and *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

[94]See GAO/GGD/AIMD-99-69 and GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1996).

The FVM Program's 10-year strategic plan identifies several food safety- and nutrition-related strategies to be pursued by the program, but FDA has not developed an implementation plan—as called for in the strategic plan—that identifies the specific actions it will implement over a shorter time frame to achieve the strategic plan's objectives. Until FDA completes an implementation plan that includes specific actions, priorities, and milestones for the FVM Program's strategic plan, it will be difficult for the agency to ensure it is prioritizing and sequencing the necessary actions to achieve its objectives.

Recommendations for Executive Action

We are making the following three recommendations to FDA:

The Commissioner of FDA should ensure that FVM Program staff uniformly document the bases for their decisions for issuing either regulations or guidance related to food safety and nutrition, such as by using concept papers or guidance initiation sheets. (Recommendation 1)

The Commissioner of FDA should ensure that the FVM Program develops performance measures with associated targets and time frames for all eight of FDA's food safety- and nutrition-related objectives. (Recommendation 2)

The Commissioner of FDA should complete an implementation plan that includes specific actions, priorities, and milestones for the FVM Program's strategic plan. (Recommendation 3)

Agency Comments

We are providing a draft of this report to the Department of Health and Human Services for review and comment. In its comments, reproduced in appendix V, the Department of Health and Human Services generally concurred with our findings and recommendations and identified several actions that FDA intends to take to address our recommendations, as discussed below. FDA also provided technical comments, which we incorporated as appropriate.

In response to our first recommendation, the Department of Health and Human Services indicated that FDA has established internal documentation and review and clearance procedures for policy documents, including regulations and guidance, to ensure policy documents conform to Administrative Procedure Act requirements, FDA's Good Guidance Practices regulations, and executive orders. The department also indicated that FDA will share templates, such as concept

papers, as we recommended, and promote more consistent application across the FVM Program.

In response to our second recommendation, the department indicated that FDA is expanding the use of outcome-based performance measures to monitor and report programmatic impact, such as in implementing FSMA. In addition, the department stated that FDA is using its established processes for developing and refining performance measures to address our recommendation, with the goal of establishing new or refined measures to monitor the outcomes for each goal and objective in the FVM Program's strategic plan. Furthermore, the department stated that, as these measures are operationalized and mature, they will also include targets and timeframes, consistent with our recommendation.

In response to our third recommendation, the department indicated that FDA intends to develop and publish a plan to implement the FVM Program's strategic plan, which will identify specific actions, priorities, and milestones, as we recommended. The department also stated that FDA intends to draft this implementation plan by the fourth quarter of fiscal year 2018.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Commissioner of FDA, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who contributed to this report are listed in appendix VI.

Steve D. Morris
Director, Natural Resources and Environment

Appendix I: Key FDA Food Safety- and Nutrition-Related Regulations and Guidance Published from January 2011 through September 2017

Tables 4 and 5 provide information on the key food safety- and nutrition-related regulations and guidance, respectively, that the Food and Drug Administration (FDA) published from January 2011 through September 2017.

To identify these key FDA regulations and guidance, we relied on several sources, including (1) the *Unified Agenda* of *Federal Regulatory and Deregulatory Actions (Unified Agenda)*, (2) the *Federal Register*, and (3) various FDA websites. The *Unified Agenda*, published biannually by OMB, is a compilation of information about federal agencies' planned rulemaking actions. Specifically, to identify FDA's planned food safety- and nutrition-related rulemaking actions since the FDA Food Safety Modernization Act's (FSMA) enactment, we reviewed each *Unified Agenda* published from January 2011 through August 2017. To verify the status of these planned actions, we compared them with the proposed and final food safety- and nutrition-related regulations published in the *Federal Register*. To identify the food safety- and nutrition-related guidance that FDA published from January 2011 through September 2017, we reviewed FDA websites, including "FSMA Rules & Guidance for Industry," "Food Guidance Documents," and "Search for FDA Guidance Documents." In addition, we evaluated FDA's written responses to our questions on this topic and updated our lists of key food safety- and nutrition-related regulations and guidance, as appropriate. For the purposes of this report, proposed or draft, and subsequent final versions of the regulations and guidance that were published during the relevant time period were counted only once.

In describing FDA's food safety- and nutrition-related activities from January 2011 through September 2017, we use the term "key" to refer to regulations and guidance that are most relevant to and substantive for this review. Specifically, we included "Level 1" guidance, which FDA regulations define as those that set initial interpretations or more-than-minor changes to interpretations, are scientifically complex, or are likely to be highly controversial. We excluded "Level 2" guidance, which FDA regulations define as those that set forth existing practices or minor changes in interpretations.

To categorize the regulations and guidance as being related to food safety, nutrition, or both, we took several steps. Specifically, we analyzed FDA written responses providing descriptions of the terms food safety and nutrition, FDA documents describing the agency's food safety and nutrition activities and goals, and the regulations and guidance. Because we found no applicable statutory definition for food safety- or nutrition-

related activities, we relied on FDA's descriptions of food safety and nutrition—for example, those from FDA's strategic plans and interviews with agency officials.[1] We categorized the regulations and guidance as being related to food safety or nutrition depending on whether the regulations or guidance advanced FDA's efforts to achieve the food safety public health outcome or the nutrition public health outcome identified in the Foods and Veterinary Medicine (FVM) Program's strategic plan for fiscal years 2016 through 2025. These two outcomes were not assumed to be mutually exclusive because some of the agency's activities cut across both the food safety and nutrition categories. Thus, a document we categorized as advancing the food safety public health outcome could also be categorized as advancing the nutrition public health outcome and vice versa. In categorizing the regulations and guidance, we focused on the primary subject matter of the document and did not take into account how resources were dedicated; we acknowledge that resources are dedicated to either food safety or nutrition, but not both. Two analysts independently reviewed and coded the regulations and guidance, and a third analyst conducted a final review in cases where the first and second analysts disagreed. Ultimately, we reached agreement on all categorizations.

The FVM Program's public health outcomes are to be achieved through activities related to food for humans and animals, including food for pets and laboratory animals. However, the scopes of tables 4 and 5 are limited to the safety and nutrition of food for humans and food-producing animals (livestock such as cattle, poultry, and swine).

[1]FDA officials told us that the agency's food safety activities encompass a range of activities to prevent or mitigate contamination of food for humans and animals. They noted that FDA's nutrition activities also encompass a range of activities to improve nutritional status in humans and animals and to reduce the prevalence of diet-related risk factors for chronic disease. Some of the agency's activities, however, cut across these two categories and, therefore, are related to both food safety and nutrition. FDA officials added that the Center for Veterinary Medicine is not engaged in activities related to the nutritional status of animals and does not receive funding for nutrition activities.

Table 4: Key Food Safety- and Nutrition-Related Regulations Published by FDA from January 2011 through September 2017

Title	Subject	*Federal Register* number	Law(s) authorizing or requiring regulation	Status[a]	Date published
Temperature-Indicating Devices; Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers	FS	76 Fed. Reg. 11,892	Federal Food, Drug, and Cosmetic Act (FFDCA)	Final rule	3/3/2011
Beverages: Bottled Water Quality Standard; Establishing an Allowable Level for Di(2-ethylhexyl)phthalate	FS	76 Fed. Reg. 64,810	FFDCA	Final rule	10/19/2011
Animal Food Labeling; Declaration of Certifiable Color Additives	FS	76 Fed. Reg. 71,248	Nutrition Labeling and Education Act (amending FFDCA)	Final rule	11/17/2011
Import Tolerances for Residues of Unapproved New Animal Drugs in Food	FS	77 Fed. Reg. 3653	FFDCA	Proposed rule	1/25/2012
Animal Drugs, Feeds, and Related Products; Regulation of Carcinogenic Compounds in Food-Producing Animals	FS	77 Fed. Reg. 50,591	FFDCA	Final rule	8/22/2012
New Animal Drugs; Updating Tolerances for Residues of New Animal Drugs in Food	FS	77 Fed. Reg. 72,254	FFDCA	Proposed rule	12/5/2012
Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption	FS & N	78 Fed. Reg. 7994	FDA Food Safety Modernization Act (FSMA) (amending FFDCA)	Final rule	2/5/2013
Food Labeling; Gluten-Free Labeling of Foods	FS & N	78 Fed. Reg. 47,154	Food Allergen Labeling and Consumer Protection Act FFDCA	Final rule	8/5/2013
Information Required in Prior Notice of Imported Food	FS	78 Fed. Reg. 32,359	FSMA (amending FFDCA)	Final rule	5/30/2013
Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements	FS	79 Fed. Reg. 18,799	FSMA (amending FFDCA)	Final rule	4/4/2014
Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids	N	79 Fed. Reg. 23,262	FFDCA	Final rule	4/28/2014
Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula	FS & N	79 Fed. Reg. 33,057	Infant Formula Act (amending FFDCA)	Final rule	6/10/2014

Title	Subject	*Federal Register* number	Law(s) authorizing or requiring regulation	Status[a]	Date published
Food Labeling; Calorie Labeling of Articles of Food in Vending Machines	N	79 Fed Reg. 71,259	Patient Protection and Affordable Care Act (amending FFDCA)	Final rule	12/1/2014
Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments	N	79 Fed. Reg. 71,156	Patient Protection and Affordable Care Act (amending FFDCA)	Final rule	12/1/2014
Veterinary Feed Directive	FS	80 Fed. Reg. 31,708	FFDCA	Final rule	6/3/2015
Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements	FS & N	80 Fed. Reg. 35,834	FFDCA	Final rule	6/23/2015
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals	FS	80 Fed. Reg. 56,170	FSMA (amending FFDCA) Public Health Service Act	Final rule	9/17/2015
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	FS	80 Fed. Reg. 55,908	FSMA (amending FFDCA) Public Health Service Act	Final rule	9/17/2015
Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods	FS & N	80 Fed. Reg. 71,990	Food Allergen Labeling and Consumer Protection Act FFDCA	Proposed rule	11/18/2015
Artificially Sweetened Fruit Jelly and Artificially Sweetened Fruit Preserves and Jams; Revocation of Standards of Identity	N	80 Fed. Reg. 72,581	FFDCA	Final rule	11/20/2015
Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications	FS	80 Fed. Reg. 74,570	FSMA (amending FFDCA)	Final rule	11/27/2015
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals	FS	80 Fed. Reg. 74,226	FSMA (amending FFDCA) Public Health Service Act	Final rule	11/27/2015
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	FS	80 Fed. Reg. 74,354	FSMA (amending FFDCA) Public Health Service Act	Final rule	11/27/2015
Use of Materials Derived from Cattle in Human Food and Cosmetics	FS	81 Fed. Reg. 14,718	FFDCA	Final rule	3/18/2016

Title	Subject	*Federal Register* number	Law(s) authorizing or requiring regulation	Status[a]	Date published
Sanitary Transportation of Human and Animal Food	FS	81 Fed. Reg. 20,092	Sanitary Food Transportation Act FSMA	Final rule	4/6/2016
Antimicrobial Animal Drug Sales and Distribution Reporting	FS	81 Fed. Reg. 29,129	FFDCA	Final rule	5/11/2016
Food Labeling: Revision of the Nutrition and Supplement Facts Labels	N	81 Fed. Reg. 33,742	FFDCA Nutrition Labeling and Education Act	Final rule	5/27/2016
Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments	N	81 Fed. Reg. 34,000	FFDCA Nutrition Labeling and Education Act	Final rule	5/27/2016
Mitigation Strategies to Protect Food against Intentional Adulteration	FS	81 Fed. Reg. 34,166	FSMA (amending FFDCA)	Final rule	5/27/2016
Amendments to Registration of Food Facilities	FS	81 Fed. Reg. 45,912	FSMA (amending FFDCA) Bioterrorism Act	Final rule	7/14/2016
Substances Generally Recognized as Safe	FS	81 Fed Reg. 54,960	FFDCA	Final rule	8/17/2016
Amendments to Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications to Provide for the User Fee Program	FS	81 Fed. Reg. 90,186	FSMA (amending FFDCA)	Final rule	12/14/2016
Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease	N	81 Fed. Reg. 91,716	FFDCA	Interim final rule	12/19/2016

Legend: FS = food safety; N = nutrition; FS & N = food safety and nutrition

Source: GAO analysis of the *Federal Register*, the *Unified Agenda of Federal Regulatory and Deregulatory Actions*, and Food and Drug Administration (FDA) documents. | GAO-18-174

Note: Regulations establish legally binding requirements and are rooted in agencies' statutory authority. Regulations are included in this table only if they were proposed (with a proposed rule published in the *Federal Register*) or final (with a final rule or interim final rule published in the *Federal Register*) during the relevant time frame.

[a]Status indicates the agency "action" published in the *Federal Register*—final rule, interim final rule, or proposed rule.

Table 5: Key Food Safety- and Nutrition-Related Guidance Published by FDA from January 2011 through September 2017

Title	Subject	Status[a]	Date published
Guidance for Industry: Letter to Firms that Grow, Harvest, Sort, Pack, or Ship Fresh Cilantro	FS	Final	March 2011
Guidance for Industry: Questions and Answers About the Petition Process	FS	Final	April 2011
Guidance for Industry on Fish and Fishery Products Hazards and Controls, Fourth Edition	FS	Final	April 2011
Guidance for Industry: Enforcement Policy Concerning Certain Prior Notice Requirements	FS	Final	June 2011
Food Safety Modernization Act Domestic and Foreign Facility Reinspections, Recall, and Importer Reinspection User Fee Rates for Fiscal Year 2012	FS	Final	August 2011
What You Need to Know about Prior Notice of Imported Food Shipments	FS	Final	August 2011
Guidance for Industry: Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Pistachio-Derived Product as an Ingredient	FS	Final	September 2011
Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Comparative Metabolism Studies in Laboratory Animals	FS	Final	September 2011
Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study to Determine the Quantity and Identify the Nature of Residues	FS	Final	September 2011
Guidance for Industry on Implementation of the Fee Provisions of the FDA Food Safety Modernization Act	FS	Final	October 2011
Guidance for Industry on Evaluating the Safety of Flood-Affected Food Crops for Human Consumption	FS	Final	October 2011
Guidance for Industry: Letter to Firms that Grow, Harvest, Sort, Pack, Process, or Ship Fresh Cantaloupe	FS	Final	November 2011
Guidance for Industry: Prevention of *Salmonella enteritidis* in Shell Eggs During Production, Storage, and Transportation	FS	Final	December 2011
Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)	FS	Final	February 2012
Guidance for Industry: Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods	FS	Final	March 2012
Guidance for Industry on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals	FS	Final	April 2012
Guidance for Industry: The Seafood List – FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce	FS & N	Final	July 2012

Title	Subject	Status[a]	Date published
Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella enteritidis* in Shell Eggs During Production, Storage, and Transportation	FS	Final	August 2012
Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)	FS	Final	December 2012
Guidance for Industry: What You Need to Know About Registration of Food Facilities: Small Entity Compliance Guide	FS	Final	December 2012
Guidance for Industry: A Food Labeling Guide	FS & N	Final	January 2013
Guidance for Industry: What You Need to Know About Administrative Detention of Foods: Small Entity Compliance Guide	FS & N	Final	March 2013
Revised Guidance for Industry on "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological Acceptable Daily Intake (ADI)"	FS	Final	March 2013
Draft Interagency Risk Assessment—*Listeria monocytogenes* in Retail Delicatessens: Notice of Availability of Documents and Request for Comment	FS	Draft	May 2013
Draft Guidance for Industry on Arsenic in Apple Juice: Action Level; Supporting Document for Action Level for Arsenic in Apple Juice; A Quantitative Assessment of Inorganic Arsenic in Apple Juice	FS	Draft	July 2013
Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella enteritidis* in Shell Eggs During Production, Storage, and Transportation (Layers With Outdoor Access)	FS	Draft	July 2013
Guidance for FDA Staff: Compliance Policy Guide Sec. 690.800 CPG Sec. 690.800 *Salmonella* in Food for Animals	FS	Final	July 2013
Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act	FS	Final	September 2013
Draft Risk Profile on Pathogens and Filth in Spices	FS	Draft	November 2013
Guidance for Industry on Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning	FS	Final	November 2013
Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with Guidance for Industry #209	FS	Final	December 2013
Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages	FS & N	Final	January 2014
Compliance Policy Guide Regarding Canned Ackee, Frozen Ackee, and Other Ackee Products—Hypoglycin A Toxin	FS	Final	April 2014
Draft Guidance for Industry: Proper Labeling of Honey and Honey Products	FS & N	Draft	April 2014
Guidance for Industry: Food and Drug Administration Records Access Authority under the Federal Food, Drug, and Cosmetic Act	FS	Final	April 2014

Title	Subject	Status[a]	Date published
Guidance for Industry: What You Need to Know About Establishment, Maintenance, and Availability of Records: Small Entity Compliance Guide	FS	Final	April 2014
Compliance Policy Guide Regarding Food Facility Registration—Human and Animal Food	FS	Final	June 2014
Environmental Protection Agency and Food and Drug Administration Advice About Eating Fish	FS & N	Draft	June 2014
Guidance for Industry: Considering Whether a Food and Drug Administration-Regulated Product Involves the Application of Nanotechnology	FS & N	Final	June 2014
Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives	FS	Final	June 2014
Guidance for Industry: Demonstration of the Quality Factor Requirements for “Eligible” Infant Formulas	N	Final	June 2014
Questions and Answers Regarding Food Facility Registration (Sixth Edition); Guidance for Industry	FS	Final	November 2014
Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods; Revised Guidance for Industry	FS	Final	March 2015
Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies; Revised Guidance for Industry	FS	Final	March 2015
Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition	FS	Final	May 2015
Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition	FS	Final	May 2015
Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry	FS	Draft	May 2015
Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing; Revised Guidance for Industry	FS	Final	May 2015
Final Determination Regarding Partially Hydrogenated Oils	FS & N	Final	June 2015
Food Allergen Labeling Exemption Petitions and Notifications; Guidance for Industry	FS	Final	June 2015
Guidance for Industry: Cell-Based Products for Animal Use	FS	Final	June 2015
Recommendations for Preparation and Submission of Animal Food Additive Petitions; Guidance for Industry	FS	Final	June 2015
Joint Food and Drug Administration/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada	FS	Final	August 2015
Use of Nanomaterials in Food for Animals; Guidance for Industry	FS	Final	August 2015
Acceptance Criteria for Confirmation of Identity of Chemical Residues Using Exact Mass Data within the Office of Foods and Veterinary Medicine	FS	Final	September 2015

Title	Subject	Status[a]	Date published
Draft Compliance Policy Guide: Crotalaria spp. Seeds in Grains	FS	Draft	September 2015
Guidance for Industry: Colored Sea Salt	FS	Final	September 2015
Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm	FS	Final	September 2015
Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm	FS	Final	September 2015
Veterinary Feed Directive Regulation Questions and Answers; Small Entity Compliance Guide; Guidance for Industry	FS	Final	September 2015
Guidance for Industry: Questions and Answers on FDA's Fortification Policy	N	Final	November 2015
Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon; Draft Guidance for Industry	FS & N	Draft	November 2015
Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants; Guidance for Industry	FS & N	Final	November 2015
Acrylamide in Foods; Guidance for Industry	FS	Final	March 2016
Ensuring Safety of Animal Feed Maintained and Fed On-Farm; Guidance for Industry	FS	Final	March 2016
Compliance Policy Guide on Crabmeat—Fresh and Frozen—Adulteration with Filth, Involving the Presence of *Escherichia coli*	FS	Final	April 2016
Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports; Guidance for Industry	FS & N	Final	April 2016
Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry	FS	Draft	April 2016
A Labeling Guide for Restaurants and Retail Establishments Selling Away- From-Home Foods—Part II (Menu Labeling Requirements in Accordance With the Patient Protection Affordable Care Act of 2010); Guidance for Industry	N	Final	May 2016
Frequently Asked Questions About Medical Foods; Second Edition; Guidance for Industry	FS & N	Final	May 2016
Ingredients Declared as Evaporated Cane Juice; Guidance for Industry	N	Final	May 2016
Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food); Draft Guidance for Industry	FS	Draft	May 2016
Prior Notice of Imported Food Questions and Answers (Edition 3); Guidance for Industry	FS	Final	June 2016
Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry	N	Draft	June 2016
General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals; Draft Guidance for Industry	FS	Draft	July 2016

Title	Subject	Status[a]	Date published
The Food and Drug Administration's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels; Guidance for Industry	N	Final	July 2016
Calorie Labeling of Articles of Food in Vending Machines; Draft Guidance for Industry	N	Draft	August 2016
Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry	FS	Draft	August 2016
Current Good Manufacturing Practice Requirements for Food for Animals; Draft Guidance for Industry	FS	Draft	August 2016
Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry	FS	Draft	August 2016
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry	FS	Draft	August 2016
Human Food By-Products for Use as Animal Food; Draft Guidance for Industry	FS	Draft	August 2016
Compliance Policy Guide Sec. 150.200 Compliance Review of Private Laboratory Analytical Packages (PLAPs)	FS & N	Final	September 2016
Labeling of Infant Formula: Guidance for Industry	FS & N	Final	September 2016
Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories (2016 Edition): Guidance for Industry	FS	Final	September 2016
Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Draft Guidance for Industry	N	Draft	September 2016
Use of the Term "Healthy" in the Labeling of Human Food Products: Guidance for Industry	N	Final	September 2016
Veterinary Feed Directive Common Format Questions and Answers; Guidance for Industry	FS	Final	September 2016
Compliance Policy Guide: Section 101.100 FDA Considerations for Recommending Charges under 21 U.S.C.§331(a) or (d) for Causing the Introduction of Violative Products into Interstate Commerce	FS & N	Final	October 2016
Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry	FS	Draft	October 2016
Frequently Asked Questions About GRAS[b] for Substances Intended for Use in Human or Animal Food: Guidance for Industry	FS	Final	October 2016
Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry	N	Draft	November 2016
Use of the Seafood List to Determine Acceptable Seafood Names; Draft Compliance Policy Guide	FS & N	Draft	November 2016
Voluntary Qualified Importer Program; Guidance for Industry	FS	Final	November 2016
Compliance Policy Guide: Sec. 615.115 Extralabel Use of Medicated Feeds for Minor Species	FS	Final	December 2016

Title	Subject	Status[a]	Date published
Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk; Draft Guidance for Industry	FS	Draft	December 2016
Questions and Answers Regarding Food Facility Registration (Seventh Edition); Revised Draft Guidance for Industry	FS	Draft	December 2016
Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Guidance for Industry and Food and Drug Administration Staff	FS	Final	December 2016
Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations; Draft Guidance for Industry	FS	Draft	January 2017
Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Revised Draft Guidance for Industry	FS	Draft	January 2017
Draft Guidance for Industry: Study Design Recommendations for Residue Studies in Honey for Establishing Maximum Residue Limits and Withdrawal Periods	FS	Draft	January 2017
Guidance for Industry: Regulation of Intentionally Altered Genomic DNA in Animals: Draft Guidance	FS	Draft	January 2017
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; Draft Guidance for Industry	N	Draft	January 2017
Reference Amounts Customarily Consumed: List of Products for Each Product Category; Draft Guidance for Industry	N	Draft	January 2017
Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Programs Regulation: Guidance for Industry	FS	Final	March 2017
Clarification on Food Establishment Waiver from Requirements of the Sanitary Transportation of Human and Animal Food Rule: Guidance for Industry	FS	Final	August 2017
Juice HACCP[c] and the FDA Food Safety Modernization Act: Guidance for Industry	FS	Final	August 2017
Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act: Guidance for Industry	FS	Final	August 2017
Seafood HACCP[c] and the FDA Food Safety Modernization Act: Guidance for Industry	FS	Final	August 2017
Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose	FS	Final	August 2017
Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry	FS & N	Final	August 2017

Legend: FS = food safety; N = nutrition; FS & N = food safety and nutrition

Source: GAO analysis of the *Federal Register* and Food and Drug Administration (FDA) documents. | GAO-18-174

[a]Status indicates whether the guidance document is in draft or final form. Guidance documents are considered to be final if there is no indication—in the corresponding *Federal Register* notice or in the guidance document itself—of its being in draft form.

[b]GRAS stands for “generally recognized as safe.”

[c]HACCP stands for “Hazard Analysis and Critical Control Point.”

Appendix II: FDA Resources for Food Safety- And Nutrition-Related Activities, Fiscal Years 2011 through 2016

Tables 6 through 10 identify the resources—both obligations and full-time equivalents (FTE)—dedicated by three Food and Drug Administration (FDA) centers and one FDA office to specific food safety- and nutrition-related activities in fiscal years 2011 through 2016.

To determine these resources, we obtained and analyzed obligations and FTE data for each relevant center and office that carries out food safety- and nutrition-related activities. Data were obtained directly from FDA databases. Specifically, we requested information on the obligations and FTEs dedicated to various food safety- and nutrition-related activities in each fiscal year from 2011 through 2016—the most recently available data at the time of our report—by four FDA components that conducted food safety- and nutrition-related work: the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Office of Regulatory Affairs, and the National Center for Toxicological Research. These organizational components used time and attendance systems to identify staff hours spent on various food safety- and nutrition-related activities; FDA then converted those hours into FTEs. Specifically:

- The Center for Food Safety and Applied Nutrition used the Resource Reporting System Via Project, its voluntary time reporting system, which captures staff hours and resources for various activities.
- The Center for Veterinary Medicine used the Activity Time Reporting system, its mandatory time reporting system.
- The Office of Regulatory Affairs used the Field Accomplishment and Compliance Tracking System—its workflow management system, which captures staff time spent on domestic activities, such as inspections or sample analysis—as well as the Operational and Administrative System for Import Support, which captures staff time on certain import activities, such as sample collection and analysis and field exams.
- The National Center for Toxicological Research used the Project Management System, through which it tracks financial data, and the NCTR Experiment Activity Tracking System, through which it tracks hours worked on various activities.

To determine the obligations for salaries and benefits, FDA officials stated that they compared their FTE data with the agency's Unified Financial Management System. Obligations data include salaries, benefits, and operational funding. We reviewed the methods FDA used to compile the data; interviewed knowledgeable agency officials about the quality and completeness of the estimated data; and conducted tests to identify

obvious errors, outliers, and missing information. When we found errors or missing data, FDA officials corrected these errors and provided us with revised data. Based on FDA's methods for compiling the data, we assessed the reliability of the obligations and FTE data and determined that the data were sufficient and appropriate to support the conclusions reached in this report.

Center for Food Safety and Applied Nutrition resources for food safety-related activities include resources for cosmetics-related activities. For budget reporting purposes, the center uses "food safety" to encompass both types of activities. Based on our review of FDA data, we determined that the center's resources for cosmetics-related activities each fiscal year represented a small proportion of the center's reported resources for food safety-related activities.

Center for Veterinary Medicine obligations to food safety-related activities are based on estimates. The center does not track obligations of operational funds by Activity Time Reporting activity codes.

FDA generally considers the FDA Headquarters and Infrastructure's resources to be either for overhead or for supporting other agency activities. FDA Headquarters and Infrastructure data for fiscal years 2014 through 2016 are based on time reporting data, whereas data from fiscal years 2011 through 2013 are based on estimates because of time reporting limitations. We did not analyze FDA Headquarters and Infrastructure resources for specific food safety- and nutrition-related activities because activity-level data were not available from fiscal years 2011 through 2016.

Table 6: Obligations, Including Salaries for Full-Time Equivalent (FTE) Staff, Dedicated by FDA's Center for Food Safety and Applied Nutrition to Food Safety- and Nutrition-Related Activities, Fiscal Years 2011 through 2013

Dollars in millions

		2011		2012		2013	
	Activity	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**
Food safety	Detection and compliance	25.4	107	28.3	106	30.2	132
	Prevention and promotion	160.5	518	158.3	521	141.7	488
	Scientific capacity	56.1	193	65.6	200	62.9	248
Food safety total		**242.0**	**818**	**252.2**	**827**	**234.8**	**868**
Nutrition	Detection and compliance	0.4	3	0.5	2	0.4	2
	Prevention and promotion	7.5	49	11.2	51	8.6	45
	Scientific capacity	0.3	2	0.4	2	1.9	8
Nutrition total		**8.2**	**54**	**12.0**	**55**	**10.9**	**55**
Total		**250.2**	**872**	**264.3**	**882**	**245.7**	**923**

Source: GAO analysis of Food and Drug Administration (FDA data). | GAO-18-174

Note: Amounts are rounded and may not sum totals. In addition, the Center for Food Safety and Applied Nutrition's obligations and FTEs for specific categories of food safety- and nutrition-related activities in fiscal years 2011 through 2013 are not comparable with data from fiscal years 2014 through 2016. These data are not comparable because the center made changes to its time reporting system in fiscal year 2014.

Table 7: Obligations, Including Salaries for Full-Time Equivalent (FTE) Staff, Dedicated by FDA's Center for Food Safety and Applied Nutrition to Food Safety- and Nutrition-Related Activities, Fiscal Years 2014 through 2016

Dollars in millions							
		2014		2015		2016	
	Activity	Dollars	FTEs	Dollars	FTEs	Dollars	FTEs
Food safety	Compliance and enforcement	32.5	175	47.2	210	49.6	230
	Education and outreach	19.0	77	22.1	83	34.4	97
	Policy development	15.8	91	20.6	101	21.5	115
	Premarket review	16.1	71	15.2	90	15.0	89
	Regulatory science	96.7	190	108.5	256	111.9	267
	Risk assessment	27.3	116	17.7	51	18.5	54
	Stakeholder engagement	46.3	165	35.6	109	34.6	116
Food safety total		**253.7**	**884**	**266.9**	**900**	**285.5**	**969**
Nutrition	Compliance and enforcement	2.1	8	2.5	14	3.1	18
	Education and outreach	2.2	12	1.2	7	3.3	8
	Policy development	1.5	10	3.2	15	2.8	17
	Premarket review	0.0	0	0.4	0	0.8	0
	Regulatory science	5.2	20	5.2	21	7.8	22
	Risk assessment	0.3	1	0.1	1	0.1	1
	Stakeholder engagement	1.3	7	0.5	3	0.5	3
Nutrition total		**12.7**	**59**	**13.1**	**61**	**18.5**	**68**
Total		**266.4**	**943**	**280.0**	**961**	**304.0**	**1,037**

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

Note: Amounts are rounded and may not sum totals. In addition, the Center for Food Safety and Applied Nutrition's obligations and FTEs for specific categories of food safety- and nutrition-related activities in fiscal years 2011 through 2013 are not comparable with data from fiscal years 2014 through 2016. These data are not comparable because the center made changes to its time reporting system in fiscal year 2014.

Table 8: Obligations, Including Salaries for Full-Time Equivalent (FTE) Staff, Dedicated by FDA's Center for Veterinary Medicine to Food Safety-Related Activities, Fiscal Years 2011 through 2016

Dollars in millions

	2011		2012		2013		2014		2015		2016	
Activity	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**
Animal food safety	37.6	235	38.4	249	36.7	234	45.2	239	45.2	241	47.2	269
Antimicrobial resistance	20.2	50	20.1	50	16.3	53	16.3	53	16.3	53	16.3	53
Total	**57.9**	**285**	**58.4**	**299**	**53.0**	**287**	**61.5**	**292**	**61.5**	**294**	**63.5**	**322**

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

Note: Amounts are rounded and may not sum to totals.

Table 9: Obligations, Including Salaries for Full-Time Equivalent (FTE) Staff, Dedicated by FDA's National Center for Toxicological Research to Food Safety-Related Activities, Fiscal Years 2011 through 2016

Dollars in millions

	2011		2012		2013		2014		2015		2016	
Activity	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**
Antimicrobial resistance	3.1	13	1.8	9	2.8	12	2.0	10	2.4	9	2.5	15
Dietary supplements	1.9	7	2.1	10	1.6	3	1.3	2	1.0	2	4.0	10
Other food safety	5.7	28	6.3	27	7.7	41	6.9	35	6.8	34	3.8	24
Total	**10.8**	**48**	**10.2**	**46**	**12.1**	**56**	**10.2**	**47**	**10.2**	**45**	**10.2**	**49**

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

Note: Amounts are rounded and may not sum to totals.

Table 10: Obligations, Including Salaries for Full-Time Equivalent (FTE) Staff, Dedicated by FDA's Office of Regulatory Affairs to Food Safety- and Nutrition-Related Activities, Fiscal Years 2011 through 2016

Dollars in millions

		2011		2012		2013		2014		2015		2016	
	Activity	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**	**Dollars**	**FTEs**
Food safety	Domestic inspections	163.8	804	153.7	727	117.1	616	116.3	582	120.3	604	140.4	703
	Domestic field exams	35.4	174	32.9	156	33.9	179	34.0	171	31.2	158	34.7	176
	Other domestic activities	133.2	569	155.5	607	148.8	634	201.5	735	216.4	775	256.5	744
	Foreign inspections	12.2	60	16.5	78	15.4	81	16.2	81	15.6	78	14.4	72
	Other foreign activities	11.6	56	12.3	58	14.7	75	16.7	82	16.8	83	24.5	102
	Import field exams	130.4	642	120.2	571	107.3	572	99.6	506	94.7	483	103.0	525
	Import label reviews	27.4	137	22.8	111	18.8	106	18.0	97	16.3	89	18.7	99
	Other import activities, such as laboratory resources	98.9	467	117.3	530	121.9	607	145.8	670	142.4	654	141.6	633
Food safety total		**612.9**	**2,909**	**631.3**	**2,838**	**577.8**	**2,870**	**648.1**	**2,924**	**653.7**	**2,924**	**733.7**	**3,054**
Nutrition	Domestic inspections	1.3	6	1.6	7	1.0	4	1.0	4	1.3	5	2.6	10
	Domestic field exams	0.9	4	0.9	4	0.7	3	0.8	3	1.0	4	2.3	9
	Other domestic activities	—	—	—	—	—	—	.3	1	—	—	.3	1
	Foreign inspections	0.2	1	0.2	1	0.2	1	0.3	1	0.3	1	0.3	1
	Import field exams	2.8	13	2.3	10	2.4	10	2.8	11	2.0	8	4.7	18
	Import label reviews	6.5	30	6.4	28	5.3	22	5.5	22	6.1	24	4.7	18
Nutrition total		**11.8**	**54**	**11.5**	**50**	**9.6**	**40**	**10.5**	**42**	**10.7**	**42**	**14.8**	**57**
Total		**624.7**	**2,963**	**642.8**	**2,888**	**587.4**	**2,910**	**658.6**	**2,966**	**664.4**	**2,966**	**748.5**	**3,111**

Legend: — = not applicable

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

Note: Amounts are rounded and may not sum to totals.

Appendix III: FDA Performance Measures for Food Safety- and Nutrition-Related Activities, Fiscal Year 2017

This appendix contains information on our analysis of the Foods and Veterinary Medicine (FVM) Program's performance measures in fiscal year 2017. The results of our analysis show how performance measures enable Food and Drug Administration (FDA) officials to assess progress toward the program's strategic goals for food safety- and nutrition-related activities. We conducted this analysis by evaluating the extent to which each FVM Program performance measure active in fiscal year 2017 aligns with food safety- and nutrition-related strategic objectives identified in the *FDA Foods and Veterinary Medicine Program Strategic Plan, Fiscal Years 2016-2025*. (See tables 11 and 12 for results.) According to FDA documentation, these objectives, in conjunction with performance measures, provide FVM Program officials with the information they need to assess how the program's efforts are helping it achieve the program's strategic goals.

In identifying the population of performance measures relevant to our analysis, we included only FVM Program performance measures for activities that affect the safety or nutrition of food for humans or food-producing animals. We excluded from our analysis performance measures for activities that do not affect the safety of foods consumed by humans, such as activities exclusively related to FDA's oversight of pet food.

Using a methodology similar to the one described in appendix I, we took several steps to categorize the performance measures as being related to food safety, nutrition, or both. Specifically, two analysts independently coded the performance measures as aligning with one or more of the FVM Program's strategic objectives and intended public health outcomes for food safety and nutrition. A third analyst conducted a final review in cases where the first and second analysts disagreed. Ultimately, we reached agreement on all categorizations. In tables 11 and 12, we list the performance measures related to food safety and nutrition, respectively.

Based on our analysis, some performance measures align with both food safety and nutrition objectives. For example, we have determined that the performance measure related to the "number of import food field exams" aligns with the three objectives related to preventive control standards, additives and dietary supplements, and nutrition information and education. We made this determination because field exams likely contribute to higher compliance rates with food safety preventive control standards, include checks for non-permitted additives, and include checks for labeling compliance. Measures that align with both food safety and nutrition objectives are included in both tables 11 and 12.

Table 11: FDA Foods and Veterinary Medicine (FVM) Program Performance Measures for Food Safety-Related Activities in Fiscal Year 2017, by Measure Title and Office or Center

Measure title	Source[a]	FDA office or center
The average number of working days to serotype priority pathogens in food (screening only)	CBJ	Center for Food Safety and Applied Nutrition
Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt	CBJ	Center for Food Safety and Applied Nutrition
GenomeTrackr Program[b]	FDA-TRACK	Center for Food Safety and Applied Nutrition
Human pathogen on plants	FDA-TRACK	Center for Food Safety and Applied Nutrition
New technologies/methodologies to assess chemical food safety	FDA-TRACK	Center for Food Safety and Applied Nutrition
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	CBJ	Center for Food Safety and Applied Nutrition
Percentage of "generally recognized as safe" notification reviews completed by Center for Food Safety and Applied Nutrition during the quarter within 180 days of filing	FDA-TRACK	Center for Food Safety and Applied Nutrition
Percentage of analytical package reviews[c] received via FDA's electronic Compliance Management System that meet Office of Compliance timeframes as specified in the quarter	FDA-TRACK	Center for Food Safety and Applied Nutrition
Promote safe production of molluscan shellfish for human consumption: vibrio forecasting and assistance	FDA-TRACK	Center for Food Safety and Applied Nutrition
Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Campylobacter species	CBJ	Center for Food Safety and Applied Nutrition
Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species	CBJ	Center for Food Safety and Applied Nutrition
Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7	CBJ	Center for Food Safety and Applied Nutrition
Reducing foodborne illness in the population. Work with federal, state, local, tribal, and industry partners, improve preventive controls in food production facilities and reduce the incidence rate (reported cases per 100,000 population per year) of *Listeria monocytogenes* infections	CBJ	Center for Food Safety and Applied Nutrition
Sequencing-based analytical methods for microbial contaminant detection	FDA-TRACK	Center for Food Safety and Applied Nutrition
Complete review and action on non-administrative abbreviated new animal drug applications and reactivations of such applications received during the fiscal year	CBJ	Center for Veterinary Medicine
Complete review and action on original new animal drug applications and reactivations of such applications received during the fiscal year	CBJ	Center for Veterinary Medicine
Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting firms to identified deviations in order to become compliant	CBJ	Center for Veterinary Medicine

Measure title	Source[a]	FDA office or center
Percentage of "generally recognized as safe" notifications reviewed by the Center for Veterinary Medicine within 300 days	FDA-TRACK	Center for Veterinary Medicine
Percentage of health hazard evaluations completed by due date	FDA-TRACK	Center for Veterinary Medicine
Percentage of warning letter recommendation packages reviewed within 25 days	FDA-TRACK	Center for Veterinary Medicine
Total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed including pet food contamination events	CBJ	Center for Veterinary Medicine
As required by the FSMA Legislation, cover 100 percent of the High Risk domestic inventory (approximately 19,500 firms) every 3 years	CBJ	Office of Regulatory Affairs
Increase laboratory surge capacity in the event of terrorist attack on the food supply (radiological and chemical samples per week)	CBJ	Office of Regulatory Affairs
Number of domestic and foreign high-risk animal drug and feed inspections	CBJ	Office of Regulatory Affairs
Number of examinations of FDA refused entries[d]	CBJ	Office of Regulatory Affairs
Number of filer evaluations[e]	CBJ	Office of Regulatory Affairs
Number of import food field exams	CBJ	Office of Regulatory Affairs
Number of prior notice import security reviews[f]	CBJ	Office of Regulatory Affairs
Number of targeted prohibited bovine spongiform encephalopathy (mad cow disease) inspections	CBJ	Office of Regulatory Affairs

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

[a]"CBJ" refers to FDA's *Justification of Estimates for Appropriations Committees* (congressional budget justification) for fiscal year 2017, and FDA-TRACK is FDA's agency-wide performance management system.

[b]Through its GenomeTrackr program, FDA intends to create a network of public health laboratories using whole genome sequencing to investigate foodborne illness outbreaks. Whole genome sequencing provides opportunities to stop outbreaks sooner than possible through traditionally used methods.

[c]FDA uses a network of laboratories to analyze regulated products and monitor compliance with regulations. If laboratory analysis shows a food or dietary supplement is potentially unsafe, FDA reviews the analytical packages to determine if regulatory actions should be taken.

[d]FDA-regulated products can be refused entry in the United States if they do not meet relevant laws and regulations. FDA is responsible for ensuring that these products are either destroyed or exported. In cooperation with U.S. Customs and Border Protection, FDA at times supervises the destruction or exportation of refused entries ("follow-up to refusal").

[e]Import filers send data to FDA, which the agency uses to assess the admissibility of potential imports. FDA conducts filer evaluations on a routine basis to determine whether filers are submitting accurate data. Evaluations are conducted by examining entry documents and comparing the information against data filed by importers.

[f]Importers of human food and animal feed are required to give FDA "prior notice" of their products being offered for entry into the United States. According to FDA, every prior notice is electronically screened. Those identified as high risk receive a security review.

Table 12: FDA Foods and Veterinary Medicine (FVM) Program Performance Measures for Nutrition-Related Activities in Fiscal Year 2017, by Measure Title and Office or Center

Measure title	Source[a]	FDA Office or center
As required by the FDA Food Safety Modernization Act, cover 100 percent of the high-risk domestic inventory (approximately 19,500 firms) every 3 years	CBJ	Office of Regulatory Affairs
Number of examinations of FDA refused entries[b]	CBJ	Office of Regulatory Affairs
Number of filer evaluations[c]	CBJ	Office of Regulatory Affairs
Number of import food field exams	CBJ	Office of Regulatory Affairs
Percentage of analytical package reviews[d] received via FDA's electronic Compliance Management System that meet Office of Compliance timeframes as specified in the quarter	FDA-TRACK	Center for Food Safety and Applied Nutrition

Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-174

[a]"CBJ" refers to FDA's *Justification of Estimates for Appropriations Committees* (congressional budget justification) for fiscal year 2017, and FDA-TRACK is FDA's agency-wide performance management system.

[b]FDA-regulated products can be refused entry in the United States if they do not meet relevant laws and regulations. FDA is responsible for ensuring that these products are either destroyed or exported. In cooperation with U.S. Customs and Border Protection, FDA at times supervises the destruction or exportation of refused entries ("examinations").

[c]Import filers send data to FDA, which the agency uses to assess the admissibility of potential imports. FDA conducts filer evaluations on a routine basis to determine whether filers are submitting accurate data. Evaluations are conducted by examining entry documents and comparing the information against data filed by importers.

[d]FDA uses a network of laboratories to analyze regulated products and monitor compliance with regulations. If laboratory analysis shows a food or dietary supplement is potentially unsafe, CFSAN reviews the analytical packages to determine if regulatory actions should be taken.

Appendix IV: FDA Foods and Veterinary Medicine Program's Goals, Objectives, and Strategies for Food Safety and Nutrition, Fiscal Years 2016 through 2025

Table 13 shows the Food and Drug Administration (FDA) Foods and Veterinary Medicine Program's goals, objectives, and strategies for food safety and nutrition, according to the program's strategic plan for fiscal years 2016 through 2025.

Table 13: Food and Drug Administration's (FDA) Foods and Veterinary Medicine (FVM) Program's Goals, Objectives, and Strategies for Food Safety and Nutrition, Fiscal Years 2016 through 2025

Goal	Objective	Strategy
Food safety	Establish and gain high rates of compliance with science-based preventive control standards across the global farm-to-table continuum.	Develop and implement a robust communication, training, and technical assistance plan for preventive control standards.
		Utilize innovative inspection and compliance strategies, backed by administrative and judicial enforcement tools to foster compliance with preventive control standards.
		Evaluate and improve the effectiveness of preventive control standards.
		Evaluate and mitigate the risks of chemical exposures in food and feed products that pose public health or regulatory concerns.
		Evaluate and mitigate the risks of microbiological hazards in food and feed products.
	Improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents.	Improve data analysis and collaboration with food and feed safety partners, including industry, academia, and other domestic and foreign regulatory bodies.
		Improve risk prediction and prioritization to focus FVM resources and the efforts of regulatory partners on high-risk commodities and firms.
		Utilize knowledge gained from previous outbreaks and other incidents to better inform risk modeling, identify best practices, and increase compliance through voluntary corrective actions.
		Improve collaboration and communication within the agency and among external stakeholders in order to improve the efficiency and effectiveness of FVM compliance actions.
	Strengthen the ability of consumers to play a proactive role in minimizing food safety risks.	Increase research, data analysis, and systematic evaluation to improve the effectiveness of food safety education in changing unsafe consumer food-handling behaviors.
		Increase consumer-based communications and outreach regarding safe food-handling practices, including leveraging a variety of community-based education programs.
		Enhance communication to consumers during and following illness outbreaks.
	Enhance the safety of food and feed additives and dietary supplements.	Implement innovative regulatory and compliance strategies to improve pre-market oversight and safety evaluation of food and feed additives, generally regarded as safe substances, and FDA's ability to verify that substances added to the food supply meet applicable safety standards.

Goal	Objective	Strategy
		In collaboration with external stakeholders, including regulatory and scientific partners, improve data-driven, post-market surveillance of substances added to the food supply to understand and assess changing use and intake patterns, emerging toxicological data, and adverse event reports.
		Make innovative use of FDA resources and collaborative initiatives with regulatory partners and industry to achieve the goals of FDA's dietary supplement Good Manufacturing Practice regulation and other standards related to the safety, quality, identity, and integrity of dietary supplements.
		Expand consumer and health care provider education regarding safe use of dietary supplements.
	Strengthen existing partnerships with international, federal, state, local, tribal, and territorial agencies to improve the effectiveness and efficiency of the FDA's food safety program for government and industry.	Enhance leveraging of food safety efforts with domestic and international regulatory and public health partners.
		Increase engagement and partnerships with domestic and international intergovernmental organizations to strengthen food safety capacity-building and food safety standards development.
		Utilize the Partnership for Food Protection[a] and its fiscal year 2015-2020 strategic plan to continue to build the national Integrated Food Safety System[b] domestically.
Nutrition	Provide and support accurate and useful nutrition information and education so consumers can choose healthier diets consistent with the Dietary Guidelines for Americans and other evidence-based recommendations.	Improve the availability and accuracy of nutrition information provided to consumers by modernizing nutrition and supplement fact labels, and by implementing the expansion of nutrition labeling to menus in restaurants, other retail establishments, and vending machines.
		Promote collaboration to advance the science underlying dietary guidance statements, medical food disease claims, and nutrition-related claims.
		Enhance understanding of how consumers notice, understand, and act on labeling and nutrition information, including nutrition facts labels, nutrition product claims, front-of-package nutrition labels, and dietary recommendations.
		Promote collaboration with stakeholders, including industry, consumer, and public health groups, to enhance consumer nutrition education directed toward age and demographic groups with specific needs.
	Monitor and assess emerging nutrition science as well as changes in the composition of foods in the marketplace in relation to the nutritional and health status of Americans.	Enhance the FVM Program's capacity to gather and analyze information about the composition and labeling of foods in the marketplace.
		Collaborate with federal partners who conduct food intake surveys to monitor overall intake of nutrients and food-related components in the U.S. population, and assess the effect of FVM initiatives on population intake (overall and in subpopulations of interest), risk factors for chronic disease, and health outcomes.
		Enhance the FVM Program's capacity to review and respond to emerging scientific and technological issues in food and nutrition.
	Encourage and facilitate new products and product reformulation to promote a healthier food supply.	Improve the nutritional profile of foods through mechanisms such as labeling, voluntary industry guidelines, and utilizing additional regulatory authorities where appropriate.

Goal	Objective	Strategy
		Collaborate with stakeholders to encourage research into healthful ingredient substitutes to support development and reformulation of healthier food options.

Source: FDA *Foods and Veterinary Medicine Program Strategic Plan*, Fiscal Years 2016-2025. | GAO-18-174

[a]The Partnership for Food Protection is a collaborative partnership of federal, tribal, state, and local governments that is intended to develop and implement procedures, best practices, and other work products that would advance integration of the U.S. food safety system.

[b]The FDA Food Safety Modernization Act, which was signed into law in January 2011, provided a mandate for FDA to build a national, integrated food safety system by taking steps to better integrate its food safety oversight with that of states, localities, tribes, and territories.

Appendix V: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JAN 18 2018

Steve Morris
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities*" (GAO-18-174).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Barbara Pisaro Clark

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - FOOD SAFETY AND NUTRITION: FDA CAN BUILD ON EXISTING EFFORTS TO MEASURE PROGRESS AND IMPLEMENT KEY ACTIVITIES (GAO-18-174)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report. The Food and Drug Administration (FDA) is committed to delivering public health outcomes by modernizing the food safety system and empowering consumers to make healthier food choices. FDA is making good progress moving towards a preventive food safety framework with the implementation of the FDA Food Safety Modernization Act (FSMA). In addition, implementation of the new Nutrition Facts label for packaged foods will make it easier for consumers to make better informed food choices. The Agency is also restructuring its Office of Regulatory Affairs, implementing a commodity-based and vertically-integrated structure, to streamline regulatory programs and better deliver public health outcomes.

As FDA continues modernization efforts, the Agency is committed to having clear implementation plans for its strategic goals and objectives and communicating its path forward to the public. FDA is also modernizing its metrics to focus on measures that demonstrate enhanced health outcomes for consumers. FDA plans to use this work to mature from primarily process-focused performance measures to outcome-based performance

Recommendation 1
The Commissioner of FDA should ensure that program staff uniformly document the bases for their decisions for issuing either regulations or guidance related to food safety and nutrition, such as using concept papers or guidance initiation sheets.

HHS Response
HHS concurs with GAO's recommendation.

FDA has established internal documentation and review and clearance procedures for policy documents, including regulations and guidances, to ensure policy documents conform to Administrative Procedure Act requirements, FDA's Good Guidance Practices regulations, and Executive Orders. FDA will continue to work with its offices to share templates, such as concept papers, and promote more consistent application across the Food and Veterinary Medicine (FVM) Program.

Recommendation 2
The Commissioner of FDA should ensure that program develops performance measures with associated targets and time frames for all eight of FDA's food safety-and nutrition-related objectives.

HHS Response
HHS concurs with GAO's recommendation.

FDA uses outcome-based performance measures for the preparation, submission, and execution of the budget. As a long-term commitment to effective management of FDA programs, FDA is expanding the use of outcome-based performance measures to monitor and report programmatic

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - FOOD SAFETY AND NUTRITION: FDA CAN BUILD ON EXISTING EFFORTS TO MEASURE PROGRESS AND IMPLEMENT KEY ACTIVITIES (GAO-18-174)

impact. For example, FDA developed frameworks to define the intermediate and strategic outcomes that inform planning and illustrate the successful implementation of FSMA. The resulting performance measures monitor progress towards the accomplishment of the FSMA public health outcome objective of the American food supply becoming safer. This expanded use of outcome-based performance measures is a result of the FDA's commitment to the effective management of available resources to provide the maximum public health gains.

In 2016, FDA began the process of refining, developing and maturing performance measures aligned to the FVM Strategic Plan and FSMA. Upon completing the transition to the new FVM Program Strategic Plan for Fiscal Years 2016-2025, FDA's existing performance management processes identified that several of FVM's strategic objectives – both food safety and nutrition-related – did not have performance measures. Also identified was the need to mature from primarily process, or output, performance measures to outcome-based performance measures. By addressing both topics, FDA will increase its ability to track and monitor progress for both the FVM Strategic Plan and FSMA. FDA is using its established processes for the development and refinement of performance measures to address this recommendation with the goal of establishing new or refined measures to monitor the outcomes for each goal and objective in the FVM Strategic Plan. As these measures are operationalized, they will be integrated into existing performance management processes and will, as the measures mature, include targets and timeframes.

Recommendation 3
The Commissioner of FDA should complete an implementation plan that includes specific action, priorities, and milestones for the program's strategic plan.

HHS Response
HHS concurs with GAO's recommendation.

In 2018, FDA is committed to the finalization of a recurring implementation planning process that will be used to develop and publish a report. The implementation plan will identify the actions that the FVM Program will execute to accomplish the objectives identified in the FVM Strategic Plan. It will include a prioritization of specific activities and include milestones to achieve over a shorter time span. Additionally, the implementation plan will identify initial and immediate results that will align with existing FDA strategic planning and performance management processes to develop or refine performance measures to ensure that progress can be monitored for each strategic objective. FDA intends to have a draft implementation plan by the 4th quarter of FY 2018.

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Steve D. Morris, (202) 512-3841 or morriss@gao.gov

Staff Acknowledgments

In addition to the contact named above, Anne K. Johnson (Assistant Director), Josey Ballenger (Analyst-in-Charge), Yue Pui Chin, and J. Daniel Paulk made major contributions to this report. Tim Bober, Kevin S. Bray, Alexandra Edwards, Cindy Gilbert, Carol Henn, Benjamin T. Licht, and Cynthia Norris also made important contributions to this report.

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