



May 2016

FOOD SAFETY

FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed

Accessible Version

GAO Highlights

Highlights of [GAO-16-425](#), a report to the Committee on Health, Education, Labor, and Pensions, U.S. Senate

Why GAO Did This Study

The safety and quality of the U.S. food supply are governed by a complex system involving more than 3,000 federal as well as nonfederal agencies at the state, local, tribal, and territorial levels. In 2011, FSMA mandated that FDA take steps that would better integrate its food safety oversight with that of nonfederal agencies. These steps relate to three new FSMA-mandated rules on produce, human food, and animal food. Among other things, FSMA required FDA to coordinate with nonfederal agencies in the areas of rule development, rule implementation, and regulator training.

GAO was asked to review FDA's coordination with nonfederal agencies on food safety, particularly in relation to FSMA. This report examines—for the rules on produce, human food, and animal food—the extent to which FDA has (1) met its regulatory consultation responsibilities in developing the rules, (2) developed plans to coordinate implementation of the rules, and (3) developed and administered plans for training regulators on the rules. GAO reviewed documentation; analyzed comments from nonfederal agencies on FDA rulemaking; and interviewed officials from FDA, associations of nonfederal officials, and industry, public interest, and other groups.

What GAO Recommends

GAO recommends that FDA (1) make certain that its tribal consultation policy explicitly provides for early tribal consultation and (2) develop a timetable for finalizing the policy. GAO provided a draft of this report to FDA. FDA agreed with these recommendations.

View [GAO-16-425](#). For more information, contact Steve D. Morris at (202) 512-3841 or morris@gao.gov.

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FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed

What GAO Found

The Food and Drug Administration (FDA) took numerous steps to ensure meaningful and timely input from nonfederal officials during development of the FDA Food Safety Modernization Act (FSMA)-mandated rules on produce, human food, and animal food but did not fully meet its tribal consultation responsibilities. Among other things, FDA—an agency within the Department of Health and Human Services (HHS)—held 13 public meetings and offered extended comment periods on the rules. However, FDA did not consult with Indian tribes before publication of the proposed rules, as directed by the HHS tribal consultation policy. Under that policy, each HHS agency is to establish its own tribal consultation policy, which should include an accountable process to ensure meaningful and timely input by tribal officials. FDA has begun to develop such a policy and issued a draft in late February 2016. FDA's draft policy, however, does not explicitly provide for early consultation on all rules with tribal implications. Without early consultation, tribes are unable to provide input at a time when it is most likely to have a meaningful impact on FDA's decision making. Moreover, FDA has not established a timetable to guide the policy's finalization, without which FDA risks continued delays.

FDA has begun to develop plans to ensure compliance with the FSMA-mandated rules through coordinated implementation with nonfederal agencies and is working to overcome related challenges. For example, according to FDA, insufficient data exist on businesses subject to the rules, making it difficult to assign inspection responsibilities, among other things. In response, FDA is taking steps, such as exploring new data sources. In addition, associations of nonfederal officials that GAO interviewed stated that nonfederal agencies have varying legal authorities and regulatory structures. For example, they stated that most nonfederal agencies lack authority to oversee produce, which is needed for coordinated implementation. In response, FDA is taking steps such as funding the National Association of State Departments of Agriculture's development of a model produce rule that states can adopt. Associations suggested that FDA consider opportunities to improve coordinated implementation, including establishing a system to share information on industry compliance and a process to answer questions from regulators on the rules. According to FDA, it is taking steps to implement these and other suggestions. For example, FDA is developing a new system to allow regulators to access information housed in existing FDA information systems before, during, and after an inspection.

FDA has developed, and begun to administer, a plan for training regulators on the human and animal food rules. As of February 2016, FDA had begun to develop, but not to administer, a plan for training regulators on the produce rule. FDA is working to overcome challenges related to regulator training. For example, one challenge relates to the thousands of regulators who must be trained. FDA plans to, among other things, use a phased training strategy, administering training in 2016 to regulators in areas with the highest concentrations of large businesses, for which compliance is due first; in 2017 to regulators in areas with the highest concentrations of small businesses, for which compliance is due later; and in 2018 to regulators in areas with the highest concentrations of very small businesses, for which compliance is due last.

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Abbreviations

AFDO	Association of Food and Drug Officials
CDC	Centers for Disease Control and Prevention
CGMP	Current Good Manufacturing Practice requirement
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
FSPCA	Food Safety Preventive Controls Alliance
HHS	Department of Health and Human Services
NASDA	National Association of State Departments of Agriculture
OCAR	Observation Corrective Action Reporting
OMB	Office of Management and Budget
PFP	Partnership for Food Protection
PRA	Paperwork Reduction Act
PSA	Produce Safety Alliance

SSA	Sprout Safety Alliance
UMRA	Unfunded Mandates Reform Act of 1995
USDA	U.S. Department of Agriculture

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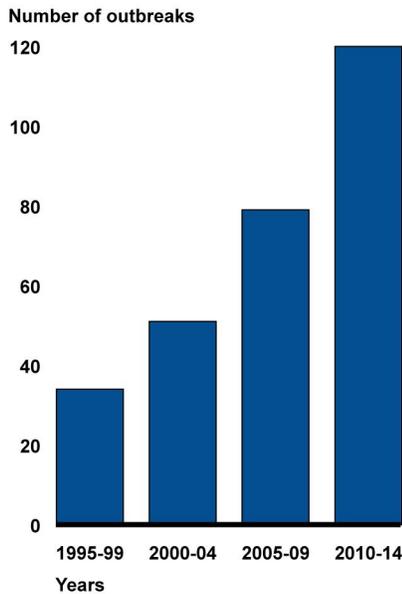


May 19, 2016

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

According to the Centers for Disease Control and Prevention (CDC), the U.S. food supply is one of the safest in the world. Nevertheless, foodborne illness remains a costly, common public health problem. Two independent studies published in 2012 estimated the cost of foodborne illness in the United States. According to a September 2013 bulletin from the U.S. Department of Agriculture's (USDA) Economic Research Service, the study that used the more conservative approach estimated the cost to be \$14.1 billion per year. CDC data indicate that as a result of foodborne illness, roughly 1 in 6 Americans (or 48 million people) get sick each year, 128,000 are hospitalized, and 3,000 die. As reflected in figure 1, CDC data also show that the number of reported multistate foodborne illness outbreaks is increasing. This is notable because multistate outbreaks constitute a small proportion of total outbreaks but affect greater numbers of people. For example, according to CDC data, 3 percent of reported outbreaks from 2010 to 2014 were multistate, but they were associated with 11 percent of illnesses, 34 percent of hospitalizations, and 56 percent of deaths. CDC cites several potential contributors to the increase in reported multistate outbreaks, including greater centralization of food processing practices, wider food distribution, and improved detection and investigation methods.

Figure 1: Number of Reported Multistate Foodborne Illness Outbreaks in the United States, 1995–2014



Source: GAO analysis of Centers for Disease Control and Prevention data. | GAO-16-425

The safety and quality of the U.S. food supply, both imported and domestic, are governed by a highly complex system stemming from at least 30 federal laws that are collectively administered by 15 federal agencies. The federal agencies with primary responsibility for food safety oversight are USDA’s Food Safety and Inspection Service (FSIS) and the Department of Health and Human Services’ (HHS) Food and Drug Administration (FDA). FSIS is responsible for the safety of meat, poultry, and processed egg products.¹ FDA is responsible for virtually all other food.

¹In addition, as a result of 2008 Farm Bill provisions amending the Federal Meat Inspection Act, regulatory responsibility for catfish inspection fell to FSIS in December 2015, when FSIS issued final regulations for a mandatory catfish examination and inspection program. The program regulations became effective in March 2016. 80 Fed. Reg. 75,590 (Dec. 2, 2015).

The federal food safety system is supplemented by states, localities, tribes, and territories, which may have their own laws and agencies to address the safety and quality of food. In all, more than 3,000 nonfederal agencies perform the great majority of government food safety activities. Among other things, these agencies investigate and contain illness outbreaks; conduct illness surveillance and monitor the food supply for contamination; inspect restaurants, grocery stores, and food processing plants; and take regulatory action to remove unsafe or unsanitary products from the market.

For several decades, FDA has taken steps to leverage the food safety work of nonfederal food safety agencies. For example, since the early 1970s, FDA has contracted with numerous state agencies to perform food safety inspections and investigations. However, over the years, we and others have identified challenges FDA faces in surveilling and inspecting the nation's approximately 154,000 food facilities and more than 2 million farms.² Many of these reports have called on FDA to take greater advantage of the food safety capabilities of nonfederal agencies.

In January 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law, representing the largest expansion and overhaul of U.S. food safety law since the 1930s.³ FSMA mandated, among other things, that FDA take steps that when taken, would better integrate its food safety oversight with that of states, localities, tribes, and territories.⁴

²See, for example, Institute of Medicine and National Research Council, *Enhancing Food Safety: The Role of the Food and Drug Administration* (Washington, D.C.: The National Academies Press, June 8, 2010); GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, [GAO-09-873](#) (Washington, D.C.: Sept. 15, 2009); Michael R. Taylor and Stephanie D. David, *Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation's Food Safety System*. (Washington, D.C.: Department of Health Policy, School of Public Health and Health Services, The George Washington University, Apr. 17, 2009); and GAO, *Food Safety: Improvements Needed in FDA Oversight of Fresh Produce*, [GAO-08-1047](#) (Washington, D.C.: Sept. 26, 2008).

³Pub. L. No. 111-353, 124 Stat. 3885 (2011).

⁴FSMA greatly expanded FDA's food safety authorities and responsibilities in other areas as well, including prevention, inspection, and response. For example, FSMA required new prevention-oriented standards for food processing facilities and farms; established mandatory inspection frequencies for domestic and foreign food facilities, based on risk; gave FDA authority to conduct mandatory recalls of all contaminated food products; and gave FDA authority to hold imported foods to the same standards as domestic foods.

Several of these steps relate to three new prevention-oriented rules required by FSMA, one governing the growing, harvesting, packing, and holding of produce, widely referred to as the produce safety rule, and the others governing the production of human and animal food, respectively, widely referred to as the preventive controls rules for human and animal food because they focus on preventing contamination. For the purposes of this report, we refer to these three rules as the rules on produce, human food, and animal food.

Among other things, FSMA directed or encouraged FDA to coordinate in the following three areas:

- **Rule development.** FSMA directed FDA to coordinate with state departments of agriculture in publishing the produce rule. FDA's rulemaking is also subject to other laws and executive orders requiring consultation with states, localities, and tribes.
- **Rule implementation.** FSMA authorized and encouraged FDA to leverage states, localities, tribes, and territories in conducting examinations, testing, and investigations under FSMA rules. For certain rules, FSMA mandated that FDA coordinate implementation.
- **Regulator training.** FSMA directed FDA to administer training and education programs for state, local, tribal, and territorial food safety officials relating to the regulatory responsibilities and policies established by FSMA.

You asked us to review issues pertaining to FDA's coordination with nonfederal agencies on food safety, particularly in relation to FSMA. This report examines—for the rules on produce, human food, and animal food—the extent to which FDA has (1) met its regulatory consultation responsibilities in developing the rules; (2) developed plans to coordinate implementation of the rules; and (3) developed and administered plans for training regulators on the rules.

To address our objectives, we reviewed relevant federal laws and regulations, including FSMA and the Federal Food, Drug, and Cosmetic Act, that prescribe FDA's coordination with nonfederal agencies on the FSMA-mandated rules on produce, human food, and animal food. We also reviewed other federal law and policy that prescribe FDA's regulatory consultation requirements, including HHS's tribal consultation policy, as well as our past work on key features and issues to consider when implementing collaborative mechanisms. We reviewed relevant documentation, such as transcripts of public meetings regarding the rules; the text of the proposed, supplemental, and final rules, including the rule

preambles and relevant documents referenced in each of the rules; and FDA documents related to rule development, implementation, and training, such as implementation and training plans.

To obtain the perspectives of nonfederal officials on FDA's rulemaking, implementation, and training efforts, we took three steps. First, we reviewed all public comments from state, local, tribal, and territorial governments, and from associations representing those entities, that were submitted in response to relevant FDA rulemaking dockets.⁵ We conducted a content analysis of these comments to identify themes related to coordination challenges faced and opportunities for improvement. Second, we interviewed representatives of selected associations of state, local, tribal, and territorial food safety officials to obtain their views on the identified challenges and opportunities, as well as their views on steps taken by FDA related to rule development, implementation, and training. Appendix I presents a more detailed description of our methodology, and appendix II lists the associations we interviewed. Third, we visited California—the state with the nation's largest agricultural and food production sectors—where we met with state and local officials to discuss their programs on produce and human and animal food. We also attended relevant food safety conferences and conducted more than 50 interviews with knowledgeable FDA and HHS officials and other stakeholders, including representatives of industry; public interest groups; and other relevant groups, such as the International Food Protection Training Institute, Food Safety Preventive Controls Alliance, Partnership for Food Protection, and Produce Safety Alliance.

We conducted this performance audit from March 2015 to May 2016 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.

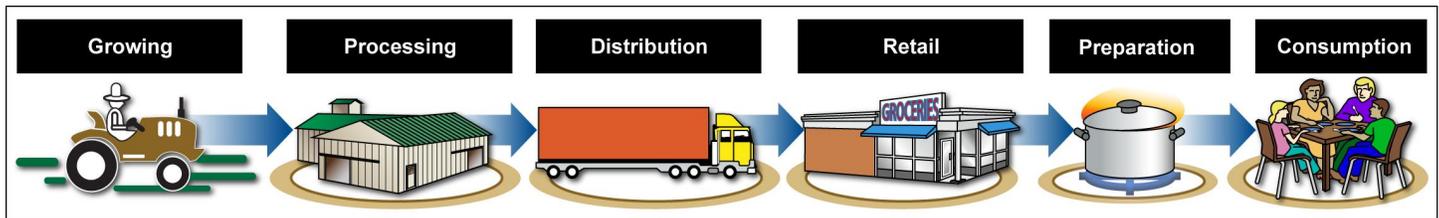
⁵A docket is a collection or repository of documents related to a rulemaking or other action.

Background

FSMA-Mandated Rules on Produce, Human Food, and Animal Food

Prior to FSMA, FDA focused on reacting to foodborne illnesses after they occurred. FSMA marked a historic turning point by requiring that FDA focus on preventing rather than reacting to foodborne illnesses. FSMA did so, in part, by requiring a number of new rules that together provide a framework for preventing foodborne illness across the food safety system. Of these rules, those on produce, human food, and animal food took aim at the entities in the earliest stages of the farm-to-fork continuum (see illustration of that continuum in fig. 2): the farms that grow and facilities that process food for human and animal consumption.⁶

Figure 2: Farm-to-Fork Continuum



Source: GAO (images). | GAO-16-425

Note: This figure illustrates the various stages in the human food chain, from agricultural production to consumption.

The Produce Rule

Produce is an important part of a healthy diet but is susceptible to contamination from numerous sources, including agricultural water, animal manure, equipment, and agricultural workers. Because produce is often consumed raw without processing to reduce or eliminate contaminants, steps to prevent contamination are key to ensuring safe consumption. Prior to FSMA, there were no enforceable national standards for on-farm practices related to produce safety. FDA and others had taken several actions to address produce safety, including issuing guidance documents and letters to industry, but in spite of these efforts, produce-associated foodborne illnesses occurred regularly. According to

⁶Other new rules required by FSMA focus on ensuring the safety of imported foods, protecting against acts of intentional contamination, and ensuring the sanitary transportation of food.

FDA, from 1996 through 2010, produce accounted for 42.3 percent of all outbreak-related illnesses linked to FDA-regulated foods.

The FSMA-mandated rule on produce established the first enforceable national standards for on-farm growing, harvesting, packing, and holding of domestic and imported produce. Among other things, the rule established standards related to agricultural water quality; the use of soil amendments, such as raw manure; the use of domesticated animals; intrusion by wild animals; worker training, health, and hygiene; and sanitation of equipment, tools, and buildings. The rule also established standards specific to sprouts, which are especially vulnerable to contamination because of the warm, moist, and nutrient-rich conditions needed to grow them. The rule included several exemptions. For example, it does not apply to produce that is rarely consumed raw, such as asparagus and black beans; produce that is to be consumed on farm; or produce that is to undergo commercial processing, such as refining produce into sugar or distilling it into wine, that adequately reduces contaminants of public health significance. In addition, the rule does not apply to farms that have an average annual value of produce sold during the previous 3-year period of \$25,000 or less.⁷

The Human Food Rule

Processing of food for human consumption is an important part of the global food industry. New and innovative food products are created daily in response to advances in science and technology as well as consumer demand. For example, ready-to-eat, refrigerated, and heat-and-serve foods are more popular than ever. Contamination of processed foods can come from a wide range of sources, including raw ingredients, processing equipment, and shipping containers. Once contamination occurs, it can spread widely because of mass production and global supply chains. For processed foods that require little to no preparation before consumption, contaminants can be especially dangerous because consumers may not take steps such as cooking to reduce or eliminate the hazard.

Prior to FSMA, FDA had issued various regulations to protect against contamination of processed foods. For example, FDA required processors to meet Current Good Manufacturing Practice requirements

⁷Many of the exemptions to the FSMA-mandated rules result from FSMA statutory language. For example, FSMA allows for the exemption of businesses based on size and amount of sales.

(CGMP), which established minimum standards for processing of human food. Among other things, the standards covered food industry personnel; operations and equipment; plants, grounds, and facilities; and warehousing and distribution. However, an FDA work group reported in 2005 that it was unclear whether the CGMPs—last updated in 1986—adequately addressed new food safety challenges, including more sophisticated and increasingly automated technologies and newly recognized contaminants. In addition to requiring processors to meet CGMPs, FDA required processors of certain food products, such as seafood and juice, to have programs in place to prevent contamination through, among other things, monitoring, recordkeeping, verification of monitoring practices, and corrective actions. However, no such requirements applied comprehensively across the food processing industry.

The FSMA-mandated rule on human food revised existing requirements for processors in a number of ways. Two key revisions were updated CGMPs and the establishment, for the first time, of requirements for contamination prevention programs (known as preventive control programs) across much of the industry.⁸ Among other things, under the preventive control programs required by the rule, food processors must develop and implement written plans that identify and evaluate known or reasonably foreseeable food safety hazards;⁹ specify the steps, or controls, that will be put in place to significantly minimize or prevent the hazards; specify how the controls will be monitored, verified, and corrected, as needed, to ensure that they are working; and maintain records documenting these actions. The rule included several exemptions. For example, it does not apply to seafood or juice processors (which are subject to separate preventive control regulations) or to farms.

⁸Although the updated human food GCMPS were promulgated in conjunction with the FSMA-mandated human food rule, the updated GCMPS were issued under previously existing authorities, according to FDA.

⁹FDA defines food safety hazards as any biological agent (including microbiological hazards, such as *Salmonella* and *Listeria monocytogenes*), chemical agent (such as pesticide and drug residues, toxins, unapproved food or color additives, and food allergens), or physical agent (such as stones, glass, or metal fragments) that has the potential to cause illness or injury.

The Animal Food Rule

Animal food is made for a variety of species, including animals from which humans obtain food, pet animals, and laboratory animals. 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 fed to livestock can cause harm both to the livestock and to humans that consume the livestock. In addition, contaminated food fed to pets can cause harm both to the pets and to humans that come in contact with the food or with items the food has touched. For example, from 2006 to 2008, 79 people in 21 states were reported ill from handling pet food manufactured in a Pennsylvania facility that was contaminated with *Salmonella*.

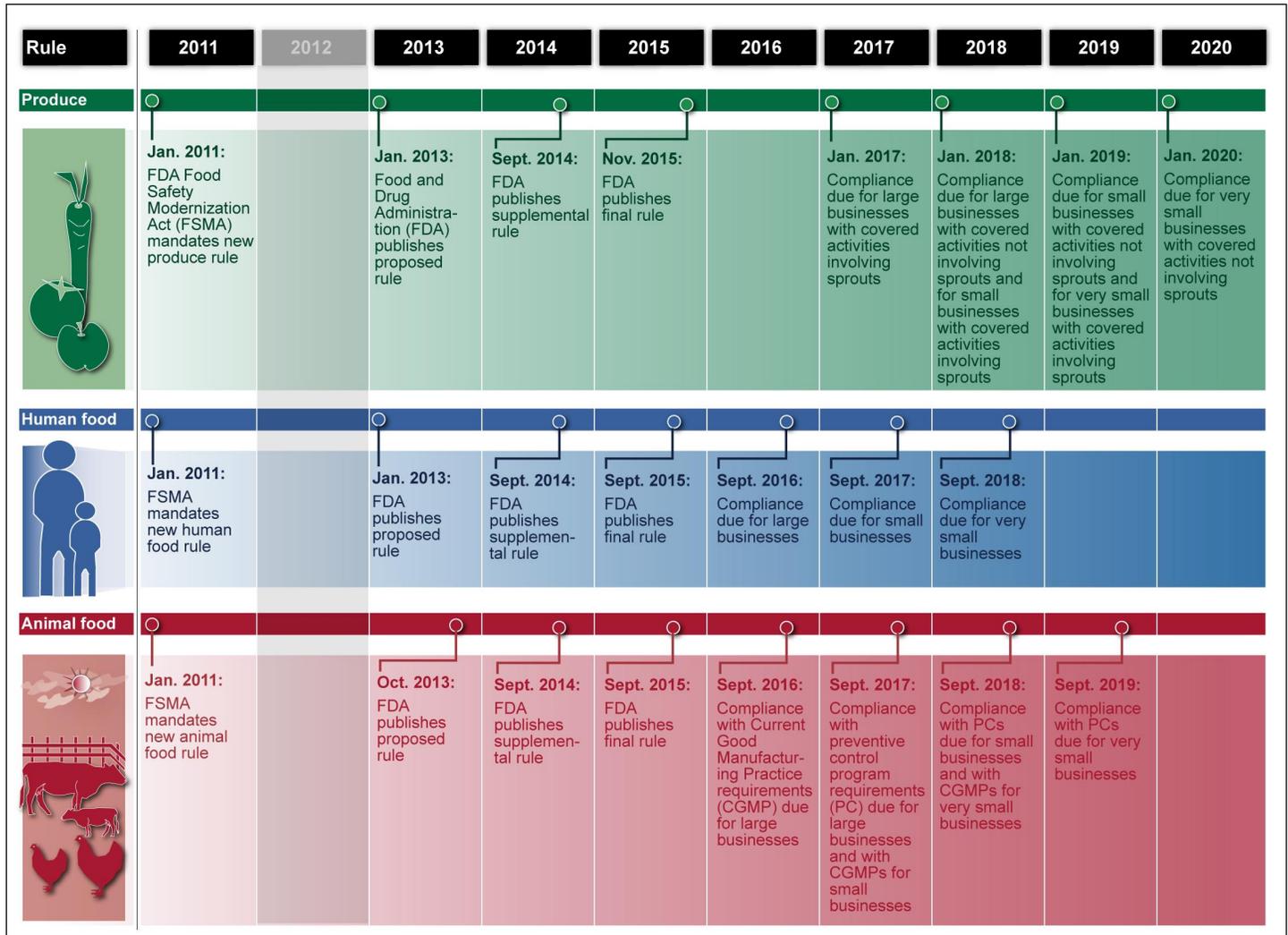
Prior to FSMA, the regulation of animal food focused on specific safety issues. For example, FDA had an animal food sampling program focused on, among other things, tracking levels of contaminants, including *Salmonella* and *Escherichia coli*, and investigating possible sources of contamination. In addition, FDA had a program aimed at protecting against Bovine Spongiform Encephalopathy (commonly known as mad cow disease) and had issued CGMPs for medicated animal feed. However, in 2010, an FDA-led work group issued a report identifying gaps in the regulation of animal food products, including the lack of federal regulations to fully address all aspects of producing safe animal food. The FSMA-mandated animal food rule was designed to fill that gap. Like the human food rule, it established two sets of requirements—one relating to CGMPs and one to preventive control programs.¹⁰ The animal food rule established CGMPs applicable across the animal food industry and mandated preventive control programs for animal food processors. Also, like the human food rule, the animal food rule included several exemptions. For example, it does not apply to farms.

Implementation Timeline

As reflected in figure 3, FDA's implementation of FSMA's mandate for new rules on produce, human food, and animal food spans several years. With the rules finalized in 2015, industry compliance with the rules is scheduled to come due between 2016 and 2020, with compliance dates phased in based on business size and other factors.

¹⁰Although the updated animal food GCMPs were promulgated in conjunction with the FSMA-mandated animal food rule, the updated GCMPs were issued under previously existing authorities, according to FDA.

Figure 3: Implementation Timeline for FSMA-Mandated Rules on Produce, Human Food, and Animal Food



Sources: GAO analysis of FSMA-mandated rules; GAO (images). | GAO-16-425

Notes:

Under the produce rule, very small businesses are those averaging more than \$25,000 but no more than \$250,000 in annual produce sales during the previous 3-year period, and small businesses are those averaging more than \$250,000 but no more than \$500,000 in annual produce sales during the previous 3-year period. We refer to all nonexempt businesses averaging more than \$500,000 in annual produce sales during the previous 3-year period as large businesses. Under the human food rule, very small businesses are those averaging less than \$1 million in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale during the previous 3-year period. Under the animal food rule, very small businesses are those averaging less than \$2,500,000 in annual sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale during the previous 3-year period. Under the human and animal food rules, small businesses are those with fewer than 500 full-time equivalent employees; we refer to all other businesses as large businesses.

Under the produce rule, FDA established earlier compliance dates for covered activities involving sprouts, given that sprouts are especially vulnerable to contamination because of the warm, moist, and nutrient-rich conditions needed to grow them.

Compliance dates differ from those in this figure for (1) produce rule requirements related to water quality and qualified exemptions, (2) human and animal food rule requirements related to supply chain programs, (3) human food requirements for businesses subject to the FDA Grade "A" Pasteurized Milk Ordinance, and (4) requirements to support a business's status as very small.

Requirements for Coordination on Rule Development, Rule Implementation, and Regulator Training

In addition to shifting FDA's focus to preventing rather than reacting to foodborne illnesses, FSMA also called on FDA to work with nonfederal agencies in carrying out the new law. Among other things, FSMA directed or encouraged FDA to coordinate on rule development, rule implementation, and regulator training.

- **Rule development.** In its rulemaking processes, FDA is subject to laws and executive orders that require consultation. These include the Unfunded Mandates Reform Act of 1995 (UMRA) and Executive Orders 12866 and 13563, which direct all federal agencies to provide for meaningful and timely input from state, local, and tribal officials during rule development.¹¹ They also require that this consultation occur before promulgation of proposed rules. Moreover, FSMA specifically required FDA to coordinate with state departments of agriculture in publishing the proposed produce rule. Further, in recognition of the unique government-to-government relationship between the federal government and Indian tribes grounded in the Constitution, separate requirements apply to consultation with tribes. Specifically, Executive Order 13175 requires federal agencies to have an accountable process to ensure meaningful and timely input by tribal officials in developing federal policies that have tribal

¹¹UMRA, Pub. L. No. 104-4, 109 Stat. 48 (codified in scattered sections of title 2 of the United States Code); Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Oct. 4, 1993); and Exec. Order No. 13563, *Improving Regulation and Regulatory Review*, 76 Fed. Reg. 3821 (Jan. 21, 2011). In addition, Executive Order 13132 established consultation requirements for developing regulatory policies with federalism implications, defined as policies having "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." FDA concluded that the rules on produce safety and human and animal food did not have federalism implications. Nonetheless, under the order, FDA is required to have an accountable process to ensure meaningful and timely input by state and local officials. Exec. Order No. 13132, *Federalism*, 64 Fed. Reg. 43,255 (Aug. 10, 1999).

implications.¹² In January 2005, HHS adopted a tribal consultation policy formalizing this requirement. Under that policy, no agency within HHS may promulgate any regulation with tribal implications unless either the federal government provides the funds necessary to pay the direct costs incurred by the tribes or the agency has consulted with the tribes throughout all stages of the process of developing the proposed regulation.

- **Rule implementation.** FSMA authorized and encouraged FDA to leverage states, localities, tribes, and territories in conducting examinations, testing, and investigations on FDA's behalf for determining compliance with all FSMA food safety provisions, including those related to the rules on produce, human food, and animal food. For the produce rule, FSMA went further in actually requiring FDA, as appropriate, to coordinate with states and localities in enforcing and ensuring compliance with the rule. In fact, FSMA required that the final produce rule provide for coordination of enforcement activities by state and local officials.
- **Regulator training.** FSMA required FDA to administer training and education programs for state, local, tribal, and territorial food safety officials relating to the regulatory responsibilities and policies established by FSMA.¹³

History of Calls for Food Safety Integration

The concept of an integrated food safety system has been in existence for several decades. The concept was first formally articulated by the Association of Food and Drug Officials in 1998, when the association described a vision for food safety integration across all levels of government. Also in 1998, the National Academy of Sciences issued a

¹²Exec. Order No. 13175, *Consultation and Coordination With Indian Tribal Governments*, 65 Fed. Reg. 67,249 (Nov. 9, 2000). The order defines “policies that have tribal implications” as regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.

¹³Specifically, FSMA directed FDA to “set standards and administer training and education programs for the employees of State, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by” the statute. Pub. L. No. 111-353 § 209(a) (codified at 21 U.S.C. §399c(a)).

report calling for a more integrated food safety system.¹⁴ In September 1998, FDA, in cooperation with other federal and nonfederal agencies, hosted a meeting of food safety officials from all 50 states (referred to as a 50-state meeting) to examine the idea of integration. Around the same time, FDA established the National Food Safety System project to strengthen partnerships among federal and nonfederal agencies to better ensure safe food and respond to outbreaks. The project had some successes until about 2002, when the project was put on hold because of a lack of funding, according to several sources, including FDA.

In November 2007, FDA renewed its focus on integration in its new Food Protection Plan.¹⁵ In that plan, FDA presented a strategy for protecting the U.S. food supply against intentional and unintentional contamination and recognized the importance of leveraging the resources of nonfederal agencies, among others, in doing so. As part of FDA's effort to implement its new plan, FDA hosted its second 50-state meeting in August 2008. At that meeting, participants reflected on accomplishments made since the initial 50-state meeting 10 years earlier and concluded that despite progress in some areas, many obstacles to integration remained. Outcomes of that meeting included creation of an FDA-state collaborative mechanism, the Partnership for Food Protection (PFP), to implement recommendations made at the 2008 meeting.

In April 2009, a study funded by the Robert Wood Johnson Foundation and led by George Washington University recognized progress that had been made toward integration and made several recommendations to further strengthen collaboration and partnerships, among other things.¹⁶ Three months later, the White House Food Safety Working Group—which was created in 2009 and stopped meeting after about 2 years—submitted

¹⁴Institute of Medicine and National Research Council, *Ensuring Safe Food: From Production To Consumption* (Washington, D.C.: The National Academies Press, Jan. 1, 1998).

¹⁵Food and Drug Administration, *Food Protection Plan* (Rockville, Md.: 2007). For more information on the *Food Protection Plan*, see GAO, *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*, [GAO-08-909T](#) (Washington, D.C.: June 12, 2008), and *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical*, [GAO-08-435T](#) (Washington, D.C.: Jan. 29, 2008).

¹⁶Taylor and David, *Stronger Partnerships for Safer Food*.

a report to the President identifying food safety integration as a priority.¹⁷ In September 2009, FDA again embraced the concept of an integrated food safety system by publishing a vision statement for achieving integration. In June of the following year, the National Academy of Sciences issued a second report on food safety, supporting, among other things, an integrated food safety system and describing remaining steps necessary to facilitate such integration.¹⁸ Two months later, FDA, under the auspices of the PFP, hosted the third 50-state meeting, with subsequent 50-state meetings held in August of 2012 and 2014.

Current Examples of Food Safety Integration

Food safety integration is seen today in a number of collaborations among food safety officials across levels of governments. These include the following:

- **State cooperative programs for milk, shellfish, and retail food safety.** FDA works with nonfederal regulatory agencies to ensure the safety of milk and raw molluscan shellfish, as well as the safety of food served in retail establishments. Regulatory responsibility and authority in these areas lies primarily with state, local, tribal, and territorial governments. However, FDA provides assistance to these nonfederal governments through three cooperative programs: the Milk Safety Program, the National Shellfish Sanitation Program, and the Retail Food Protection Program. These programs are governed by memorandums of understanding that FDA entered into with the National Conference on Interstate Milk Shipments, the Interstate Shellfish Sanitation Conference, and the Conference for Food Protection, respectively, which represent the nonfederal regulatory agencies. Under these cooperative programs, FDA provides guidance, training, certification, and other technical assistance. This includes promoting the adoption, implementation, and enforcement of

¹⁷We reported in December 2014 that this group, which served as a centralized mechanism for broad-based food safety collaboration, resulted in a number of accomplishments but that the group stopped meeting about 2 years after it was established. We suggested that Congress consider formalizing the group through statute to help ensure sustained leadership across food safety agencies over time. See GAO, *Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration*, [GAO-15-180](#) (Washington, D.C.: Dec. 18, 2014).

¹⁸Institute of Medicine and National Research Council, *Enhancing Food Safety: The Role of the Food and Drug Administration* (Washington, D.C.: The National Academies Press, June 8, 2010).

the FDA Grade “A” Pasteurized Milk Ordinance, the National Shellfish Sanitation Program Model Ordinance, and the FDA Model Food Code, each developed by FDA in collaboration with state and local food safety agencies.

- **National standards for oversight of retail food, manufactured food, and animal food.** FDA has developed national regulatory program standards for oversight of retail food, manufactured food, and animal food. These standards—the Voluntary National Retail Food Regulatory Program Standards, the Manufactured Food Regulatory Program Standards, and the Animal Feed Regulatory Program Standards¹⁹—serve as guides for nonfederal agencies in the design and management of food safety regulatory programs, helping to foster consistency across programs and their continuous improvement. The retail program standards were first released in 1999, the manufactured food program standards in 2007, and the animal feed program standards in 2014. As of January 2016, 682 nonfederal agencies, including state, tribal, territorial, and local agencies, were enrolled in the retail standards; 42 state agencies in 40 states were implementing the manufactured food standards; and 21 state agencies in separate states were implementing the animal feed standards.
- **Federal-state collaborative mechanisms for foodborne illness surveillance and outbreak response.** FDA is involved in a number of collaborative mechanisms focused on foodborne illness surveillance and outbreak response. For example, FDA co-chairs the steering committee of the Food Emergency Response Network, which integrates the nation’s food-testing laboratories at the federal and nonfederal levels to better respond to emergencies involving biological, chemical, or radiological contamination of food. In addition, FDA coordinates the Electronic Laboratory Exchange Network, a web-based information network that allows federal and nonfederal food safety officials to compare, share, and coordinate laboratory analysis findings. FDA also collaborates with other federal and nonfederal agencies through mechanisms including the National Antimicrobial

¹⁹Under the Animal Feed Regulatory Program Standards, animal feed refers to “food for animals other than man,” including food for food-producing animals and pets. In contrast, under the FSMA-mandated animal food rule, animal feed is not defined but, according to FDA, generally refers to food for food-producing animals. The animal food rule defines animal food as food for animals other than man, including pet food, animal feed, and raw materials and ingredients.

Resistance Monitoring System, which tracks whether foodborne and other bacteria are resistant to the antibiotics used to treat and prevent the spread of illness; PulseNet, which connects cases of foodborne illness to potential outbreaks; and the Foodborne Diseases Active Surveillance Network, which estimates the number of foodborne illnesses, monitors trends in incidence of specific foodborne illnesses over time, and attributes illnesses to specific foods and settings, among other things. In addition, since 2008, FDA has awarded cooperative agreements to states to develop rapid response teams aimed at, among other things, creating integrated and sustained response capabilities for food emergencies.

These and other collaborations illustrate the progress that has been made toward food safety integration. However, prior to FSMA, a key limitation to full integration was the lack of a statutory mandate to integrate. In 2010, 1 year before FSMA was signed into law, the National Academy of Sciences reported that it agreed with the recommendations of the George Washington University-led study published the prior year. The study found that the most fundamental prerequisite for achieving integration was high-level political commitment to that goal and accountability for achieving it. The study noted that the absence of an integration mandate did not by itself preclude collaboration, as evidenced by the extensive collaboration that already existed, but it meant that in the end officials were not fully empowered and accountable for integrating their food safety efforts. Accordingly, the study's first recommendation was for a congressional mandate and accountability at the federal level for building an integrated food safety system. In January 2011, FSMA was signed into law, providing such a mandate by requiring FDA to take steps that when taken, would better integrate its food safety oversight with that of states, localities, tribes, and territories.²⁰

²⁰The George Washington University study also found that the federal leadership needed to achieve integration was impaired by the fragmented federal food safety system, resulting in the lack of a clear federal focal point for interaction on many food safety matters. The study recommended that Congress establish an intergovernmental leadership council on food safety. The 2010 Institute of Medicine report agreed with this recommendation, stating that the Food Safety Working Group could serve the proposed function. We have long reported on problems stemming from the fragmented federal food safety system, with the issue included on our High Risk List since 2007 and, since 2011, in our annual report to Congress on federal initiatives that have duplicative goals or activities. To help address fragmentation, we suggested in December 2014 that Congress consider formalizing the Food Safety Working Group—which stopped meeting after about 2 years—through statute to help ensure sustained leadership across food safety agencies over time. See [GAO-15-180](#).

FDA Took Steps to Meet Its Regulatory Consultation Responsibilities but Did Not Consult Early with Tribes

FDA took numerous steps to meet its responsibilities under UMRA and Executive Orders 12866 and 13563 to ensure meaningful and timely input from the public and stakeholders during development of the FSMA-mandated rules on produce, human food, and animal food. FDA stated that it met its requirement under FSMA to coordinate with state departments of agriculture in publishing the proposed produce rule; representatives of state agriculture departments had varying views on the quality of the coordination. FDA did not fully meet its responsibility to consult with tribes throughout all stages of development of the proposed rules.

Selected Regulatory Consultation Responsibilities

- **Unfunded Mandates Reform Act of 1995.** Agencies are to develop a process to permit elected officers of state, local, and tribal governments (or their designees) to provide meaningful and timely input into the development of regulatory proposals containing significant intergovernmental mandates. Before promulgating any proposed or final rule that may result in the expenditure of \$100 million or more (adjusted for inflation) in any 1 year by state, local, or tribal governments in the aggregate or by the private sector, agencies must prepare a written statement including, among other things, a description of the extent of the agency's prior consultation with state, local, and tribal governments and a summary and evaluation of those governments' comments and concerns.
- **Executive Order 12866.** Each agency shall provide the public meaningful participation in the regulatory process. Before issuing a notice of proposed rulemaking, each agency shall seek the views of those likely to be affected, including state, local, and tribal officials.
- **Executive Order 13563.** Before issuing a notice of proposed rulemaking, each agency should seek the involvement of those likely to be affected and those expected to be subject to the rulemaking (including, specifically, state, local, and tribal officials).
- **Executive Order 13175.** Each agency shall have an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications. Agencies are to consult with tribal officials early in the process of developing proposed regulations.

Sources: Pub. L. No. 104-4, 109 Stat. 48 (1995) (codified in scattered sections of title 2 of the United States Code); Exec. Order No. 13563, *Improving Regulation and Regulatory Review*, 76 Fed. Reg. 3821 (Jan. 21, 2011); Exec. Order No. 12866, *Regulatory Planning and Review*, 58 Fed. Reg. 51,735 (Oct. 4, 1993); and Exec. Order No. 13175, *Consultation and Coordination With Indian Tribal Governments*, 65 Fed. Reg. 67,249 (Nov. 9, 2000). | GAO 16 425

FDA Took Steps to Meet Certain Regulatory Consultation Responsibilities

FDA took numerous steps to meet its responsibilities under UMRA and Executive Orders 12866 and 13563 to ensure meaningful and timely input from the public and stakeholders during development of the FSMA-mandated rules on produce, human food, and animal food. Among other things, as reflected in table 1, FDA held 13 public meetings from April 2011 through October 2015 related to these three rules. To accommodate broader audiences, FDA made 7 of these meetings accessible via live webcast and posted transcripts of 12 and recordings of 9 to its website following the meetings.

Table 1: FDA Public Meetings Related to FSMA-Mandated Rules on Produce, Human Food, and Animal Food

Date	Topic	Location
Oct. 20, 2015	Final human and animal food rules.	Chicago, IL
Apr. 23-24, 2015	Implementation strategy for seven foundational FDA Food Safety Modernization Act (FSMA) rules, including the ones on produce and human and animal food.	Washington, DC
Feb. 10, 2015	Draft environmental impact statement for proposed produce rule.	College Park, MD
Nov. 13, 2014	Four supplemental FSMA rules, including the ones on produce and human and animal food.	College Park, MD
Apr. 4, 2014	Draft environmental impact statement for proposed produce rule.	College Park, MD
Dec. 6, 2013	Proposed animal food rule.	Sacramento, CA
Nov. 25, 2013	Proposed animal food rule.	Chicago, IL
Nov. 21, 2013	Proposed animal food rule.	College Park, MD
Mar. 27-28, 2013	Proposed produce and human food rules.	Portland, OR
Mar. 11-12, 2013	Proposed produce and human food rules.	Chicago, IL
Feb. 28-Mar. 1, 2013	Proposed produce and human food rules.	Washington, DC
June 6-7, 2011	FSMA provisions related to inspections and compliance, pertinent to rules including those on human and animal food.	Silver Spring, MD
Apr. 20-21, 2011	FSMA-mandated human and animal food rules.	Silver Spring, MD

Source: GAO analysis of Food and Drug Administration (FDA) information. | GAO-16-425

FDA also opened dockets in the *Federal Register* requesting information to inform its rulemaking.²¹ For example, in February 2010, while FSMA was still being debated in Congress, FDA opened a docket requesting

²¹The *Federal Register* is the official daily publication for federal rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents. Through the website www.regulations.gov, the public can search for and provide comments on federal rulemaking and other dockets that are open for comment and published in the *Federal Register*.

information about, among other things, coordination of produce safety practices and federal, state, local, and tribal government statutes and regulations related to produce safety.²² Additionally, in response to stakeholder requests, FDA extended its initial 120-day comment period for each of the three proposed rules to about 300 days for the produce and human food rules and to about 150 days for the animal food rule. By the close of these periods, FDA had received about 36,000 comments on the produce rule, more than 8,000 on the human food rule, and more than 2,400 on the animal food rule. In December 2013, FDA announced that based on extensive stakeholder input, FDA planned to make significant changes to key provisions of the produce and human food rules. In March 2014, FDA made a similar announcement regarding the animal food rule. Accordingly, in September 2014, FDA published supplemental proposed rules for each, providing an approximately 75-day comment period. In response, FDA received more than 2,400 comments on the produce rule, more than 1,300 on the human food rule, and more than 140 on the animal food rule.

FDA Stated That It Met the Requirement to Coordinate with State Agriculture Departments; State Representatives Had Varying Views on the Quality of the Coordination

FDA stated that it met its requirement under FSMA to coordinate with state departments of agriculture in publishing the proposed produce rule. In the preamble to the proposed rule, FDA stated that it met the requirement and referenced in support a memorandum in the docket file. In the memorandum, FDA listed 13 meetings held from February 2010 to May 2012 and also listed 24 state departments of agriculture. FDA indicated in the memorandum that each of the listed departments was represented during at least one of the 13 meetings. FDA did not, however, provide detailed information in the memorandum regarding the specific attendees or the extent or nature of the discussions, making it difficult to assess whether the requirement was met.

We contacted officials from 8 of the listed state departments of agriculture.²³ These officials confirmed that one or more representatives from each of their departments attended at least one of the meetings referenced by FDA. All of these officials agreed that FDA met the FSMA

²²75 Fed. Reg. 8086 (Feb. 23, 2010). By the end of the comment period, which FDA extended from 90 to approximately 150 days, FDA had received about 880 comments.

²³We were unable to speak with officials from the remaining state departments of agriculture for various reasons, including several officials having retired since the meetings took place and FDA lacking records of attendees at each meeting.

requirement to coordinate with state departments of agriculture, but they had varying views on the quality of FDA's coordination. Specifically, officials from 2 departments characterized the quality as very good, 3 characterized it as good, 2 characterized it as moderately good, and 1 characterized it as very poor. Officials from one of the departments that characterized the coordination as very good explained that FDA was very open to discussing states' concerns. One of the officials that characterized the coordination as moderately good stated that FDA did not seek as much input from states as the official would have liked. The official that characterized the coordination as very poor noted that states had many outstanding concerns that had not been addressed, including the produce rule's complexity and compliance costs.

We also interviewed officials from two associations that represent state departments of agriculture. According to one of these associations, FDA was more willing to discuss its general intent for the rule than has previously been FDA's practice, which the association said was helpful, but this did not constitute coordination. The other association said that FDA coordinated well with it, holding monthly meetings with the association since FSMA's enactment.

FDA Did Not Fully Meet Its Tribal Consultation Responsibilities

FDA did not fully meet its tribal consultation responsibilities. In particular, FDA did not consult with tribes throughout all stages of development of the proposed rules, as is directed under the HHS tribal consultation policy for all rules with tribal implications where the federal government does not provide the funds necessary to pay the direct compliance costs incurred by tribes. The FSMA mandate that FDA develop rules on produce and human and animal food had several tribal implications. For example, FSMA authorized and encouraged FDA to leverage tribal agencies, among other nonfederal agencies, in conducting activities to determine compliance with all FSMA food safety provisions. Other potential implications included the effect of compliance costs on the sustainability of tribal businesses, the effect of produce rule requirements on traditional farming practices, questions regarding who would be responsible for ensuring compliance on tribal lands, and the effect of water standards on tribal water rights.

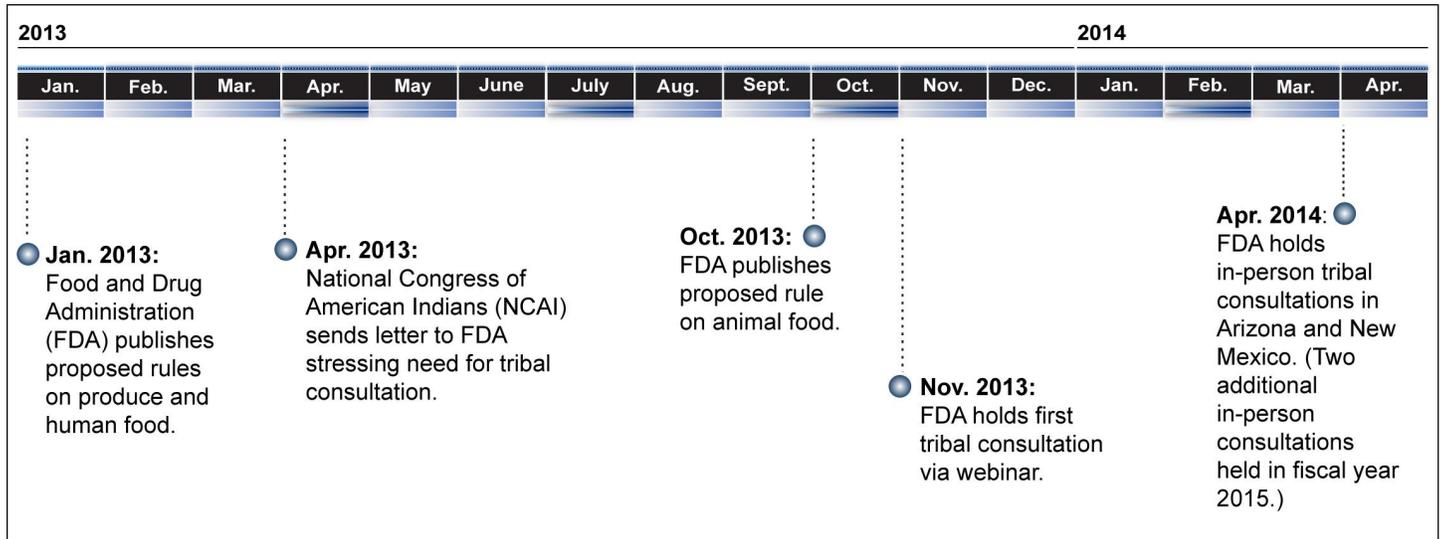
Given the tribal implications and the fact that the federal government did not provide the funds necessary to pay the direct compliance costs incurred by tribes, FDA should have consulted with tribes before publishing the proposed rules. Instead, the first formal consultation took place 1 month after publication of the proposed rule on animal food and 10 months after publication of the proposed rules on produce and human

food. As reflected in figure 4, the proposed rules on produce and human food were published in January 2013, with an initial comment period set to end in May 2013. As of April 2013, FDA had conducted no direct outreach to tribes. On April 4, the National Congress of American Indians wrote a letter to FDA stressing the need for tribal consultation. On April 24, FDA announced that it would extend the comment period for the proposed produce and human food rules; the comment periods were ultimately extended to late November 2013. FDA's formal efforts to consult with tribes began with a letter sent by mail in mid-August 2013 to all federally recognized tribes, notifying them of FDA's intent to prepare an environmental impact statement for the produce rule and inviting consultation on that statement. In mid-September 2013, FDA sent another letter to all federally recognized tribes, notifying them of a 2-hour consultation webinar on the FSMA rules to be held with all interested tribes in early October 2013.²⁴ FDA subsequently rescheduled the webinar for early November 2013, the month after FDA published the proposed rule on animal food.²⁵ Starting in April 2014, FDA also held four in-person consultations with some tribes. According to FDA, attendees were tribes that had requested consultation or that had responded to FDA invitations to consult.

²⁴FDA also offered informational webinars for tribes on the FSMA rules in May and August 2013, but these are not consistent with the government-to-government relationship and dialogue called for in Executive Order 13175 or the HHS tribal consultation policy, and at least one federal court has made a similar assertion.

²⁵According to FDA, the webinar was rescheduled because of the October 2013 federal government shutdown.

Figure 4: Key Steps in FDA’s Tribal Consultation on Proposed Rules on Produce, Human Food, and Animal Food



Sources: GAO analysis of FDA and NCAI data. | GAO-16-425

FDA acknowledged that its official tribal consultation did not begin prior to promulgation of the proposed rules but noted that it held public meetings at which tribes could have provided input. However, meetings for the general public are not consistent with the government-to-government relationship and dialogue called for in Executive Order 13175²⁶ or the HHS tribal consultation policy,²⁷ and at least one federal court has made that assertion.²⁸ FDA also stated that tribal consultation can be initiated when either the agency or tribes identify potential tribal implications but

²⁶See Exec. Order No. 13175, *Consultation and Coordination With Indian Tribal Governments*, 65 Fed. Reg. 67,249, (Nov. 9, 2000), secs. 2 and 5.

²⁷See Department of Health and Human Services, *Tribal Consultation Policy* (Dec. 14, 2010), secs. 1, 4, 8, and 9.

²⁸*Wyoming v. U.S. DOI*, No. 2:15-CV-043-SWS, ___ F. Supp. 3d ___, 2015 U.S. Dist. LEXIS 135044 (D. Wyo. Sept. 30, 2015). The court granted a preliminary injunction against the U.S. Bureau of Land Management, enjoining the agency from enforcing a final rule related to hydraulic fracturing on federal and Indian lands. The court based its injunction on different grounds but stated that regional consultation meetings and distributing draft copies of the proposed rule reflected “little more than that offered to the public in general.”

that no tribal concerns were brought to FDA's attention until the spring of 2013. FDA stated that once it was notified of tribal concerns, the agency began taking steps to formally consult with tribal leaders and did so before the final rules were drafted. The HHS tribal consultation policy does allow for identification of potential tribal implications by either an agency or tribes but places the onus on the agency to initiate the consultation and to ensure that it occurs in a timely manner. Moreover, early consultation is clearly emphasized in the HHS tribal consultation policy. In fact, the requirement that consultation occur "throughout all stages" of the rulemaking process was specifically added to the HHS policy when it was revised in December 2010. According to HHS, this change was made to ensure that tribal concerns are heard and that responses are given in a timely manner whenever possible.

Under the HHS tribal consultation policy, each agency within HHS must establish its own tribal consultation policy, which should include an accountable process—one that among other things, measures and reports on the results and outcomes of the agency's tribal consultation performance—to ensure meaningful and timely input by Indian tribes. A senior HHS official told us that each agency within HHS that does not have its own consultation policy, such as FDA, follows the HHS policy. However, the HHS policy establishes a minimum set of requirements and expectations—including collaboration with tribes on meeting development and reporting on consultation outcomes—and directs agencies to establish their own processes to ensure compliance with those directives and expectations, which FDA has not done. We discussed this issue with FDA officials several times from July 2015 through February 2016. On each occasion, these officials stated that they were in the process of developing a draft tribal consultation policy but did not have a timetable for finalizing the policy. On February 29, 2016, FDA released its draft tribal consultation policy and published a notice in the *Federal Register* inviting comments through May 31, 2016.²⁹ FDA also sent the draft by mail to all federally recognized tribes and notified the tribes of a teleconference to be held on April 21 to provide an overview of the draft and to hear comments and answer questions about it.

We reviewed the draft policy and noted that unlike the HHS policy, it did not explicitly provide for early consultation with tribes on all rules with

²⁹81 Fed. Reg. 10,256 (Feb. 29, 2016).

tribal implications where the federal government does not provide the funds necessary to pay the direct compliance costs incurred by tribes, including before promulgation of proposed regulations. For example, whereas the HHS policy discusses consultation “throughout all stages of the process of developing the proposed regulation,” the draft FDA policy removes “proposed” from this statement. According to FDA officials, they did not intend to exclude early consultation and instead consider early consultation to be implicitly included in the phrase “throughout the process of developing the regulation.” However, without early consultation explicitly provided for—as it is in the HHS policy—there is a risk that it may not occur. According to FDA, the most frequent comment made by tribes and tribal organizations on the FSMA rules, generally, was that FDA should have done more to consult with the tribes when the proposed FSMA rules were being drafted. FDA’s draft tribal consultation policy does not explicitly ensure that this concern will be addressed in future rulemaking. Courts have found that early consultation is important because, by the time an agency has published a proposed rule, the agency has already narrowed down and largely determined the regulatory approach it plans to take.³⁰ Going forward, the final rule is required to be a logical outgrowth of what the agency has previously proposed.³¹ Consultation before publication of a proposed rule allows for input at a time when it is most likely to have the greatest impact on the agency’s decision making and also allows for public comment and discourse on the results of that input.

In addition, as of February 2016, FDA still did not have a timetable for finalizing its tribal consultation policy. Our body of work has shown that timetables with milestones and interim steps can be used to show progress toward implementing efforts or to make adjustments to those efforts when necessary, and that without defined tasks and milestones, it is difficult for an agency to set priorities, use resources efficiently, measure progress, and provide management a means to monitor this

³⁰See, for example, *Cal. Wilderness Coalition v. United States DOE*, 631 F.3d 1072, 1093, 1094 (9th Cir. 2011), and *Campanale & Sons, Inc. v. Evans*, 311 F.3d 109, 117-120 (1st Cir. 2002).

³¹See *Shell Oil Co. v. EPA*, 950 F.2d 741, 747 (D.C. Cir. 1991); *USW v. Marshal*, 647 F.2d 1189, 1315 (D.C. Cir. 1980); and *Taylor Diving & Salvage Co. v. U.S. Dep’t of Labor*, 599 F.2d 622 (5th Cir. 1979).

progress.³² Developing a draft tribal consultation policy and releasing it for comment are good first steps, but without setting a timetable with milestones and interim steps, it will be difficult for FDA to set priorities, use resources efficiently, measure progress, and provide management a means to monitor this progress in finalizing the policy. FDA therefore risks continued delays in establishing a process to ensure meaningful and timely tribal consultation. As a November 2009 presidential memorandum on tribal consultation states, “[h]istory has shown that failure to include the voices of tribal officials in formulating policy affecting their communities has all too often led to undesirable and, at times, devastating and tragic results. By contrast, meaningful dialogue between Federal officials and tribal officials has greatly improved Federal policy toward Indian tribes. Consultation is a critical ingredient of a sound and productive Federal-tribal relationship.”³³

FDA Has Begun to Develop Plans for Coordinated Rule Implementation and Is Working to Overcome Challenges

FDA has begun to develop plans to ensure compliance with the FSMA-mandated rules on produce, human food, and animal food through coordinated implementation with nonfederal agencies. Through our discussions with officials from FDA and from associations representing nonfederal food safety officials, we identified numerous challenges that FDA is working to overcome in its development of plans for coordinated implementation. The associations we interviewed also identified a number of opportunities to improve coordinated implementation of the rules, some of which FDA has taken steps to implement.

³²See, 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).

³³74 Fed. Reg. 57,881 (Nov. 9, 2009).

FDA Has Begun to Develop Plans for Coordinated Implementation

FDA has begun to develop plans to ensure compliance with the FSMA-mandated rules on produce, human food, and animal food through coordinated implementation with nonfederal agencies. To develop plans for FSMA implementation, FDA established a variety of work groups, including one on the produce rule, formed in December 2012, and one on the human and animal food rules, formed in January 2013. FDA charged these work groups with, among other things, developing strategies to coordinate implementation with nonfederal agencies. FDA also established a separate state strategy work group in May 2015 to focus on a broad range of issues related to nonfederal agency involvement in FSMA implementation. These issues include under what mechanisms FDA should provide funding to nonfederal agencies for work done to implement FSMA-mandated rules, how to coordinate FDA and nonfederal agency inspections and compliance activities under the FSMA-mandated rules, how best to share information between FDA and nonfederal agencies, and how to maintain the competency of FDA and nonfederal agency investigators.

To obtain the input of nonfederal agencies, each of these FDA work groups includes at least two nonfederal representatives. According to FDA officials, these nonfederal representatives are selected based on recommendations by the PFP. FDA officials told us that these nonfederal representatives are able to share the views of their respective agencies, in addition to the views of associations to which the representatives belong. For example, several nonfederal representatives are members of the Association of Food and Drug Officials (AFDO), which is made up of state, local, and territorial food safety officials. Therefore, the nonfederal representatives are able to obtain input from AFDO and its members and convey that input to the FDA work group.

FDA has also obtained input from nonfederal agencies in other ways. For example, in September 2014, FDA awarded a 5-year cooperative agreement to the National Association of State Departments of Agriculture (NASDA), which represents the commissioners, secretaries, and directors of the state agriculture departments in all 50 states and four U.S. territories.³⁴ Under this cooperative agreement, NASDA is, among other things, developing a plan that will outline processes for state

³⁴In executing the cooperative agreement, NASDA is collaborating with AFDO and the Association of State and Territorial Health Officials.

agriculture departments to consider as they develop regulatory programs for the produce rule, with applicability to the other FSMA-mandated rules as well. The plan will describe processes for information sharing, regulator training, funding, and dispute resolution, among other things. According to FDA officials and NASDA representatives, FDA meets with NASDA periodically to discuss and provide technical assistance on various aspects of the plan. FDA officials and NASDA representatives told us that NASDA intended to present a preliminary draft of its plan to its members in March 2016.

In late 2015, when we interviewed officials in the FDA work groups developing plans for coordinated implementation of the FSMA-mandated rules on produce and human and animal food, each group expected its work to continue through roughly 2020, when the final compliance dates under the rules come due. Each had few details to share about the specific role nonfederal agencies will ultimately play in rule implementation. In broad terms, each FDA work group emphasized that FDA cannot implement the rules alone and that successful implementation will require the assistance of nonfederal agencies.

FDA Faces Numerous Challenges Related to Coordinated Implementation and Is Working to Overcome Them

Through our discussions with officials from FDA and from associations representing nonfederal food safety officials, we identified numerous challenges that FDA faces in developing plans for coordinated implementation of the FSMA-mandated rules on produce, human food, and animal food. FDA is working with nonfederal agencies to overcome these challenges. Appendix II lists the associations we interviewed.

Nonfederal Agency Resources

Officials from FDA and nearly all of the associations we interviewed said that nonfederal agencies generally do not have the resources to take on new responsibilities for implementing the FSMA-mandated rules.³⁵

³⁵We use the following terms to quantify association responses: “some” refers to more than 15 percent but less than or equal to 30 percent of association responses, “several” refers to more than 30 percent but less than or equal to 50 percent of association responses, “most” refers to more than 50 percent but less than or equal to 80 percent of association responses, “nearly all” refers more than 80 percent but less than 100 percent of association responses, and “all” refers to 100 percent of association responses. See app. I for a full description of our methodology and app. II for a list of the associations we interviewed.

Representatives of several associations told us that nonfederal agencies are concerned that these new responsibilities represent an unfunded mandate.³⁶ They said that nonfederal agencies are generally unwilling to assist FDA with implementation of the FSMA-mandated rules until dedicated federal funding is first made available. One association representative explained that since the last recession, state legislators have generally been unwilling to even discuss new responsibilities for federal initiatives, regardless of their merits, unless the federal government commits to long-term funding of any costs incurred.

To address this issue, FDA, through its state strategy work group and in coordination with NASDA and other stakeholder groups, is exploring funding mechanisms to provide nonfederal agencies with resources for carrying out new responsibilities related to implementation of the FSMA-mandated rules. FDA officials told us that for the produce rule, this mechanism may be in the form of a cooperative agreement that would provide flexibility to nonfederal agencies by adjusting their funding amounts based on their level of involvement and the types of activities they undertake to implement the rule. This could include funding for start-up costs incurred in developing new regulatory structures for overseeing produce. FDA officials said that for the human and animal food rules, the initial funding mechanism may continue to be contracts, which FDA has used since the 1970s to reimburse nonfederal agencies for inspections of processed food facilities. As of December 2015, FDA had not made any final decisions regarding funding mechanisms. However, in March 2016, FDA issued a federal funding opportunity announcement making available \$19 million for cooperative agreement awards to assist nonfederal agencies in implementing the produce rule.

Inventories of Businesses Subject to the Rules

FDA officials discussed challenges related to developing inventories of businesses that will be subject to the rules on produce, human food, and animal food. According to FDA officials, such inventories are essential to coordinated implementation because they allow FDA and nonfederal agencies to allocate resources and assign inspection responsibilities, among other things. FDA's existing business inventory data are drawn from information provided by businesses required to register with FDA.

³⁶An unfunded mandate is a statute or regulation that requires nonfederal agencies to expend resources to achieve legislative goals without being provided federal funding to cover the costs.

Farms, however, are not required to register. According to FDA officials, the lack of a registration requirement for farms limits the available data that it can use to inform its implementation of the produce rule. Human and animal food businesses are required to register with FDA.³⁷ However, the information provided by these businesses generally does not include key data needed to inform implementation of the FSMA-mandated human and animal food rules, such as annual business sales or total number of employees, which influence business compliance dates under the rules. In addition, FDA officials said that nonfederal agencies generally do not collect inventory data in a uniform and consistent manner, which limits their ability to share and benefit from one another's data. Moreover, FDA officials said that inventory data can be out of date because new businesses are frequently established and existing ones relocate or shut down.

FDA is working to address these inventory challenges in several ways. For example, FDA is working with NASDA to develop farm inventories and is exploring potential data sources maintained by other government and private sector entities. To help promote consistency in data collection across FDA and nonfederal agencies, FDA has also worked with the PFP work group on information technology to develop a dictionary of common data elements. To help keep inventory data up to date, FDA officials told us that they are working with nonfederal agencies on ways to share one another's data. FDA officials noted that business inventories will never be perfectly accurate or current and that they must be consistently updated and verified through in-person inspections.

Varying Legal Authorities

Representatives of most of the associations we interviewed said that nonfederal agencies' varying legal authorities pose challenges to coordinated implementation of the FSMA-mandated rules. For example, some association officials noted that because there were no pre-FSMA national standards for on-farm practices related to produce safety and because many states base their food safety statutes and regulations on

³⁷The Federal Food, Drug, and Cosmetic Act requires that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered. 21 U.S.C. § 350d(a). As defined in the act, a facility includes a factory, warehouse, or establishment that manufactures, processes, packs, or holds food. However, it does not include farms, restaurants, other retail food establishments, certain nonprofit food establishments, or fishing vessels. 21 U.S.C. § 350d(c). Also under the act, food is defined to include food for man or other animals. 21 U.S.C. § 321(f).

federal law, most nonfederal agencies lack authority under state law to conduct on-farm inspections related to produce. These agencies generally must seek such authority from their legislatures. Some association officials stated that for each of the new FSMA-mandated rules, some jurisdictions will have adopted them by reference through language in their state law that automatically adopts federal rules, but other jurisdictions do not have such language and must revise their agencies' existing legal authorities. Consequently, the resulting authorities are likely to vary considerably across jurisdictions.³⁸ Moreover, the process of revising legal authorities can take many years. One association representative explained that some state legislatures do not meet each year and most do not operate year-round. As already discussed, representatives of most associations said that nonfederal agencies are generally unwilling to assist FDA with FSMA implementation until dedicated federal funding is first made available and therefore may not seek new authority until that occurs.

FDA is taking various steps to overcome these challenges. For example, as already discussed, FDA is exploring funding mechanisms to provide nonfederal agencies with additional resources for carrying out new responsibilities related to FSMA implementation. In addition, FDA has entered into a cooperative agreement with AFDO, the Association of State and Territorial Health Officials, and the National Conference of State Legislatures to catalogue state food safety authorities, track changes in those authorities, and gauge state legislators' willingness to modify legal authorities in response to the new FSMA-mandated rules, among other things. Further, under its cooperative agreement with FDA, NASDA is working with AFDO to develop a model produce rule that states can adopt. The model rule is intended to help expedite the process of drafting new legal authorities and to promote consistency in those authorities across jurisdictions. FDA's national regulatory program standards for oversight of manufactured food and animal feed will also help to foster consistency of laws because participant agencies are required to identify areas in which their legal authorities differ from federal authorities. Until the requisite nonfederal authorities are obtained, FDA

³⁸This variation is heightened by the fact that states are also free to fill voids in food safety regulation that have not been addressed at the federal level.

officials told us that they are able to commission some nonfederal officials to conduct certain implementation activities under federal authority.³⁹

Varying Regulatory Structures

Representatives from most of the associations we interviewed said that varying nonfederal agency regulatory structures also pose challenges to coordinated implementation of the FSMA-mandated rules. For example, according to our analysis, state and local governments generally carry out food safety responsibilities through separate departments of agriculture and public health. However, some states' and localities' food safety authority resides in another department—such as a department of consumer protection—or in a university-affiliated body. In addition, regulatory activities—including inspections—may be housed in different departments across jurisdictions or shared by more than one. For example, in Georgia, inspections of human food facilities are the responsibility of the state department of agriculture, but in West Virginia, this responsibility is shared by the state departments of agriculture and public health. According to FDA and association officials, this variation in regulatory structures makes coordinated implementation difficult because there is no one-size-fits-all approach that FDA can use with each jurisdiction. Instead, FDA must tailor its approach to the unique circumstances of each. In addition, the variation makes it more likely that implementation activities will be carried out inconsistently across jurisdictions.

To address these challenges, FDA is taking various actions to promote uniformity of regulatory programs across jurisdictions. These actions include promoting FDA's national regulatory program standards for oversight of manufactured food and animal feed. These standards serve as guides for agency managers in the design and management of food safety regulatory programs, helping to foster consistency across programs and continuous improvement of participating agencies. In addition, as is discussed in greater detail below, FDA is working to develop and administer training for regulators across jurisdictions to help promote consistent implementation of the FSMA-mandated rules.

³⁹According to FDA, its Commissioning Program was designed to better utilize state and local officials in the performance of specific functions—such as inspections—subject to federal jurisdiction and confidentiality requirements. Commissioning is usually limited to a specified period of time.

Volunteer Status of Nonfederal Participants

FDA officials discussed challenges related to the status of nonfederal participants in work groups focused on planning for FSMA implementation. They explained that the nonfederal participants serve in these roles on a voluntary basis, in addition to fulfilling their primary duties at their respective agencies. Therefore, these participants have limited time to devote to work group activities. Participation in work group activities is further strained by limited resources at the participants' respective agencies. In addition, FDA officials stated that some nonfederal officials are prohibited from using their agencies' or federal resources to travel outside their home states to attend periodic in-person meetings.⁴⁰ FDA officials also explained that there are a number of nonfederal officials with the expertise needed by the various work groups, but many cannot participate for various reasons, such as competing demands on their time. Therefore, the same nonfederal officials are frequently asked to participate in a number of different groups, further limiting their ability to contribute to each.⁴¹

FDA is working to address this challenge through its state strategy work group. Specifically, the state strategy work group has conducted outreach to the PFP and associations representing food safety officials to identify additional officials that are qualified, able, and willing to participate. In addition, FDA said that the funding mechanism it is exploring to compensate nonfederal agencies for work done to implement the produce rule may also cover expenses related to participation in FDA work groups.

Paperwork Reduction Act

FDA officials told us that the time and effort required to comply with the Paperwork Reduction Act (PRA) poses a challenge to FDA's ability to collect information from nonfederal agencies on a timely basis to inform

⁴⁰Our prior work has highlighted the importance of in-person meetings to build relationships and trust. See GAO, *Managing for Results: Implementation Approaches Used to Enhance Collaboration in Interagency Groups*, [GAO-14-220](#) (Washington, D.C.: Feb. 14, 2014).

⁴¹Our prior work on key issues to consider when implementing collaborative mechanisms has discussed challenges that agencies face in ensuring that participants are able to regularly attend group activities. See, for example, GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

policy decisions.⁴² FDA officials said that developing coordinated implementation plans frequently requires such information. To save time, FDA has taken advantage of the Office of Management and Budget's (OMB) fast-track clearance process, which OMB established in 2011 to expedite certain information requests. In addition, FDA officials told us that they leverage surveys conducted by associations representing nonfederal food safety officials with whom FDA has cooperative agreements. FDA officials said that viewing these survey results can help FDA avoid duplication of work and overburdening of nonfederal agencies. However, FDA officials said that because they cannot control the design and reporting mechanisms of these surveys, the information gleaned from them is often incomplete and of limited use to FDA. We have previously found that other federal agencies also reported difficulties in complying with PRA requirements.⁴³

Stakeholders Identified Opportunities to Improve Coordinated Implementation

The associations we interviewed identified a number of opportunities to improve coordinated implementation of the FSMA-mandated rules, some of which FDA has taken steps to implement. Several of these opportunities are consistent with our prior work on key features and issues to consider when implementing collaborative mechanisms.⁴⁴

⁴²Under the PRA, agencies must obtain Office of Management and Budget (OMB) approval for identical collections of information from 10 or more nonfederal entities. Information collections include surveys, questionnaires, and reports. To obtain approval, agencies must provide to OMB (1) a description of the information to be collected, (2) the reason the information is needed, and (3) estimates of the time and cost imposed on respondents. Agencies must also seek public comment on the proposed information collections and consult with those affected on ways to minimize the associated burden. See 44 U.S.C. § 3507(a), (d).

⁴³We have noted in prior reports that it is important to recognize that the PRA requirements were established to minimize the paperwork burden and maximize the utility of federal information collection, among other purposes. See, for example, GAO, *Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews*, [GAO-07-791](#) (Washington, D.C.: July 16, 2007).

⁴⁴See, for example, [GAO-14-220](#); [GAO-12-1022](#); and GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005). For additional information about our related work, see our web page on best practices and leading practices in collaboration at www.gao.gov/key_issues/leading_practices_collaboration.

Clarifying Roles and Responsibilities

Officials from several of the associations we interviewed agreed that FDA should engage in discussions with nonfederal agencies regarding the role each will play in implementing the FSMA-mandated rules. Officials from most of these associations also said that these discussions had already begun to occur. Several association officials further noted that FDA had made clear that it plans to have nonfederal agencies conduct the majority of inspections under the FSMA-mandated rules on produce, human food, and animal food, but that FDA had not provided details regarding how this would occur, particularly in light of the many challenges that must be overcome before nonfederal agencies can begin implementation activities. As we discussed earlier in this report, FDA is aware of and working to overcome the challenges to coordinated implementation of the rules. In addition, FDA officials have stated that they intend to continue their discussions with stakeholders throughout FSMA implementation to ensure that all participants understand and carry out their roles in food safety. Our prior work on interagency collaboration has found that all collaborative mechanisms, regardless of complexity and scope, benefit from clarifying roles and responsibilities.⁴⁵

Regular Communication

Officials from all of the associations we interviewed agreed that FDA should foster regular communication with nonfederal agencies to help ensure well-coordinated implementation. Officials from several of these associations said that FDA is in the process of doing so. For example, most association representatives commended FDA for its willingness to hold outreach sessions and send FDA officials to association meetings to share information. Several of these association representatives noted that FDA had improved its efforts to communicate with stakeholders since FSMA's enactment. For example, FDA has initiated regular conference calls with nonfederal officials to ensure early identification and resolution of critical issues and increase communication. According to FDA officials, the agency intends to continue communicating with stakeholders throughout implementation of the FSMA-mandated rules to ensure that all participants understand and carry out their roles in food safety. Our prior work on interagency collaboration has found that frequent communication among collaborating agencies is a means to facilitate working across agency boundaries and to prevent misunderstanding.⁴⁶

⁴⁵See [GAO-12-1022](#).

⁴⁶See [GAO-06-15](#).

Comprehensive Funding Mechanism

Officials from nearly all of the associations we interviewed agreed that FDA should develop a comprehensive funding mechanism to reimburse nonfederal agencies for activities undertaken to implement the FSMA-mandated rules. Officials from most of the associations said that this funding mechanism should take the form of a cooperative agreement rather than a contract. In the past, FDA has used contracts to reimburse nonfederal agencies for activities undertaken to implement pre-FSMA regulations. Some association representatives explained that contracts are generally awarded on a short-term basis to compensate for a narrow set of activities—such as per inspection—and therefore do not provide sufficient coverage for the numerous, long-term activities nonfederal agencies must undertake to implement the new FSMA-mandated rules. These activities include obtaining new legal authorities and establishing appropriate regulatory structures, where necessary, and hiring, training, and retaining new staff. Several association representatives explained that cooperative agreements would be a more appropriate funding model to cover these varied activities and assure nonfederal agencies of the continued financial support they will need for successful implementation. As we discussed earlier in this report, FDA officials are exploring funding mechanisms to provide nonfederal agencies with resources for carrying out new responsibilities related to implementation of the FSMA-mandated rules. Furthermore, in March 2016, FDA issued a federal funding opportunity announcement making available \$19 million for cooperative agreement awards to assist nonfederal agencies in implementing the produce rule.

Information-Sharing System

Officials from most of the associations we interviewed agreed that FDA should develop a system to rapidly share information with nonfederal agencies related to industry compliance. Currently, FDA uses an information-sharing system known as the Field Accomplishments and Compliance Tracking System, through which nonfederal agencies that conduct inspections for FDA enter data through a web portal. Internally, FDA has a variety of other information systems that house data related to industry compliance; however, the various systems are not connected to one another. This means that FDA staff must frequently access and analyze data from multiple systems to answer questions about industry compliance.

According to FDA officials, the agency is currently developing a new system, called the Observation Corrective Action Reporting system (OCAR), that will serve as a platform through which users can access information housed in existing FDA information systems related to industry compliance. In addition, they said OCAR will include a portal

through which FDA and nonfederal regulators can access and enter information before, during, and after an inspection. According to FDA officials, regulators will be able to use OCAR before an inspection to access information regarding a business's compliance history, past recalls, and results from samples taken during prior inspections, among other things. Regulators may also use the system to access resource materials, including training videos and fact sheets. FDA officials said that regulators will use OCAR during an inspection to enter data regarding a business's compliance with relevant rule requirements. According to FDA, OCAR will also include an industry portal through which businesses can access their inspection reports and input information regarding corrective actions. FDA officials said that OCAR will result in numerous benefits, including improved data quality; data analysis; and information sharing between FDA, nonfederal regulators, and industry. FDA expects OCAR to be fully operational by 2019; however, numerous steps remain before that can occur. Our prior work on interagency collaboration has found that information-sharing websites, integrated electronic reporting processes and procedures, and negotiated data-sharing arrangements are valuable in enhancing and sustaining joint activities.⁴⁷

Process to Address Questions regarding the Rules

Officials from most of the associations we interviewed agreed that FDA should establish a process to quickly answer questions from industry and regulators regarding the FSMA-mandated rules. Some association representatives explained that this would help promote consistency in the way that the rules are understood and implemented. In September 2015, FDA launched a FSMA Technical Assistance Network, through which industry, regulators, and the public may submit questions to subject matter experts at FDA regarding the FSMA-mandated rules. Currently, inquiries may be submitted to the Technical Assistance Network via an online web portal or via mail. According to FDA, by 2017—when FDA plans to begin conducting inspections under the rules—regulators will be able to contact the Technical Assistance Network during, or in preparation for, inspections and speak directly with FDA subject matter experts to get answers to their questions regarding the rules. FDA officials told us that the Technical Assistance Network will also allow FDA to identify trends in the type of questions asked, which will indicate areas in which FDA may need to develop guidance. In addition to the Technical Assistance Network, FDA officials told us that they plan to establish a Produce Safety

⁴⁷See [GAO-12-1022](#).

Network, which will station FDA staff at various locations around to country to provide education and technical assistance, among other things, to industry and regulators as they implement the produce rule.

Dispute Resolution System

Officials from all of the associations we interviewed agreed that FDA should develop a system to promptly arbitrate disputes between industry and regulators regarding rule interpretation. Several association representatives explained such a system would be important once inspections under the rules are under way to help promote consistency in the way the rules are implemented. As noted earlier, NASDA is developing a process for dispute resolution as part of the regulatory program plan it is drafting under a cooperative agreement with FDA. FDA officials stated that they agree in principle with the need for an arbitration system, but that they will not make any final decisions regarding implementation of such a system until they have reviewed NASDA's proposal. They stated that NASDA plans to convene a work group to develop this proposal and that the work group will include FDA representatives. However, the work group has not yet been established. In the meantime, FDA officials told us that in 2015, they hired an ombudsman in their Office of Regulatory Affairs to serve as an independent arbiter of disputes between FDA, industry, and nonfederal regulators on a variety of regulatory issues, including those related to the FSMA-mandated rules.

FDA Has Begun to Develop and Administer Plans for Regulator Training and Is Working to Overcome Challenges

FDA has developed a plan for training regulators on the FSMA-mandated human and animal food rules and has begun to administer that plan. As of February 2016, FDA had begun to develop, but not to administer, a plan for training regulators on the FSMA-mandated produce rule. Through our discussions with FDA officials and associations representing nonfederal food safety officials, we identified several challenges that FDA is working to overcome in its development and administration of plans for regulator training.

FDA Has Developed and Begun to Administer a Regulator Training Plan on the Human and Animal Food Rules

FDA has developed a plan for training regulators on the FSMA-mandated human and animal food rules and has begun to administer that plan. The plan has two components: (1) a series of optional courses aimed at familiarizing regulators with important background information and key concepts and (2) mandatory courses focused on the skills, tools, and knowledge that regulators will need to ensure industry compliance with the rules.

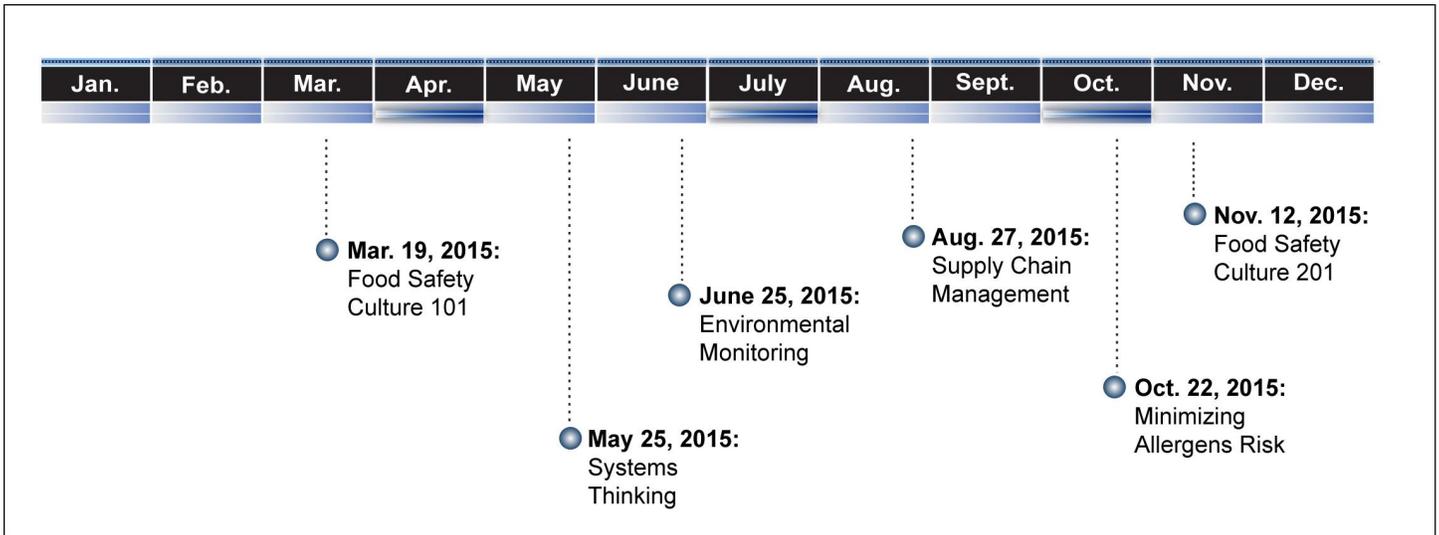
Optional Training on Industry Best Practices

From March 2015 to November 2015, FDA offered six 1-1/2-hour optional courses via webinar, as shown in figure 5. Rather than focusing on the specific requirements of the rules—which were not finalized until September 2015—these courses focused on a range of topics presented by FDA and industry officials aimed at familiarizing regulators with industry best practices. The courses included two on food safety culture, defined as the alignment of values and behaviors with respect to food safety, from management or owners through to frontline workers. Other courses focused on the following industry best practices.

- **Systems thinking.** A problem solving approach that views components of a system in relation to one another and to other systems, rather than in isolation.
- **Environmental monitoring.** A process used to verify the effectiveness of controls in minimizing or preventing contamination by environmental pathogens.
- **Supply chain management.** The identification and control of hazards associated with raw materials and other ingredients in the supply chain.
- **Minimizing allergens risk.** Practices to reduce the risk of allergens, including accurate product labeling and prevention of cross-contamination.

Each of these courses was recorded and made available for subsequent viewing by FDA and nonfederal officials.

Figure 5: Optional FDA Training for Regulators on the Human and Animal Food Rules



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-16-425

Required Training on Rule Requirements and Regulator Skills, Tools, and Knowledge

According to FDA, the agency planned to begin providing required regulator training on the human food rule in May 2016 and on the animal food rule in June 2016. Under this required training, regulators are first to take courses developed and administered by the Food Safety Preventive Controls Alliance (FSPCA) under a grant from FDA.⁴⁸ These FSPCA courses focus on the requirements of the human and animal food rules. They were designed with an industry audience in mind to help industry comply with the new rules. However, FDA decided that regulators would benefit from taking these courses together with industry to ensure that both groups were receiving the same information and to facilitate learning from one another.

FDA made the FSPCA courses a prerequisite to subsequent courses for regulators only, which focus on the skills, tools, and knowledge that regulators would need to ensure industry compliance with the human and

⁴⁸FDA created the FSPCA in 2011 under a grant to the Illinois Institute of Technology's Institute for Food Safety and Health. FDA tasked the FSPCA with developing a standardized training and education program and a technical assistance network to help industry comply with the requirements of the human and animal food rules.

animal food rules. According to FDA, the regulator-only courses on the human and animal food rules are scheduled to begin in the summer of 2016 and to continue through the fall of 2018. FDA officials told us that these courses are being developed by FDA subject matter experts, some of whom will subsequently train selected FDA and nonfederal officials to serve as course instructors. Those instructors will then administer the courses at various locations around the country. FDA officials told us that they are still working to develop the regulator-only courses, identify instructors, and finalize details regarding how and where the training will be delivered.

FDA Has Begun to Develop a Regulator Training Plan on the Produce Rule

As of February 2016, FDA had begun to develop, but not to administer, a plan for training regulators on the FSMA-mandated produce rule. At that time, the draft plan included two components. First, certain regulators would be trained to conduct on-farm readiness reviews.⁴⁹ Second, all regulators responsible for conducting regulatory inspections and ongoing compliance and enforcement activities would be trained to perform those responsibilities.

Training for On-Farm Readiness Reviews

According to FDA's draft plan, regulator training for the on-farm readiness reviews is to begin with a course developed and administered by the Produce Safety Alliance (PSA).⁵⁰ Like the FSPCA courses, the PSA course was designed with an industry audience in mind. However, FDA decided that regulators would benefit from taking the course, along with industry, to ensure that regulators and industry received the same information and to facilitate their learning from one another. As with the FSPCA courses, FDA plans to make the PSA course a prerequisite to subsequent regulator-only courses. According to FDA's draft plan, the regulator-only courses for the on-farm readiness reviews will focus on the goals of the reviews and regulator roles and responsibilities, among other things. According to FDA, the agency is working closely with NASDA to develop this training. As of February 2016, FDA planned to conduct a

⁴⁹On-farm readiness reviews are voluntary, nonregulatory visits during which regulators assess farms against rule requirements to educate farmers and promote compliance with the rule prior to regulatory inspections.

⁵⁰FDA established the PSA in 2010, in cooperation with USDA and Cornell University, to provide the produce industry and associated groups with training and educational opportunities related to current best practices and guidance and future regulatory requirements.

pilot of these reviews in the spring of 2017, with training provided in advance to staff participating in the pilot and subsequently to remaining staff responsible for conducting these reviews. According to FDA, the pilot will be coordinated by NASDA in collaboration with FDA and state representatives.

Training for Regulatory Inspections and Ongoing Compliance and Enforcement Obligations

Like the training for the on-farm readiness reviews, training for regulatory inspections and ongoing compliance and enforcement activities is to begin with prerequisite courses designed for and taken together with industry. In this case, these prerequisite courses are to be administered by the PSA and the Sprout Safety Alliance (SSA).⁵¹ Next, FDA plans to have regulators complete regulator-only courses focused on the skills, tools, and knowledge regulators will need to conduct regulatory inspections and ongoing compliance and enforcement activities under the produce rule. As of February 2016, FDA planned to deliver the training for regulatory inspections and ongoing compliance and enforcement activities—including the PSA and SSA courses—beginning in the fall of 2016 for regulators responsible for inspecting sprouts growers, who come into compliance first, and in the fall of 2017 for remaining regulators. From the fall of 2016 through the winter of 2019, FDA also planned to develop and deliver webinars on specific areas of the produce rule, best practices, and observations from on-farm readiness reviews, among other things.

FDA Is Working to Overcome Challenges Related to Regulator Training

Through our discussions with officials from FDA and from associations representing nonfederal food safety officials, we identified several challenges that FDA is working to overcome in developing and administering regulator training. Some of these challenges are the same as those related to developing coordinated implementation plans.

New and Updated Training Courses

Officials from FDA and several of the associations we interviewed discussed challenges related to the need for entirely new and updated training courses on the FSMA-mandated rules. As previously discussed, the FSMA-mandated rules marked a major shift in food safety regulation by, among other things, establishing the first enforceable national standards for on-farm practices related to produce, establishing the first

⁵¹FDA established the SSA in 2012, in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, to enhance the sprout industry's understanding and implementation of best practices for improving sprout safety.

CGMPs for the animal food industry, updating CGMPs for the human food industry, and mandating preventive control programs across the human and animal food industries. This, in turn, required the development of entirely new regulator training courses on produce standards and animal food CGMPs and preventive controls and updated courses on human food CGMPs. In addition, because the produce industry has not been subject to routine regulatory inspections to date, FDA officials and association representatives explained that the produce training courses will need to train regulators on how to interact with an industry that is unaccustomed, and potentially resistant, to government oversight. According to FDA, the agency is taking numerous steps to meet these challenges, including developing the regulator training plans that we discussed earlier, which include a focus on “farm etiquette,” describing key considerations in overseeing the produce industry.

Number of Regulators to Be Trained

Officials from FDA and several of the associations we interviewed discussed challenges related to the thousands of regulators who must be trained. For example, one association representative explained that compliance with each rule begins to come due roughly 1 year after the final rule is published, leaving little time for regulators across the country to receive training on the rule requirements and compliance verification duties. To reach greater numbers of regulators and reduce attendees’ travel time and cost, FDA officials stated that they are considering creating training hubs around the country and offering as much online training as possible. In addition, FDA recognizes that it is not feasible to train all regulators simultaneously. Therefore, FDA officials stated that they plan to use a phased training strategy to administer regulator training in accordance with industry compliance dates. Specifically, FDA officials stated that they plan to administer training in 2016 to regulators in areas with the highest concentrations of large businesses, for which compliance is due first. FDA then plans to administer training in 2017 to regulators in areas with the highest concentrations of small businesses, for which compliance is due later. Finally, FDA plans to administer training in 2018 to regulators in areas with the highest concentrations of very small businesses, for which compliance is due last.⁵²

⁵²According to FDA, the agency also plans to administer training in 2018 to regulators in areas with the highest concentrations of businesses subject to the FDA Grade “A” Pasteurized Milk Ordinance.

Inventories of Businesses
Subject to the Rules

According to FDA officials, implementing the phased training strategy that the agency plans to use is complicated by the business inventory challenges discussed earlier in this report. Without an accurate inventory of businesses covered under the rules, FDA is unable to determine when and where to target its training.

Varying Legal Authorities

Representatives of most of the associations we interviewed discussed challenges related to nonfederal agencies' varying legal authorities. For example, as we noted earlier in this report, representatives of some associations stated that most nonfederal agencies lack authority to conduct on-farm inspections related to produce. However, having such authority is a prerequisite to hiring regulators to carry out produce inspections, and hiring regulators must occur before they can be trained.

Varying Regulatory Structures

Representatives of most of the associations we interviewed discussed challenges related to nonfederal agencies' varying regulatory structures. For example, just as most nonfederal agencies lack legal authority to conduct on-farm inspections related to produce, according to some association representatives, most nonfederal agencies have no regulatory structure for overseeing produce. Like legal authority, a regulatory infrastructure for overseeing produce is a prerequisite to hiring regulators to carry out produce inspections, and hiring regulators must occur before they can be trained.

Conclusions

The safety and quality of the U.S. food supply are governed by a highly complex system involving more than 3,000 nonfederal agencies at the state, local, tribal, and territorial levels. FSMA mandated, among other things, that FDA take steps that once taken, would better integrate its food safety oversight with that of nonfederal agencies. Integrating food safety oversight across federal, state, local, tribal, and territorial jurisdictions is a daunting task that is complicated by numerous coordination challenges. FDA has demonstrated progress working with nonfederal agencies to address these challenges, but many hurdles remain as FDA continues its work to implement the FSMA-mandated rules on produce, human food, and animal food.

FSMA's mandated steps related to integration touch on areas including rulemaking. FDA's rulemaking is also subject to other laws and executive orders requiring consultation with nonfederal agencies. We found that FDA took steps to work with nonfederal agencies on developing the FSMA-mandated rules on produce, human food, and animal food and developing plans for coordinated implementation of those rules. However,

FDA did not consult with tribes throughout all stages of developing the proposed rules, as is directed by HHS's tribal consultation policy for all rules with tribal implications where the federal government does not provide the funds necessary to pay the direct compliance costs incurred by tribes. In particular, FDA did not consult with tribes before publication of the proposed rules. Instead, FDA's first formal consultation took place 1 month after it published the proposed animal food rule and 10 months after it published the proposed produce and human food rules.

Under the HHS tribal consultation policy, each agency within HHS must establish a tribal consultation policy, which should include an accountable process to ensure meaningful and timely input by tribal officials. More than 11 years after establishment of the HHS tribal consultation policy, however, FDA has not established an agency-level policy. FDA has begun to develop such a policy and issued a draft in late February 2016. FDA's draft policy, however, does not explicitly provide for early consultation with tribes on all rules with tribal implications where the federal government does not provide the funds necessary to pay the direct compliance costs incurred by tribes, including before promulgation of proposed regulations. Without early consultation, tribes are unable to provide input at a time when it is most likely to have a meaningful impact on the agency's decision making. Moreover, FDA has not established a timetable to guide the policy's finalization. Developing a draft policy is a good first step, but without setting a timetable, with milestones and interim steps, it will be difficult for FDA to set priorities, use resources efficiently, measure progress, and provide management a means to monitor this progress in finalizing the policy. FDA therefore risks continued delays in establishing a process to ensure meaningful and timely tribal consultation, a critical element of a sound and productive federal-tribal relationship.

Recommendations for Executive Action

To help ensure meaningful and timely consultation with Indian tribes on future rulemaking, we recommend that the Secretary of Health and Human Services direct the Commissioner of the FDA to take the following two actions:

- make certain that FDA's tribal consultation policy explicitly provides for early consultation with tribes on all rules with tribal implications where the federal government does not provide the funds necessary to pay the direct compliance costs incurred by tribes, including before promulgation of proposed regulations, and

-
- develop a timetable, with milestones and interim steps, for finalizing FDA's tribal consultation policy.

Agency Comments and Our Evaluation

We provided a draft of this report for review and comment to the Secretary of Health and Human Services. HHS provided written comments, which are presented in appendix III. In its written comments, HHS agreed with our recommendations. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staffs 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. Key contributors to this report are listed in appendix IV.



Steve D. Morris
Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

Our review provides information regarding the Food and Drug Administration's (FDA) coordination with nonfederal agencies in relation to the FDA Food Safety Modernization Act (FSMA)-mandated rules on produce, human food, and animal food. In particular, the review examines the extent to which FDA has (1) met its regulatory consultation requirements in developing the rules, (2) developed plans to coordinate implementation of the rules, and (3) developed and administered plans for training regulators on the rules.

To address all of our objectives, we first identified and reviewed authorities governing FDA's coordination with nonfederal agencies on the FSMA-mandated rules on produce, human food, and animal food. For each objective, these authorities included FSMA and the Federal Food, Drug, and Cosmetic Act. For our objective on regulatory consultation, these authorities also included the Unfunded Mandates Reform Act of 1995; Executive Orders 12866, 13563, 13175, and 13132; the Department of Health and Human Services' (HHS) tribal consultation policy; FDA's draft tribal consultation policy; and relevant presidential memorandums and case law. In addition, for our objective on regulatory consultation, we reviewed our body of work on key implementation practices, including timetables with interim tasks and milestones. Moreover, for our objective on coordinated implementation, we reviewed our prior work on key features and issues to consider when implementing collaborative mechanisms.

For all objectives, we obtained and reviewed relevant documentation, including transcripts of and slide presentations from FDA public meetings related to the three rules; the text of the proposed, supplemental, and final rules, including the rule preambles; and relevant documents referenced in each of the rules. For our objective on regulatory consultation, we also reviewed notices that FDA published in the *Federal Register* requesting information to inform the agency's rulemaking and records of outreach to nonfederal agencies, including tribes. In addition, for our objectives on coordinated implementation and regulator training, we reviewed relevant FDA plans and proposals, as well as cooperative agreements and grants awarded to stakeholder organizations. Furthermore, for our objective on regulator training, we reviewed curricula documents on courses delivered to date.

For all objectives, we also attended relevant food safety conferences and interviewed knowledgeable FDA officials and other stakeholders, including representatives of industry; public interest groups; and other relevant groups, such as the Partnership for Food Protection.¹ In addition, for our objective on regulatory consultation we interviewed officials from HHS and eight state departments of agriculture. Moreover, for our objective on regulator training, we conducted interviews with relevant training organizations, including the International Food Protection Training Institute, the Food Safety Preventive Controls Alliance, and the Produce Safety Alliance. Furthermore, to obtain perspectives of nonfederal officials on each of our objectives, we took three additional steps.

- **Review of public comments on FDA rulemaking.** We reviewed all public comments from state, local, tribal, and territorial governments, and from associations representing those entities, that were submitted in response to the proposed and supplemental rules on produce, human food, and animal food. We obtained these comments from regulations.gov, a website through which the public can search for and provide comments on federal rulemaking and other dockets that are open for comment and published in the *Federal Register*. We began by downloading from regulations.gov lists of all public comments on these rules. We then reviewed those lists to determine which comments were provided by state, local, tribal, and territorial governments and associations representing those entities. Next, we conducted a content analysis of these comments to identify themes related to coordination challenges faced and opportunities for improvement.
- **Interviews with associations of nonfederal officials.** We developed a set of closed-ended and open-ended questions based, in part, on our analysis of public comments. Next, we administered those questions to representatives of selected associations of state, local, tribal, and territorial food safety officials to obtain their views on the identified challenges and opportunities, as well as their views on steps taken by FDA related to rule development, implementation, and training. We then analyzed and summarized the association responses. In all, we interviewed representatives from 10 associations. These associations were selected based on their

¹The Partnership for Food Protection is an FDA-state collaborative mechanism focused on integrating food safety oversight across jurisdictions.

participation in the Council of Association Presidents;² their membership in the “Big Seven” associations of state and local officials;³ and recommendations received during preliminary interviews that we conducted with FDA, industry or trade associations, and public interest groups. We excluded some associations whose areas of focus were outside the scope of our review. For example, several associations’ areas of focus were surveillance and outbreak response, and these associations were therefore unable to answer questions regarding the FSMA-mandated rules on produce, human food, and animal food. Appendix II lists the associations we interviewed.

- **Site visit.** We visited California—the state with the nation’s largest agricultural and food production sectors—where we conducted interviews with a range of officials from state and local agencies, and from university and industry groups, to discuss their programs on produce, human food, and animal food.

We conducted this performance audit from March 2015 to May 2016 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.

²The Council of Association Presidents consists of the following 11 major state and local public health and regulatory professional associations whose outreach capacity extends to virtually all state and local public health officials: the Association of American Feed Control Officials, the Association of Food and Drug Officials, the Association of Public Health Laboratories, the Association of State and Territorial Health Officials, the Council of State and Territorial Epidemiologists, the National Association of City and County Health Officials, the National Association of Local Boards of Health, the National Association of State Animal Health Officials, the National Association of State Departments of Agriculture, the National Environmental Health Association, and the U.S. Animal Health Association.

³The “Big Seven” refers to a coalition of the following seven national associations whose members represent state and local elected and appointed officials: the Council of State Governments, the International City/County Management Association, the National Association of Counties, the National Conference of State Legislatures, the National Governors Association, the National League of Cities, and the U.S. Conference of Mayors.

Appendix II: List of Associations

Name	Description
Association of American Feed Control Officials	An association of local, state, and federal agencies charged by law to regulate the sale and distribution of animal feeds and animal drug remedies.
Association of Food and Drug Officials	An association representing state, territorial, and local officials from departments of health and agriculture, whose mission is to advance uniform food and drug safety laws, regulations, and guidelines.
Council of State Governments	A forum for officials in all three branches of state government whose mission is to champion excellence in state government to advance the common good.
National Association of County and City Health Officials	An association of local health department officials, whose mission is to protect and improve the health of all people and all communities.
National Assembly of State Animal Health Officials	An association of the chief animal health officials in each state, whose mission is to speak with one voice in matters of animal health science and public policy.
National Association of State Departments of Agriculture	An association representing the commissioners and directors of state departments of agriculture, whose mission is to support and protect the American agriculture industry while protecting consumers and the environment.
National Conference of State Legislatures	An organization representing state legislators and their staffs, whose mission is to improve the quality and effectiveness of state legislatures; promote policy innovation and communication among state legislatures; and ensure a strong, cohesive voice for state legislatures in the federal system.
National Congress of American Indians	An organization of American Indian and Alaska Native tribes, whose mission is to protect and enhance treaty and sovereign rights; secure traditional Native American laws, cultures, and ways of life for their descendants; promote a common understanding of the rightful place of tribes in the family of American governments; and improve the quality of life for Native communities and peoples.
National Environmental Health Association	An association of environmental health professionals in the public and private sectors, academia, and the uniformed services, whose mission is to advance the environmental health and protection professional for the purpose of providing a healthful environment for all.
U.S. Animal Health Association	An association of state and federal animal health officials and allied organizations, whose mission is to serve as a national forum for communication and coordination on efforts to prevent, control, and eliminate livestock diseases.

Source: GAO analysis of association information. | GAO-16-425

Appendix III: 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

APR 29 2016

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

Dear Mr. Steve Morris,

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed*" (GAO-16-425).

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

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
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: FDA COORDINATING WITH STAKEHOLDERS ON NEW RULES BUT CHALLENGES REMAIN AND GREATER TRIBAL CONSULTATION NEEDED (GAO-16-425)

HHS appreciates GAO's effort in examining the extent to which FDA coordinated with non-federal agencies in rule development and implementation, as well as regulator training, for three Food Safety Modernization Act (FSMA)-mandated rules related to produce, human food, and animal food. As this report and our response demonstrate, enormous strides have been made toward advancing the national integrated food safety system (IFSS), but we agree there is still more to do. While FSMA specifically required FDA to form and enhance partnerships with both federal and non-federal regulatory and public health partners, a significant level of food safety integration efforts were already underway prior to the enactment of FSMA. Some, but not all, of these efforts were highlighted in the report including:

- Implementation of state cooperative programs that provide guidance, standardization, consultation, training, technical assistance, and model rules and ordinances for Grade "A" milk, molluscan shellfish, and retail food safety regulatory programs.
- Development and implementation of national regulatory standards [i.e., Manufactured Food Regulatory Program Standards (MFRPS), Animal Feed Regulatory Program Standards (AFRPS), and Voluntary National Retail Food Regulatory Program Standards (VNRFRPS)] to build the capacity and effectiveness of non-federal manufactured food, animal food, and retail food regulatory programs.
- Dedicated funding to support implementation of federal-state initiatives [namely the Food Emergency Response Network (FERN) and Federal-State Rapid Response Teams (RRTs)] that enhance national foodborne illness outbreak surveillance, response time, and capacity.

FDA believes it is important to emphasize these and other significant efforts underway that promote the IFSS and build the necessary infrastructure and capacity of state, local, territorial, and tribal regulatory and public health agencies. For example, to promote the IFSS, FDA has invested over \$100 million in grants and cooperative agreements to our non-federal regulatory and public health partners in the last five years alone. Without this funding and the following FDA initiatives, it would not have been possible to accomplish the FSMA integration work noted by GAO:

- Establishing, supporting, and collaborating with the Manufactured Food Regulatory Program Alliance (MFRPA) in order to strengthen interagency collaboration, improve states' regulatory and surveillance protection programs for manufactured food, and promote the MFRPS.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FOOD SAFETY: FDA COORDINATING WITH STAKEHOLDERS ON NEW RULES BUT CHALLENGES REMAIN AND GREATER TRIBAL CONSULTATION NEEDED (GAO-16-425)

- Verifying the implementation and conformance status of state programs enrolled in the MFRPS and AFRPS utilizing objective audit criteria.
- Providing funding to state food laboratories to achieve and maintain Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2005 laboratory accreditation which benefits the IFSS by ensuring quality microbiological and chemical food analyses performed by state manufactured food regulatory programs.
- Establishing a cooperative agreement with the Association of Public Health Laboratories (APHL), the Association of American Feed Control Officials (AAFCO), and the Association of Food and Drug Officials (AFDO) to develop laboratory data acceptance criteria and support state laboratories seeking ISO 17025:2005 accreditation.
- Establishing, supporting, and collaborating with the Partnership for Food Protection (PFP) to develop and implement the IFSS by identifying and fostering best practices related to interagency communication, industry compliance, emergency response, laboratory and regulatory science, training, and certification.
- Supporting the formation and activities of 16 State Food Protection Task Forces which create an effective infrastructure for enhancing and coordinating outreach, response, and information sharing between regulatory, industry, and academic food protection partners within participating states.
- Launching the development of an electronic resource library that will provide resource tools (e.g., special instructions and assignments; training materials and resources; industry best practices; guidance documents; links to commodity-specific processing videos; fact sheets describing commodity-specific processes, potential hazards, and controls; and a contact list identifying subject matter experts) to aid FDA and non-federal regulatory staff performing preventive controls and produce inspection and compliance work.
- Supporting state contract inspection work which enhances regulatory oversight of FDA's regulated firms, provides states with technical training, familiarizes states with federal requirements, and improves enforcement of food protection laws.
- Auditing state contract inspections to ensure the quality and adequacy of inspections, compliance with contract requirements, and implementation of corrective actions to address systemic problems to protect the public health, if necessary.
- Commissioning/credentialing non-federal regulatory officials and establishing 20.88 information sharing agreements with regulatory agencies and associations to facilitate interagency cooperation and leverage our non-federal regulatory partners in conducting inspections and other FDA-sanctioned activities on our behalf.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FOOD SAFETY: FDA COORDINATING WITH STAKEHOLDERS ON NEW RULES BUT CHALLENGES REMAIN AND GREATER TRIBAL CONSULTATION NEEDED (GAO-16-425)

- Providing training, on a national scope, to state, local, tribal, and territorial regulatory and public health partners (and the financial resources to attend that training) to ensure they have the knowledge, skills, and abilities to perform our collective public health mission.
- Providing funding and working collaboratively with the International Food Protection Training Institute (IFPTI) and PFP to develop a comprehensive national food safety training curriculum based on competency assessments for all levels and specialties of food safety professionals in the IFSS.
- Dedicating resources to host an annual Public Health and Regulatory Food and Feed Training Summit that brings together federal and non-federal partners to chart a strategic plan for training nationwide.
- Standing up an FDA Integration Staff and network of State Liaisons dedicated to measuring, tracking, and promoting the IFSS through leadership, technical assistance, consultation, and guidance.
- Launching mutual reliance pilots with select states to evaluate inspection and compliance activities so that work products can be counted towards each other's inspectional obligations and partner agency's work products can be utilized to support enforcement actions.
- Establishing a technical assistance network of subject matter experts to support FDA and state food safety staff performing inspections and compliance activities under the various FSMA rules.

To highlight some of the most critical foundation elements, FDA is strengthening the integrated food safety system in several ways. Specifically, we want to emphasize the development and implementation of regulatory program standards; enhancing the quality and capacity of laboratory science; ensuring fluid information exchange with FDA's non-federal regulatory partners; and providing training opportunities for regulatory and public health professionals.

The MFRPS, AFRPS, and VNRFPS establish a uniform foundation for the design and management of state, local, tribal, and territorial programs that have the responsibility for regulating human and animal food. The goal of these standards is to leverage resources and share best practices to build systems within regulatory food programs. FDA utilizes objective criteria to conduct periodic audits to verify the implementation and conformance status of state programs enrolled in the MFRPS and AFRPS.

The Regulatory Program Standards advance the IFSS by:

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FOOD SAFETY: FDA COORDINATING WITH STAKEHOLDERS ON NEW RULES BUT CHALLENGES REMAIN AND GREATER TRIBAL CONSULTATION NEEDED (GAO-16-425)

- Encouraging programs to adopt the best practices and continuous improvement models contained within nationally-recognized regulatory program standards and codes.
- Utilizing performance measures and metrics to identify priorities and measure effectiveness.
- Fostering partnerships through food protection task forces, technical support, program evaluation, funding, training, and information technology.
- Enhancing laboratory services by promoting national program standards and accreditation.
- Conducting outreach programs to enhance food safety and public health.
- Promoting capacity building, accountability, cost efficiency, transparency, and exchange of best practices.
- Facilitating enhanced communication and collaboration between internal and external stakeholders.
- Promoting a nationally integrated approach to food safety and public health.

Food laboratories play a vital role in ensuring the safety and quality of the food supply. FDA is working with our state, local, territorial, and tribal partners to develop and maintain a nationally integrated laboratory science system that:

- Facilitates the sharing of results between regulatory partners.
- Assures comparability of analytical methods and acceptability of laboratory results between partners.
- Recommends processes to leverage laboratory resources to increase information about the food supply chain.
- Prepares human and animal food testing laboratories to achieve and maintain ISO accreditation.

FDA works collaboratively with the Partnership for Food Protection (PFP) to advance the IFSS. Established in 2009, PFP is a group of dedicated professionals from federal, state, and local governments with roles in protecting the food supply and public health. PFP has developed a six-year strategic plan that will advance the IFSS in seven key areas: Outreach; Work planning and Inspections; Compliance and Enforcement; Surveillance, Response, and Post-Response; Laboratory Science; Training and Certification; and Information Technology. Projects within these seven key areas are developed and implemented collaboratively with our state partners and the results feed into our overall IFSS efforts.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FOOD SAFETY: FDA COORDINATING WITH STAKEHOLDERS ON NEW RULES BUT CHALLENGES REMAIN AND GREATER TRIBAL CONSULTATION NEEDED (GAO-16-425)

FDA cannot make FSMA a reality without its partnerships with state, local, tribal, and territorial regulatory partners. FDA's contract inspection programs benefit states with technical training, familiarity with federal requirements, and uniform enforcement of consumer laws. State contracts allow FDA to work collaboratively with states to expand coverage of domestic food processing facilities. Contract inspection programs are in place for Human Food, Animal Food/Bovine Spongiform Encephalopathy (BSE), Tissue Residue, Milk Drug Residue, and other non-food related commodity areas. Each year, over 16,500 facility inspections/visits and 8,800 sample collections are performed by at least 53 state agencies under human and animal food-related contracts. FDA conducts audits to ensure the quality and adequacy of inspections and compliance with contract requirements. Systemic problems are identified and corrected during audits in order to protect the public health.

The commissioning program was developed to make interagency cooperation and sharing of information among regulatory partners more effective. Through commissioning, FDA legally grants authority to state, local, and territorial partners to conduct inspections and investigations, collect samples, receive and review confidential information, and copy and verify records. Currently, there are over 3,600 state and local officials commissioned by FDA.

Another information sharing mechanism that extends the commissioning process is provided in Chapter 21 of the Code of Federal Regulations (CFR) 20.88. Commonly referred to as "20.88's," these agreements allow FDA to share certain non-public information with state and local government officials, regulatory agencies, and regulatory associations. Examples of information that can be shared through 20.88's include confidential commercial information (CCI), personal privacy information (PPI), and pre-decisional information (PDI). These agreements have been especially useful in sharing information related to foodborne illness outbreak investigations.

The FDA provides free instructor-led and web-based training and educational opportunities for state, local, tribal, and territorial regulatory and public health professionals to strengthen the infrastructure and capacity of the IFSS. These trainings cover a variety of subject matters including manufactured food, animal food, tissue residue, emergency response, milk, shellfish, and retail food establishments. In addition, FDA provides funding opportunities to help our non-federal partners travel to training. As an example, in FY2015, FDA provided approximately \$1.2 million to fund non-federal regulatory partners' travel to various training opportunities. FDA is diligently working towards the goal of FSMA subject matter integration into training opportunities, with resources devoted to national training curriculum development and a new landmark initiative to host an annual Public Health and Regulatory Food and Feed Training Summit.

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FDA is committed to improving and maintaining a strong public health and regulatory infrastructure and foundation among state, local, tribal and territorial partners and ensuring that we collectively communicate, coordinate, and collaborate in order to safeguard the food supply. Our experience indicates that the IFSS must be built with ongoing strategic input and full participation from our public health and regulatory partners which can only be sustained through adequate multi-year funding.

Responses to GAO Recommendations

To ensure timely consultation with Indian tribes on future rulemaking, GAO recommends that FDA take two actions. FDA should (1) make certain that its tribal consultation policy explicitly provides for early tribal consultation, and (2) develop a timeline for finalizing the policy.

GAO Recommendation #1: FDA should make certain that its tribal consultation policy explicitly provides for early tribal consultation.

HHS Response: FDA concurs with the GAO's recommendation and any comments submitted by stakeholders and work to ensure that FDA's intent is clearly understood in the final Tribal Consultation Policy will be considered. The draft FDA Tribal Consultation Policy proposes that FDA consult with Indian Tribes "throughout" the process of developing any regulation that has tribal implications. This includes regulations that preempt tribal law or impose substantial direct-compliance costs on Indian Tribal governments, and that are not required by statute. FDA considered the term "throughout" to be inclusive of all of the key stages and phases leading up to and including formal promulgation of a rule.

Recommendation #2: FDA should develop a timeline for finalizing the policy.

HHS Response: FDA concurs with the GAO's recommendation and continues to work toward finalization of the Tribal Consultation Policy. On February 29, FDA issued a draft Tribal Consultation Policy and sent a letter inviting tribal leaders to a consultation on the draft policy during an All Tribes Call held on April 21, 2016. In addition, FDA announced the establishment of a docket to receive comments on the draft FDA Tribal Consultation Policy from tribal officials, tribal organizations, individual tribal members and other interested persons. The comment period for the draft policy closes on May 31, 2016. FDA looks forward to finalizing the policy upon reviewing and consideration of the comments received. FDA intends for its Tribal Consultation Policy to serve as a platform for the Agency to create consistent and

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meaningful tribal consultation across FDA Centers and Offices. The timeframe for finalizing the policy will depend on the extent of the comments received.

Appendix IV: 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), Cheryl Arvidson, Timothy Bober, Kevin Bray, Ellen Fried, Megan Kizzort, Armetha Liles, Perry Lusk, Josie Ostrander, Steven Putansu, and Emmy Rhine Paule made key contributions to this report.

Appendix V: Accessible Data

Agency Comment Letter

Text of Appendix III:
Comments from the
Department of Health and
Human Services

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DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation

Washington, DC 20201

APR 29 2016

Mr. Steve D. Morris

Director, Natural Resources and Environment Team

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

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

Sincerely,

Jim R. Esquea

Assistant Secretary for Legislation

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Page 2

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and verify records. Currently, there are over 3,600 state and local officials commissioned by FDA.

Another information sharing mechanism that extends the commissioning process is provided in Chapter 21 of the Code of Federal Regulations (CFR) 20.88. Commonly referred to as "20.88's," these agreements allow FDA to share certain non-public information with state and local government officials, regulatory agencies, and regulatory associations. Examples of information that can be shared through 20.88's include confidential commercial information (CCI), personal privacy information (PPI), and pre-decisional information (PDI). These agreements have been especially useful in sharing information related to foodborne illness outbreak investigations.

The FDA provides free instructor-led and web-based training and educational opportunities for state, local, tribal, and territorial regulatory and public health professionals to strengthen the infrastructure and capacity of the IFSS. These trainings cover a variety of subject matters including manufactured food, animal food, tissue residue, emergency response, milk, shellfish, and retail food establishments. In addition, FDA provides funding opportunities to help our non-federal partners travel to training. As an example, in FY2015, FDA provided approximately \$1.2 million to fund non-federal regulatory partners' travel to various training opportunities. FDA is diligently working towards the goal of FSMA subject matter integration into training opportunities, with resources devoted to national training curriculum development and a new landmark initiative to host an annual Public Health and Regulatory Food and Feed Training Summit.

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FDA is committed to improving and maintaining a strong public health and regulatory infrastructure and foundation among state, local, tribal and territorial partners and ensuring that we collectively communicate, coordinate, and collaborate in order to safeguard the food supply. Our experience indicates that the IFSS must be built with ongoing strategic input and full participation from our public health and regulatory partners which can only be sustained through adequate multi-year funding.

Responses to GAO Recommendations

To ensure timely consultation with Indian tribes on future rulemaking, GAO recommends that FDA take two actions. FDA should (1) make certain that its tribal consultation policy explicitly provides for early tribal consultation, and (2) develop a timeline for finalizing the policy.

GAO Recommendation #1: FDA should make certain that its tribal consultation policy explicitly provides for early tribal consultation.

HHS Response: FDA concurs with the GAO's recommendation and any comments submitted by stakeholders and work to ensure that FDA's intent is clearly understood in the final Tribal Consultation Policy will be considered. The draft FDA Tribal Consultation Policy proposes that FDA consult with Indian Tribes "throughout" the process of developing any regulation that has tribal implications. This includes regulations that preempt tribal law or impose substantial direct-compliance costs on Indian Tribal governments, and that are not required by statute. FDA considered the term "throughout" to be inclusive of all of the key stages and phases leading up to and including formal promulgation of a rule.

Recommendation #2: FDA should develop a timeline for finalizing the policy.

HHS Response: FDA concurs with the GAO's recommendation and continues to work toward finalization of the Tribal Consultation Policy. On February 29, FDA issued a draft Tribal Consultation Policy and sent a letter inviting tribal leaders to a consultation on the draft policy during an All Tribes Call held on April 21, 2016. In addition, FDA announced the establishment of a docket to receive comments on the draft FDA Tribal Consultation Policy from tribal officials, tribal organizations, individual tribal members and other interested persons. The comment period for the draft policy closes on May 31, 2016. FDA looks forward to finalizing the policy upon reviewing and consideration of the comments received. FDA intends for its Tribal Consultation Policy to serve as a platform for the Agency to create consistent and

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meaningful tribal consultation across FDA Centers and Offices. The timeframe for finalizing the policy will depend on the extent of the comments received.

Data
Tables/Accessible
Text

Data Table for Figure 1: Number of Reported Multistate Foodborne Illness Outbreaks in the United States, 1995–2014

Years	Number of outbreaks
"1995-99"	34
"2000-04"	51
"2005-09"	79
"2010-14"	120

Accessible Text for Figure 2: Farm-to-Fork Continuum

Growing Processing Distribution Retail Preparation Consumption

Note: This figure illustrates the various stages in the human food chain, from agricultural production to consumption.

Accessible Text for Figure 3: Implementation Timeline for FSMA-Mandated Rules on Produce, Human Food, and Animal Food

Rule	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Produce	Jan. 2011: FDA Food Safety Modernization Act (FSMA) mandates new produce rule	(empty cell)	Jan. 2013: FDA publishes proposed rule	Sept. 2014: FDA publishes supplemental rule	Nov. 2015: FDA publishes final rule	(empty cell)	Jan. 2017: Compliance due for large businesses with covered activities involving sprouts	Jan. 2018: Compliance due for large businesses with covered activities not involving sprouts and for small businesses with covered activities involving sprouts	Jan. 2019: Compliance due for small businesses with covered activities not involving sprouts and for very small businesses with covered activities involving sprouts	Jan. 2020: Compliance due for very small businesses with covered activities not involving sprouts
Human food	Jan. 2011: FSMA mandates new human food rule	(empty cell)	Jan. 2013: FDA publishes proposed rule	Sept. 2014: FDA publishes supplemental rule	Sept. 2015: FDA publishes final rule	Sept. 2016: Compliance due for large businesses	Sept. 2017: Compliance due for small businesses	Sept. 2018: Compliance due for very small businesses	(empty cell)	(empty cell)
Animal food	Jan. 2011: FSMA mandates new animal food rule	(empty cell)	Oct. 2013: FDA publishes proposed rule	Sept. 2014: FDA publishes supplemental rule	Sept. 2015: FDA publishes final rule	Sept. 2016: Compliance with Current Good Manufacturing Practice requirements (CGMP) due for large businesses	Sept. 2017: Compliance with preventive control program requirements (PC) due for large businesses and with CGMPs for small businesses	Sept. 2018: Compliance with PCs due for small businesses and with CGMPs for very small businesses	Sept. 2019: Compliance with PCs due for very small businesses	(empty cell)

Accessible Text for Figure 4: Key Steps in FDA’s Tribal Consultation on Proposed Rules on Produce, Human Food, and Animal Food

Jan. 2013: Food and Drug Administration (FDA) publishes proposed rules on produce and human food.	Apr. 2013: National Congress of American Indians (NCAI) sends letter to FDA stressing need for tribal consultation.	Oct. 29, 2013: FDA publishes proposed rule on animal food.	Nov. 2013: FDA holds first tribal consultation via webinar.	Apr. 2014: FDA holds in-person tribal consultations in Arizona and New Mexico. (Two additional in-person consultations held in fiscal year 2015.)
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Accessible Text for Figure 5: Optional FDA Training for Regulators on the Human and Animal Food Rules

Mar. 19, 2015: Food Safety Culture 101	May 25, 2015: Systems Thinking	June 25, 2015: Environmental Monitoring	Aug. 27, 2015: Supply Chain Management	Oct. 22, 2015: Minimizing Allergens Risk	Nov. 12, 2015: Food Safety Culture 201
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