United States Government Accountability Office

Report to Congressional Committees

November 2017

FOOD SAFETY

FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule

Accessible Version

GAO-18-85

GAO Highlights

Highlights of GAO-18-85, a report to congressional committees

November 2017

FOOD SAFETY

FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule

Why GAO Did This Study

Although the United States has one of the safest food supplies in the world, foodborne illness is a common public health problem; some of this illness can be linked to produce. For example, in 2017, a *Salmonella* outbreak linked to imported papayas sickened more than 200 people in 23 states and killed 1. FDA's produce rule, one of a number of rules required by the FDA Food Safety Modernization Act, established the first enforceable national food safety standards for produce. The Agricultural Act of 2014 required that the produce rule include "a plan to systematically…develop an ongoing process to evaluate and respond to business concerns" about the rule and a provision for GAO to report on FDA's efforts 1 year after the promulgation of the final rule and again the following year. In November 2016, GAO issued the first report.

In this follow-up report, GAO examined (1) steps FDA has taken since GAO's 2016 review to evaluate and respond to business concerns regarding the produce rule, (2) steps FDA has taken to assess the effectiveness of its efforts to evaluate and respond to business concerns regarding the rule, and (3) challenges FDA officials reported facing in evaluating and responding to business concerns regarding the rule. GAO examined TAN questions submitted by businesses; interviewed FDA officials and representatives from groups, such as the Produce Safety Alliance, working with FDA to implement the rule; and interviewed representatives from produce industry associations and a farming organization.

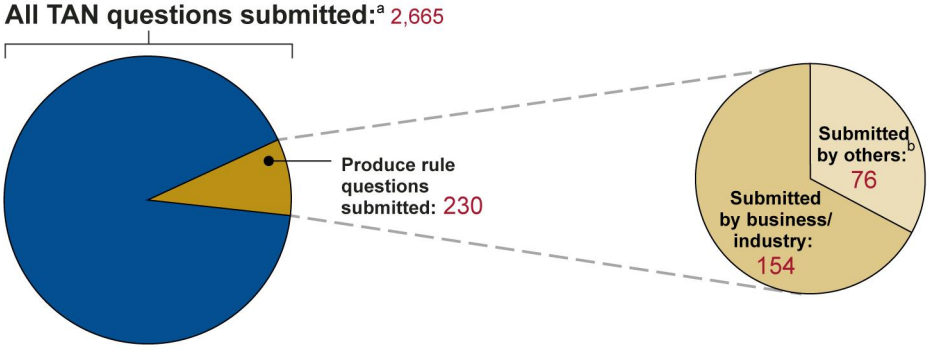
GAO is not making any recommendations.

View GAO-18-85. For more information, contact Steve D. Morris at (202) 512-3841 or morriss@gao.gov.

What GAO Found

Since GAO's November 2016 report on the Food and Drug Administration's (FDA) 2015 produce rule, the agency has continued to use its Technical Assistance Network (TAN) to evaluate and respond to questions and concerns about the rule. GAO found that since the issuance of its 2016 report, which contained data as of September 3, 2016, 2,665 more questions were submitted to the TAN, 230 of which pertained to the produce rule, and of those 230 questions, 154 were submitted by businesses (see fig.).

Questions Submitted to the Technical Assistance Network (TAN), September 4, 2016, through June 30, 2017



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-85

[a]The TAN also receives questions about other rules pertaining to the FDA Food Safety Modernization Act, such as rules on imported food and the sanitary transportation of food.
[b]Others include members of academia, consumers, and federal or state regulators.

Most produce rule-related TAN questions concerned agricultural water standards, such as methods for testing water. In addition to the TAN, FDA has taken other steps to evaluate and respond to business concerns, including funding training for industry and visiting farms. FDA is also reviewing the rule's water standards and published a proposed rule in September 2017 to extend the compliance dates associated with those standards in response to concerns.

FDA has begun collecting survey results on the web page used for submitting TAN questions and continues to develop a survey to assess the timeliness and quality of TAN responses. FDA also continued to develop metrics intended to assess its overall efforts to evaluate and respond to business concerns, officials reported. Produce industry representatives told GAO that FDA is open to hearing questions and concerns, but businesses need more information to comply with the rule and are awaiting FDA's forthcoming guidance on parts of the rule.

FDA officials reported facing two challenges in evaluating and responding to business concerns: identifying businesses subject to the rule and providing consistent, region-specific information in response to concerns. Officials said that the agency's cooperative agreement with 43 states plays a key role in addressing these challenges, as does the Produce Safety Network, a network of region-based FDA food safety experts.

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Abbreviations

FDA	Food and Drug Administration
FSMA	FDA Food Safety Modernization Act
PSA	Produce Safety Alliance
SSA	Sprout Safety Alliance
TAN	Technical Assistance Network

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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November 27, 2017

Congressional Committees

Although the United States has one of the safest food supplies in the world, foodborne illness is a common public health problem. Some of this illness can be linked to produce. For example, beginning in the summer of 2017, a *Salmonella* outbreak linked to imported papayas sickened more than 200 people in 23 states and killed 1, according to the Centers for Disease Control and Prevention; in 2011, 147 people fell ill and 33 died as a result of eating cantaloupes contaminated with *Listeria*. Other produce-related outbreaks in recent years have involved cucumbers, hot peppers, alfalfa sprouts, bean sprouts, and packaged salads. The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, is responsible for ensuring the safety of produce, along with many other foods. Overall, FDA is responsible for ensuring the safety of more than 80 percent of the U.S. food supply.[1]

Because produce is often consumed raw, without processing to reduce or eliminate contaminants, preventing contamination is key to ensuring safe consumption. 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.[2] FSMA, according to FDA, marked a historic turning point by focusing on preventing rather than reacting to foodborne illnesses. FSMA does so, in part, by requiring FDA to promulgate new rules that, combined, provide a framework for industry to implement preventive measures and for FDA to oversee implementation. In response to FSMA, FDA developed seven foundational rules; among them is the rule entitled *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*—also known as the produce rule.[3] This rule, which FDA promulgated in November 2015, established the first enforceable national

[1]FDA is responsible for ensuring that all domestic and imported foods—excluding meat, poultry, catfish, and processed egg products—are safe, wholesome, sanitary, and properly labeled.

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

[3]80 Fed. Reg. 74354 (codified at 21 C.F.R. pt. 112). Other rules required by FSMA that have been promulgated include rules about preventive measures to ensure the safety of human food, animal food, and imported foods; the sanitary transportation of food; and protection against acts of intentional contamination.

standards for on-farm growing, harvesting, packing, and holding of domestic and imported produce.[4] Among other things, the rule established standards related to agricultural water quality; the use of soil amendments, such as raw manure; the presence of domesticated and wild animals; worker training, health, and hygiene; and sanitation of equipment, tools, and buildings.

Some in the produce industry have raised questions and expressed concerns about the produce rule standards, including questions about the types of produce covered by the rule. Others have expressed concerns about the costs necessary to comply with the rule, particularly for smaller businesses. The Agricultural Act of 2014, also referred to as the 2014 Farm Bill, required that FDA ensure the final produce rule include "a plan to systematically … develop an ongoing process to evaluate and respond to business concerns."[5]

The act included a provision for GAO to report, 1 year after the promulgation of the final produce rule and again the following year, on the ongoing evaluation and response process. In November 2016, we issued our first report.[6] We found that FDA developed an information clearinghouse, called the Technical Assistance Network (TAN), to evaluate and respond to questions and concerns from businesses regarding implementation of the produce rule and other FSMA rules. In addition to using the TAN to respond to questions, FDA uses TAN questions to help inform the development of FSMA policy, guidance, and training to help businesses understand and comply with the produce rule and other FSMA rules. FDA officials told us the agency was developing a survey, along with other metrics, to assess the effectiveness of the TAN.

[4]80 Fed. Reg. 74354, 74354. In the rule, FDA defines "produce," in part, as any fruit or vegetable, including mushrooms, sprouts, peanuts, tree nuts, and herbs. 80 Fed. Reg. 74354, 74551 (codified at 21 C.F.R § 112.3). Produce that is rarely consumed raw—such as asparagus, potatoes, pumpkins, and sweet corn—is not covered by the rule. 80 Fed. Reg. 74354, 74549 (codified at 21 C.F.R § 112.2(a)(1)). Businesses covered by the rule are those averaging more than $25,000 in annual monetary value of produce sold during the previous 3-year period, with certain exceptions. 80 Fed. Reg. 74354, 74552 (codified at 21 C.F.R §§ 112.4, 112.5).

[5]Pub. L. No. 113-79, §12311(a)(3), 128 Stat. 649, 992 (2014).

[6]GAO, *Food Safety: FDA's Efforts to Evaluate and Respond to Business Concerns Regarding the Produce Rule*, GAO-17-98R (Washington, D.C.: Nov. 28, 2016).

This follow-up report examines (1) the steps FDA has taken since GAO's 2016 review to evaluate and respond to business concerns regarding the produce rule;[7] (2) the steps FDA has taken to assess the effectiveness of its efforts to evaluate and respond to business concerns regarding the rule; and (3) the challenges FDA officials reported facing in evaluating and responding to business concerns regarding the rule.

To examine the steps FDA has taken since GAO's 2016 review to evaluate and respond to business concerns regarding the produce rule, we reviewed information on FSMA and the produce rule on FDA's website; attended relevant food safety conferences, including the Association of Food and Drug Officials conference in Houston, Texas; interviewed FDA officials involved in implementation of the rule; and obtained data from FDA on the number of questions submitted to the TAN. To better understand the types of issues businesses were communicating to FDA, we also examined the full text of questions and concerns about the rule that businesses submitted to the TAN. We classified the questions and concerns into categories based on the type of question, such as requests for additional information or clarification regarding the produce rule. We assessed the reliability of the TAN data by interviewing agency officials knowledgeable about the data and determined that the data were sufficiently reliable for our report. In addition, we interviewed representatives from four organizations assisting FDA with implementation of the rule and an official from one state department of agriculture.[8] We also interviewed representatives from two produce industry associations and a farming organization from the northeastern United States.[9] We selected groups with large memberships; those representing both large and small business; those representing specific produce commodities, such as sprouts; those involved with educating businesses on produce rule implementation; and those representing different geographic locations across the United States. The information we obtained from these interviews is not

[7]We define "business concerns" as any concerns related to the produce rule raised by businesses covered by the rule.

[8]These organizations were the National Association of State Departments of Agriculture; the Produce Safety Alliance; the Sprout Safety Alliance; and the Southern Center for Training, Education, Extension, Outreach, and Technical Assistance to Enhance Produce Safety. We also interviewed an official with the North Carolina Department of Agriculture and Consumer Services.

[9]We interviewed representatives from the Produce Marketing Association, United Fresh Produce Association, and the New England Farmers Union.

generalizable to all produce industry associations, businesses, or others affected by the produce rule, but it provides illustrative examples. To examine the steps FDA has taken to assess the effectiveness of its efforts to evaluate and respond to business concerns, we interviewed FDA officials to learn about any ongoing or planned efforts. To examine the challenges FDA faces in evaluating and responding to business concerns, we interviewed FDA officials.

We conducted this performance audit from December 2016 to November 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

This section provides an overview of the produce rule and describes how FDA is partnering with states to implement the rule.

Overview of the Produce Rule and Compliance Dates

Produce is an important part of a healthy diet but is susceptible to contamination from numerous sources, including agricultural water, animal manure, equipment, and farm workers. The produce rule established standards to help ensure the safe growing and handling of produce. For example, the rule requires that businesses take steps to ensure that agricultural water that comes into contact with produce is safe and of adequate sanitary quality for its intended use. As part of this, the rule established microbial water criteria to determine the presence of generic *E. coli*, which is the most commonly used indicator of fecal contamination, and referenced a testing method published by the Environmental Protection Agency to test for the presence of generic *E. coli*.[10] The rule also established standards specific to sprouts, which are

[10]Generic *E. coli* is an indicator of fecal contamination because it is common in the intestinal tract of food animals. While most *E. coli* are harmless, the intestinal tract is also the primary pathway for contamination by pathogenic *E. coli* that can cause illness, such as *E. coli* O157:H7. According to FDA documentation, indicator organisms, such as generic *E. coli* have long been used in the United States to demonstrate the safety of drinking water and adequacy of water treatment.

especially vulnerable to contamination because of the warm, moist, and nutrient-rich conditions needed to grow them. In addition to the general requirements of the produce rule, the rule also includes requirements for businesses specifically related to preventing contamination of sprouts, which have been associated with foodborne illness outbreaks.[11]

The rule applies to businesses that grow, harvest, pack, or hold produce, including produce that will be imported or offered for import, with some exemptions based on the produce commodity and the size of a business. For example, the rule does not apply to produce that is rarely consumed raw, such as asparagus or black beans, and produce that is to be consumed on the farm.[12] In addition, the rule does not apply to businesses that have an average annual monetary value of $25,000 or less of produce sold during the previous 3-year period.

FDA's implementation of the produce rule will occur over several years. According to the rule, compliance dates are phased in from 2017 through 2022 based on business size and other factors.[13] Compliance dates for certain agricultural water standards and for sprouts differ from the compliance dates for other provisions in the rule.[14] For example, compliance for large businesses under certain agricultural water standards with covered activities not involving sprouts is due in January 2020; compliance for small businesses under certain agricultural water standards with covered activities not involving sprouts is due in January 2021; and compliance for very small businesses under certain agricultural

[11]80 Fed. Reg. 74354, 74561 (Nov. 27, 2015) (codified at 21 C.F.R §§ 112.141-112.150). According to FDA, from 1996 to July 2016, there were 46 reported outbreaks in the United States associated with sprouts that caused 2,474 illnesses, 187 hospitalizations, and 3 deaths.

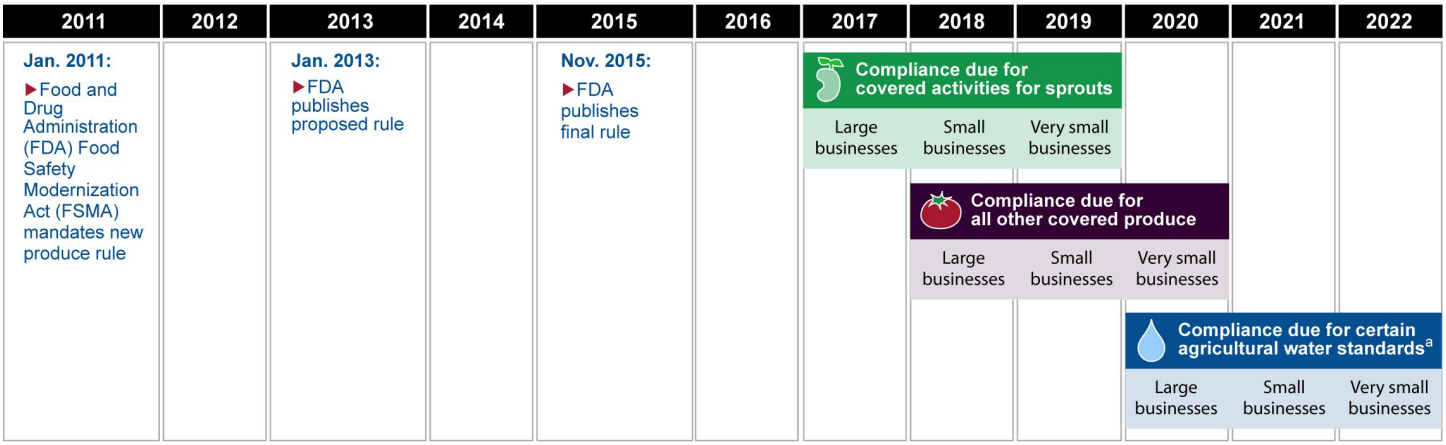
[12]Produce receiving commercial processing, such as refining produce into sugar or distilling it into wine, that adequately reduces the presence of microorganisms of public health significance is also eligible for exemption from the rule.

[13]According to the produce rule, very small businesses are those averaging more than $25,000 but no more than $250,000 in annual monetary value of produce sold during the previous 3-year period; small businesses are those averaging more than $250,000 but no more than $500,000 in annual monetary value of produce sold during the previous 3-year period. All other businesses, which we refer to as "large businesses," are those averaging more than $500,000 in annual monetary value of produce sold during the previous 3-year period.

[14]These agricultural water standards include microbial water quality criteria, frequency of testing of agricultural water, and corrective measures that must be taken if water does not meet microbial quality criteria. 21 C.F.R. §§ 112.44, 112.45, 112.46(b)(i)(A).

water standards with covered activities not involving sprouts is due in January 2022. In 2019, FDA intends to start inspecting produce businesses, other than those growing sprouts. At that time, FDA is to assess compliance with the produce rule, with the exception of the agricultural water standards, for all produce other than sprouts.[15] See fig. 1 for more information on implementation timelines.

Figure 1: Current Implementation Timeline for the Produce Rule



Source: GAO analysis of FDA produce safety rule. | GAO-18-85

Note: According to the produce rule, very small businesses are those averaging more than $25,000 but no more than $250,000 in annual monetary value of produce sold during the previous 3-year period; small businesses are those averaging more than $250,000 but no more than $500,000 in annual monetary value of produce sold during the previous 3-year period. All other businesses, which we refer to as "large businesses," are those averaging more than $500,000 in annual monetary value of produce sold during the previous 3-year period.

[a]"Certain agricultural water standards" apply to all covered produce other than sprouts and do not include all provisions of the rule that relate to agricultural water. See 80 Fed. Reg. 74354, 74461 (Nov. 27, 2015).

FDA-State Partnership in Helping to Ensure Compliance with the Rule

FSMA authorized and encouraged FDA to coordinate with states in helping to ensure compliance with the produce rule. According to FDA officials, developing a working relationship with states to implement the rule is of critical importance because states may have an understanding

[15]FDA originally intended to begin inspections in January 2018. In September 2017, FDA announced that it would start inspections 1 year later than originally planned to allow the agency extra time to provide additional training and outreach to businesses.

of farming practices as a result of their historically close relationship with farms. To facilitate coordination with states, FDA established the State Produce Implementation Cooperative Agreement Program. The program is to provide funds to support a variety of state activities, including educating and providing technical assistance to produce businesses, to the 43 participating states.[16] Through the program, FDA obligated approximately $22 million in 2016 to 42 states and approximately $31 million in 2017 to 43 states to help these states implement the rule.

In addition, in September 2014, FDA entered into a 5-year cooperative agreement with the National Association of State Departments of Agriculture—an organization representing state agriculture departments in all 50 states and 4 U.S. territories. Under this cooperative agreement, the association is working with FDA to support implementation of the produce rule by, among other things, providing technical assistance to states to help them implement their produce safety programs. FDA renewed the cooperative agreement in 2016 with an expanded scope to include states' assistance with helping businesses understand what is expected of them ahead of compliance dates.

FDA Has Continued to Take Steps to Evaluate and Respond to Business Concerns and Is Reviewing the Produce Rule Water Standards

Since we last reported on the produce rule, FDA has continued to use its information clearinghouse, the TAN, to take steps to evaluate and respond to questions and concerns from businesses and other stakeholders regarding the produce rule. FDA has also taken other steps, including funding training for industry, conducting visits to farms, and publishing guidance, to evaluate and respond to concerns. In addition, FDA is reviewing the produce rule agricultural water standards and in September 2017 published a proposed rule to extend compliance dates associated with those standards.

[16]FDA officials said they will rely on inspectors from 40 of the 43 states participating in the program to inspect businesses within their jurisdictions. The remaining 3 states in the program did not apply for program funding to support inspection and enforcement activities. For these 3 states, as well as other states not participating in the program, officials told us FDA will conduct inspections. FDA officials also told us that states can apply to participate in the program at any time.

FDA Continues to Evaluate and Respond to Business Concerns through Its Information Clearinghouse

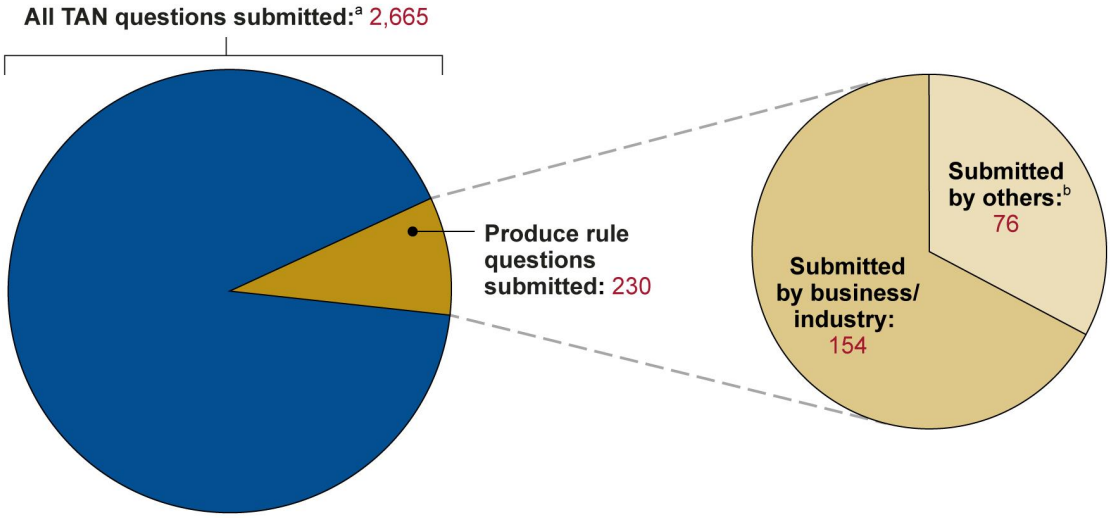
FDA has continued to use the TAN to evaluate and respond to questions and concerns from businesses and other stakeholders regarding all of the FSMA rules, including the produce rule. Since our last report, we found that FDA received 2,665 additional questions submitted to the TAN from September 4, 2016, through June 30, 2017.[17] Of those 2,665 additional questions, 230 questions (about 9 percent) pertained to the produce rule.[18] Of those 230 questions, 154 questions (about 67 percent) came from individuals who self-identified as belonging to "business/industry."[19] (See fig. 2.)

[17]In our last report, we examined data on TAN questions received by FDA from September 10, 2015, when the TAN began operating, through September 3, 2016. We found that FDA received 2,626 TAN questions during that period. See GAO-17-98R. FDA received a total of 5,291 TAN questions from September 10, 2015, through June 30, 2017.

[18]Other questions submitted to the TAN included those pertaining to the other FSMA rules, such as the rules on human food, animal food, imported food, and the sanitary transportation of food.

[19]FDA reported the total number of TAN questions received from individuals who self-identified as belonging to "business/industry" was from both domestic and foreign businesses.

Figure 2: Produce Rule Questions Submitted to the Technical Assistance Network (TAN), September 4, 2016, through June 30, 2017



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-18-85

[a]The TAN also receives questions about other rules pertaining to the FDA Food Safety Modernization Act, such as rules on human food, animal food, imported food, and the sanitary transportation of food.

[b]Others include members of academia, consumers, and federal or state regulators.

We reviewed the full text of questions about the produce rule that were submitted to the TAN by those who identified themselves as belonging to business/industry. We reviewed all such questions submitted since September 10, 2015, when the TAN first began operating, through March 31, 2017, the date of the most recently available information when we conducted our audit work (321 total questions). Questions spanned a variety of topics related to the rule, with the most commonly asked questions pertaining to the rule's agricultural water standards. For example, some businesses submitted questions to clarify whether a specific water testing method they intended to use was acceptable. Other commonly asked questions related to the types of produce covered by the rule and whether a particular business was subject to the produce rule or a related FSMA rule known as the preventive controls for human food rule, which mandates new food safety requirements for food facilities, such as food processing businesses. For example, one business owner who grows almonds and also processes them submitted a question about whether the business is subject to the produce rule or the preventive controls rule. In addition, we found that most submissions (281 questions, or 88 percent) contained requests for additional information or clarification

from FDA about implementing the produce rule.[20] Examples of questions about the produce rule that were submitted by businesses are shown in figure 3.

Figure 3: Examples of Questions about the Produce Rule Submitted by Businesses to the Food and Drug Administration's Technical Assistance Network

Source: GAO analysis of Food and Drug Administration data. | GAO-18-85

According to FDA data, as of June 2017, the agency had responded to about 84 percent (312) of the 372 questions specifically about the produce rule submitted by businesses to the TAN since it began operating. The agency's median response time to these questions was 48 business days. As of June 2017, FDA had responded to 81 percent (4,307) of all 5,291 questions submitted to the TAN, with a median

[20]Among the remaining 12 percent of submissions, some (about 5 percent) voiced concerns about or suggested revisions to the produce rule. Other submissions (about 5 percent) neither requested additional information nor expressed a concern about the rule. For example, these included solicitations from businesses seeking to assist FDA with implementing the produce rule. We did not categorize 10 questions (about 3 percent), including those that were unintelligible or duplicates of other questions. Percentages do not sum to 100 percent due to rounding.

response time of 16 business days. Officials we interviewed said that FDA's longer median response time for produce rule questions submitted by businesses was because the agency needed additional time to address several unique produce rule questions that were not considered during the rulemaking process.

To understand produce businesses' concerns in detail, FDA officials said they track questions submitted to the TAN. For example, these officials said they track the number of questions requesting more information about implementing the standards in the produce rule. These officials said that FDA is using these data to inform the development of resources to help businesses comply with the rule. For example, the officials told us that they are developing a set of commonly asked TAN questions about the produce rule that businesses can examine on FDA's website prior to submitting their questions to the TAN. FDA has already published similar commonly asked TAN questions for some of the other FSMA rules. Representatives we interviewed from two industry associations said that such a list of questions would be helpful as businesses work to comply with the produce rule.

FDA Has Taken Other Steps to Evaluate and Respond to Business Concerns, Including Funding Training for Industry and Conducting Visits to Farms

Since we last reported on the produce rule, FDA has taken steps in addition to the TAN to evaluate and respond to business concerns regarding the produce rule.

Training: FDA has funded partnerships to deliver training to help produce businesses meet the new requirements under the produce rule.

- The Produce Safety Alliance (PSA)—a collaboration involving Cornell University, FDA, and the U.S. Department of Agriculture—has developed a standardized national training curriculum about the produce rule and has conducted training sessions for more than 6,100 industry participants in the United States and foreign countries. In addition to serving an educational role, PSA training sessions help FDA evaluate and respond to business concerns. For example, FDA officials told us the agency uses questions submitted to the TAN to inform PSA course content, thereby helping to ensure that the training sessions address the most commonly asked questions. In addition, FDA officials and PSA representatives we interviewed said that PSA

trainers are able to respond to questions from industry participants during the training sessions. These representatives said that they forward questions that PSA trainers are not able to answer during training sessions to FDA using the TAN and through regular meetings with FDA officials. One PSA trainer we interviewed said that face-to-face interactions with businesses at training sessions are the major way her organization hears about business questions and concerns.

- The Sprout Safety Alliance (SSA) is a collaboration between the Illinois Institute of Technology and FDA to enhance the sprout industry's understanding of the produce rule. SSA has developed a training curriculum to help businesses comply with produce rule standards related to sprout production. SSA has conducted training courses for over 100 industry participants in the United States and Canada. According to an SSA representative, SSA has addressed questions and concerns from sprout industry participants during trainings. This representative also said SSA communicates with FDA about questions SSA trainers are unable to answer.

Table 1 provides information about trainings provided by PSA and SSA.

Table 1: Produce Safety Alliance (PSA) and Sprout Safety Alliance (SSA) Trainings: Numbers of Courses and Participants

Number of	PSA	SSA
Training courses (within the United States)	222	12
States hosting training courses	39	6
Industry participants	6,131	102

Source: PSA and SSA data. | GAO-18-85

Note: PSA data are from September 13, 2016, through September 14, 2017; SSA data are from August 30, 2016, through June 28, 2017. Both PSA and SSA have also conducted training courses outside the United States. The number of industry participants includes those outside the United States, such as from Mexico and Canada.

Educational Farm Visits: FDA officials participated in educational farm visits in 2016 and 2017 across the United States. According to FDA officials we interviewed, these visits were intended to broaden FDA's knowledge of industry practices on these farms and were not for compliance or inspection purposes. FDA officials said they learned about a variety of industry concerns during these visits, including industry's concerns with the water standards under the produce rule. FDA conducted these visits in a number of states, including Alaska, Arizona, California, Colorado, Georgia, Maine, Maryland, Nevada, New Mexico, Oregon, Texas, Vermont, Washington, Wisconsin, and the U.S. Virgin Islands, according to agency officials.

Outreach to Produce Industry Associations: According to FDA officials, the agency performs outreach to various produce industry associations to educate businesses about the produce rule, answer questions, and learn about produce business concerns. For example, FDA officials said that, since we last reported on the produce rule, they have attended industry conferences and held outreach meetings with produce industry associations and they learned about specific concerns, such as businesses' need for additional training on the produce rule and for information on how to identify materials that are suitable to properly sanitize surfaces with which produce comes into contact.

On-farm Readiness Reviews: According to agency officials, these are voluntary reviews during which state inspectors and educators, accompanied by FDA officials, review businesses' progress toward meeting the produce rule standards to promote compliance with the rule. States and FDA piloted the program in 2016 and, according to agency officials, they plan to roll out the full program in late 2017 or early 2018.[21] In addition to helping businesses comply with the rule, FDA officials said these reviews have helped the agency learn about businesses' questions and concerns. For example, officials said they learned during these reviews that some businesses needed additional information regarding water testing methods under the rule, including information on the number of water samples to be collected and the locations of testing laboratories.

Produce Safety Network: Recognizing regional differences in growing practices, FDA established the Produce Safety Network in 2017 to address the unique needs of produce businesses in various parts of the country, according to agency officials. This network was established, in part, to respond to business questions and concerns, according to FDA officials. The network is made up of FDA produce safety experts and specialized investigators based in different parts of the country who help evaluate and respond to questions from businesses, state regulators, and other stakeholders in their regions, according to agency officials. For example, according to FDA officials, these produce safety experts learned about business questions regarding FDA's list of produce the agency considers rarely consumed raw and not subject to the produce rule. In response to these concerns, the network developed a fact sheet outlining FDA's rationale for developing the list.

[21]FDA completed five pilot on-farm readiness reviews in Florida, Michigan, New Jersey, North Carolina, and Vermont in 2017, according to FDA.

Guidance: According to FDA officials, the agency has been working on guidance to assist businesses in complying with the produce rule. FDA officials said guidance allows FDA to respond to questions and concerns related to the rule. For example, in January 2017, FDA published draft guidance on sprout-specific requirements under the rule.[22] FDA officials told us they conducted outreach to sprout businesses before releasing this guidance to let businesses know why the guidance was issued and that it was available for public comment. In developing the guidance, FDA also took into account public comments made during the rulemaking process, according to FDA officials. An SSA representative we interviewed confirmed this, saying that the draft guidance was responsive to comments made by sprout businesses during rulemaking that asked FDA to include specific examples of how businesses were to comply with requirements. This representative said the draft guidance contained relevant examples. In addition, in early September 2017, FDA published guidance to help small businesses comply with the produce rule.[23] The guidance provides small businesses with information about who must comply with the rule, training required, and which businesses are eligible for qualified exemptions from the rule, among other things. See appendix I for a list of published and forthcoming FDA produce rule guidance.

FDA Is Reviewing the Produce Rule Water Standards in Response to Business Concerns and Is Proposing to Extend Compliance Dates

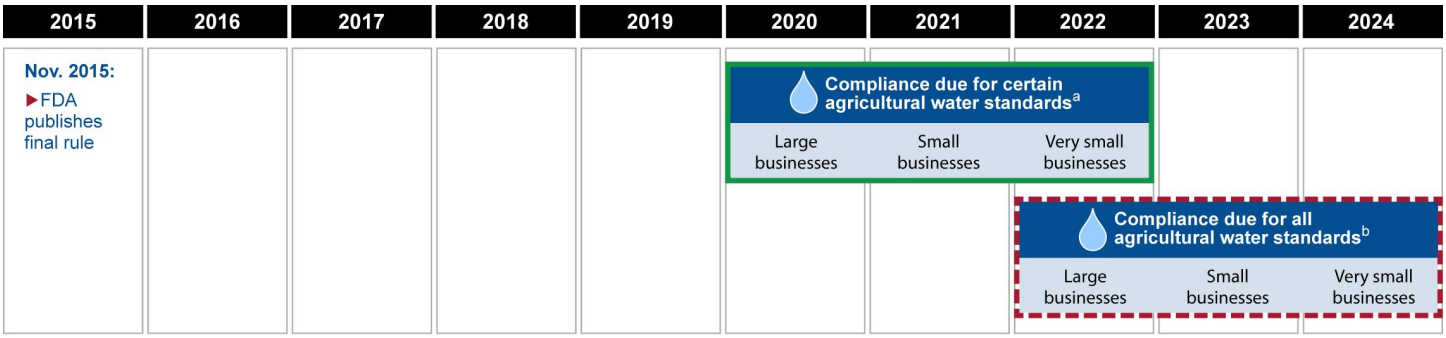
FDA announced in March 2017 that it would conduct a review of the agricultural water standards under the produce rule and, in September 2017, the agency published a proposed rule in the *Federal Register* that would extend the compliance dates for the water standards by an

[22]Food and Drug Administration, *Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry* (Washington, D.C.: 2017).

[23]Food and Drug Administration, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation-Small Entity Compliance Guide: Guidance for Industry-Small Entity Compliance Guide* (Washington, D.C.: 2017). FDA prepared the guidance in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996. Pub. L. No. 104-121, Tit. II, § 212, 110 Stat. 857, 858.

additional 2 years from the original compliance dates, depending on business size, for produce other than sprouts (see fig. 4).[24]

Figure 4: Implementation Timeline for the Produce Rule's Current and Proposed Agricultural Water Standards



Source: GAO analysis of FDA produce safety rule. | GAO-18-85

[a]"Certain agricultural water standards" apply to all covered produce other than sprouts and do not include all provisions of the rule that relate to agricultural water. See 80 Fed. Reg. 74354, 74461 (Nov. 27, 2015).

[b]According to FDA, the proposed rule would also simplify the compliance framework to give all of the water requirements a 4-year delay compared to compliance dates for other requirements under the rule. Currently, the produce rule includes a delay of 2 years in the compliance dates for certain agricultural water requirements, but for other water requirements there is no delay.

According to FDA, its review of the water standards is an effort to simplify the standards and make them easier for businesses to comply with. FDA also said that it would use the extended compliance period to work with produce businesses as it considers the best approach to respond to their concerns about the standards. The extended compliance period will also allow FDA to provide additional outreach and training.

FDA officials we interviewed said that their decision to review the water standards and extend compliance dates was in response to industry

[24]FDA proposed to extend the compliance dates to January 26, 2022, for large businesses and to January 26, 2023, and January 26, 2024, for small and very small businesses, respectively. The proposed rule would also simplify the compliance framework to give all of the water requirements a 4-year delay in the compliance dates. Currently, the produce rule includes a delay of 2 years in the compliance dates for certain agricultural water requirements, but for other water requirements there is no delay. On September 13, 2017, FDA established a 60-day public comment period for the proposed changes. FDA stated that sprouts remain subject to the applicable agricultural water requirements under the original compliance dates. 82 Fed. Reg. 42963, 42965. (Sept. 13, 2017).

concerns. They also said that they learned about these concerns through some of the steps they have taken, which we identify in this report. For example, FDA officials said they heard numerous questions and concerns from businesses about the water standards during educational farm visits. Also, as we note above, questions about the water standards were the most common produce rule-related questions submitted to the TAN. According to representatives we interviewed from two industry associations, some businesses did not fully understand the water standards because, among other things, they said the standards do not provide a clear definition of "agricultural water," leaving some businesses uncertain about what water sources and water uses are subject to the rule. In addition, according to documentation from an industry meeting with FDA, some businesses have expressed concerns about costs associated with the new water testing requirements. Some businesses have also expressed concerns that the water testing method described in the standards has not traditionally been used by industry and that finding laboratories that use this method will be difficult. The standards allow for the use of alternative testing methods, but some businesses have expressed concerns that FDA has not specified these alternative testing methods, thereby leaving businesses uncertain about what methods will be acceptable to FDA.[25] Along with its announcement of a review of the water standards, in September 2017, FDA announced a list of eight water testing methods it determined to be equivalent to the method described in the standards. According to FDA officials, the list was established in response to business concerns, and the agency will add to this list as additional equivalent methods are identified.

FDA officials we interviewed did not provide specific details or a timeline for the agency's review of the water standards. These officials said the agency is considering adding clarifying information on the standards in forthcoming guidance and, if necessary, making changes to the standards themselves by revising the produce rule. In addition, officials said they plan on hosting a water summit in early 2018 with stakeholders and technical experts.

[25]See Center for Produce Safety, *Report on Agricultural Water Testing Methods Colloquium* (Irvine, CA: IDS Decision Sciences, April 6 and 7, 2017).

FDA Has Collected Some Survey Results to Assess the Effectiveness of the TAN and Has Continued to Develop Metrics to Assess Outcomes of Its Other Mechanisms

FDA has begun collecting survey results to assess the effectiveness of its information clearinghouse, the TAN, and has continued to develop metrics that will assess outcomes related to the agency's overall efforts to evaluate and respond to business concerns. In October 2016, FDA implemented the first part of its survey assessing the TAN. This first part of the survey, which FDA sent to businesses and other stakeholders that submitted questions to the TAN, solicited feedback about the TAN web page provided for submitting questions. This survey included questions about how stakeholders learned about the TAN web page, the clarity of the page, and how FDA could improve the page. Officials told us they have begun making changes to the TAN web page based on the survey results. For example, FDA increased the character limit for questions submitted and provided additional information about FSMA on the web page. FDA is also developing the second part of its TAN survey, which will solicit feedback from stakeholders on the timeliness and quality of answers provided by FDA through the TAN. FDA officials told us that the agency will begin sending out this survey with its responses to TAN questions in spring 2018.

In addition to its assessment of the effectiveness of the TAN, FDA officials told us that the agency is continuing to develop metrics intended to assess a number of desired outcomes resulting from implementation of the rule, including outcomes related to FDA's efforts to evaluate and respond to business concerns. These outcomes are specified in a draft strategic framework the agency has developed to monitor implementation of the produce rule. The framework includes outcomes such as businesses' compliance with the produce rule, expanded use of incentives for compliance, and increased dissemination of good practices and other on-farm findings. According to FDA officials, outcomes in the framework that relate to FDA's efforts to evaluate and respond to business concerns include:

- increased effectiveness of technical assistance provided to businesses by FDA and its partners,
- improved working relationships with businesses, and

- increased capacity of FDA partners to educate businesses.

Performance metrics are to be targeted to measure these outcomes, officials said. These officials also stressed that the draft strategic framework is subject to change.

Because FDA officials we interviewed said they are in the early stages of assessing the TAN and the agency's other efforts to evaluate and respond to business concerns, we asked produce industry representatives for their perspectives on FDA's efforts, including representatives from two produce industry associations, a farming organization, and four organizations working with FDA to implement the produce rule. Regarding the TAN, representatives we interviewed from two of these groups said that they had received timely responses from FDA to some questions they had submitted to the TAN, and most groups we interviewed said that at least some of the TAN responses they received provided useful information. However, representatives we interviewed also had two major concerns:

- Representatives from three groups said that responses were often slow to arrive; representatives from one of these three groups commented that response times remained largely unchanged since we last reported on the produce rule in November 2016.[26] Representatives from another group commented that FDA's response times to TAN questions seemed to be related to the complexity of a question. For example, questions that required straightforward answers often received faster responses, while questions requiring more complex answers often got slower responses and, in some cases, FDA responded that the question would be answered in forthcoming guidance.
- Representatives from four groups we interviewed also said that some responses lacked sufficient clarity or specificity to adequately address questions and that industry needed more specific, tailored responses from FDA. For example, some FDA responses restated information from the published produce rule without providing additional detail, and other responses contained "canned" language that did not directly address the question.

[26]We previously reported that industry representatives told us wait times for answers from the TAN were long and that some representatives had not received answers to their questions. For example, representatives from one industry association told us it took 4 months to receive an answer through the TAN. See GAO-17-98R.

FDA officials acknowledged that it has been challenging for the agency to provide timely and complete responses to TAN questions, especially early on in the TAN's operation, but that the agency has to work through complex policy questions related to the rule in order to respond. These officials said they are working to respond more quickly to TAN questions and are revising the FDA review process for TAN responses. Officials also stated that they anticipate posting commonly asked produce rule questions and responses on the TAN web page to provide immediate assistance to businesses for some questions. This is similar to what the agency has done for other FSMA rules, officials said.

Regarding FDA's other efforts to evaluate and respond to business concerns, representatives from one group we interviewed told us that FDA continues to be open to hearing questions and concerns from the produce industry. Nevertheless, representatives from four groups told us that businesses need more information from FDA to comply with the produce rule and are awaiting FDA's forthcoming guidance pertaining to the rule. Representatives from one of these groups also commented that guidance is needed to explain the produce rule in plain language so that businesses can more easily understand the rule. In addition, representatives from two of these groups said that the produce rule training available to businesses is helpful but limited in the absence of guidance. For example, some questions cannot be answered completely during trainings without additional information from guidance.

FDA officials told us they are aware of businesses' concerns about the need for additional guidance. These officials said they are working to publish guidance on various topics related to the produce rule, as we have described elsewhere in this report. For example, officials said they planned to issue draft compliance and implementation guidance near the first compliance date of January 2018 for businesses producing commodities other than sprouts (see app. I).

FDA Officials Reported Facing Challenges Identifying Businesses Subject to the Produce Rule and Providing Consistent and Region-Specific Information in Their Responses

Through interviews with FDA officials, we identified two key challenges that the agency faces in evaluating and responding to business concerns about the produce rule: (1) identifying businesses subject to the produce rule; and (2) providing consistent, region-specific information to businesses in response to their questions and concerns. FDA officials told us the agency's State Produce Implementation Cooperative Agreement Program plays a key role in addressing these challenges, as does the Produce Safety Network.

Identifying businesses subject to the produce rule: While the produce rule specifies the types of commodities subject to the rule, FDA does not have an inventory of farms producing those commodities and therefore does not know which businesses are subject to the rule. As we have previously reported, FDA's existing business inventory data are drawn from information provided by businesses required to register with FDA.[27] Farms, however, are not required to register. According to FDA officials, the lack of a registration requirement for farms limits the data the agency has to inform its implementation of the produce rule. For example, FDA officials we interviewed said that not having data regarding farms can make it difficult for FDA to connect businesses with the educational and technical assistance resources to help them comply with the rule. FDA officials told us the agency's State Produce Implementation Cooperative Agreement Program should help address this challenge. The program, which provides resources to each participating state to support a variety

[27]See GAO, *Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed*, GAO-16-425 (Washington, D.C.: May 19, 2016). The Federal Food, Drug, and Cosmetic Act directs the Secretary of Agriculture to require 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); see also 21 C.F.R. 1.225(a). As defined in the act, a facility includes a factory, warehouse, or establishment that manufactures, processes, packs, or holds food. 21 U.S.C. § 350d(c)(1). However, it does not include farms, restaurants, other retail food establishments, certain nonprofit food establishments, or fishing vessels. 21 U.S.C. § 350d(c)(1). Also under the act, food is defined to include articles used for food or drink for man or other animals. 21 U.S.C. § 321(f)(1).

of state activities related to implementing and enforcing the produce rule, includes funding for states to develop and maintain an inventory of businesses subject to the rule. According to the program's funding announcement, inventory data will be used to determine education and outreach needs related to the produce rule as well as to plan compliance and enforcement activities. FDA officials told us that states participating in the program have started to build their inventories of farms. According to these officials, participating states plan to have their inventories completed before they begin inspections of produce businesses. For states not participating in the cooperative agreement program, FDA officials said the agency is developing farm inventories.

Providing consistent and region-specific responses to business questions and concerns: FDA officials told us that it can be a challenge to ensure that FDA and its state partners provide consistent responses to businesses' questions that are also tailored to account for regional differences in growing conditions. For example, officials said that if a business in one part of the country receives information from one of FDA's state partners, it can be a challenge to ensure that businesses in other parts of the country also receive the same information, whether from states or from FDA. At the same time, however, information provided to businesses may need to be tailored to account for regional differences in growing conditions. FDA officials told us that, to address this challenge, FDA's Produce Safety Network staff are stationed around the United States and work closely with states participating in FDA's Cooperative Agreement Program. According to these officials, this relationship provides a mechanism for states and FDA to share information about the produce rule and helps ensure that information provided by states is consistent with FDA's interpretation of the rule. In addition, these officials stated that having network staff in different growing regions allows those staff members to develop expertise in the growing conditions and practices in their regions, which in turn enhances their ability to provide outreach and technical assistance that is specifically tailored to the unique needs of those regions. For example, according to FDA officials, if a state in the Cooperative Agreement Program receives a question about the rule from a business, Produce Safety Network staff work with the state and FDA subject matter experts to craft a response that the state can provide to the business and that is tailored to the growing practices and conditions in the region. This approach helps ensure that FDA and its state partners speak with one voice about the produce rule and that the information provided is sensitive to regional differences in the produce industry, officials said.

Agency Comments

We provided a draft of this product to HHS. HHS provided us with 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 staff have any questions about this report, please contact me at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix II.

Steve D. Morris
Director, Natural Resources and Environment

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Appendix I: FDA Outreach and Guidance Related to the Produce Rule

Table 2: Food and Drug Administration (FDA) Outreach to Produce Businesses, December 2016 through June 2017

Type of outreach	Date(s)	Location of outreach activity	Produce rule standard(s) addressed (water testing, soil, etc.)
FDA meeting with Produce Industry Coalition	Multiple	College Park, MD	Various aspects of the produce rule
Farm Visits by Produce Safety Network	Multiple	Texas, Oregon, California (Salinas Valley), Alaska, Wisconsin, Arizona, U.S. Virgin Islands	Various aspects of the produce rule
FDA meeting with International Sprout Growers Association	December 15, 2016	College Park, MD	Sprouts
FDA meeting with National Onion Association	February 13, 2017	College Park, MD	Various aspects of the produce rule
Sprout Safety Alliance webinar by FDA staff on Draft Sprout Guidance to implement produce rule	March 6, 2017	Webinar	Sprouts
FDA meeting with Almond Board of California	June 2, 2017	Conference call	Written assurances
FDA meeting with California Leafy Greens Marketing Association	June 6, 2017	College Park, MD	All
FDA meeting with Almond Board of California	June 7, 2017	College Park, MD	Scope
FDA meeting with National Sustainable Agriculture Coalition	June 9, 2017	Silver Spring, MD	Various aspects of the produce rule
FDA meeting with California Wine Grape Growers	June 21, 2017	College Park, MD	Various aspects of the produce rule

Source: FDA. | GAO-18-85

Table 3: Published and Forthcoming Food and Drug Administration (FDA) Produce Rule Guidance

FDA guidance documents

Produce rule topic covered by guidance	Actual or anticipated publication date
Draft Guidance on Sprout Production	January 2017
Produce Rule Small Entity Compliance Guide	September 2017
Produce Rule Draft Compliance & Implementation Guidance (excluding agricultural water)	January 2018

Produce rule topic covered by guidance	Actual or anticipated publication date
Draft Updated Good Agricultural Practices	2020
Region- and commodity- specific guidance documents	As necessary
Draft Packinghouse Guidance	As necessary

Source: FDA. | GAO-18-85

Appendix II: 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), Ramsey Asaly, Tim Bober, Kevin Bray, Alexandra Edwards, Ellen Fried, Cindy Gilbert, Hayden Huang, Dan Royer, Kiki Theodoropoulos, and Rajneesh Verma made key contributions to this report.

Appendix III: Accessible Data

Data Tables

Data Table for Highlights figure, Questions Submitted to the Technical Assistance Network (TAN), September 4, 2016, through June 30, 2017

- All TAN questions received to date: 2,665
- Produce rule questions received to date: 230 (8.63% of total questions received)
- Produce rule questions submitted by business/industry: 154
- Produce rule questions submitted by other categories: 76

Data Table for Figure 1: Current Implementation Timeline for the Produce Rule

- Jan. 2011:
  - Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) mandates new produce rule
- Jan. 2013:
  - FDA publishes proposed rule

- Nov. 2015:
  - FDA publishes final rule
- 2017-2019:
  - Compliance due for covered activities for sprouts, Large businesses, Small businesses, Very small businesses
- 2018-2020:
  - Compliance due for all other covered produced, Large businesses, Small businesses, Very small businesses
- 2020-2022:
  - Compliance due for certain agricultural water standards, Large businesses, Small businesses, Very small businesses

Data Table for Figure 2: Produce Rule Questions Submitted to the Technical Assistance Network (TAN), September 4, 2016, through June 30, 2017

- All TAN questions received to date: 2,665
- Produce rule questions received to date: 230 (8.63% of total questions received)
- Produce rule questions submitted by business/industry: 154
- Produce rule questions submitted by other categories: 76

Data Table for Figure 3: Examples of Questions about the Produce Rule Submitted by Businesses to the Food and Drug Administration's Technical Assistance Network

Water standards

Should we take samples only during the time we planted vegetables? Where do we have to sample—from the canal? From the water outlet on the reservoir?

Training

Where can I get classes/seminars about the Food Safety Modernization Act?

Qualified exemption from rule

I have a small farm. We sell less than $25,000 of produce locally at farmers markets and to local grocery stores. We also sell garlic online,

mostly seed but some for eating as well. Our garlic sales may exceed $25,000. Where do we fall as far as exempt or non -exempt status?

Produce covered by the rule

Are raisins subject to the produce rule?

Definition of farm

How is a farm defined for the purpose of the compliance dates, if a farm in a foreign country does not only grow one single kind of fruit?

Data Table for Figure 4: Implementation Timeline for the Produce Rule's Current and Proposed Agricultural Water Standards

- Nov. 2015:
  - Food and Drug Administration (FDA) publishes final rule
- 2020-2022
  - Compliance due for certain agricultural water standards, Large businesses, Small businesses, Very small businesses
- 2022-2024:
  - Compliance due for all agricultural water standards, Large businesses, Small businesses, Very small businesses

Related GAO Products

High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others. GAO-17-317. Washington, D.C.: February 15, 2017.

Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight. GAO-17-74. Washington, D.C.: January 13, 2017.

Food Safety: FDA's Efforts to Evaluate and Respond to Business Concerns Regarding the Produce Rule. GAO-17-98R. Washington, D.C.: November 28, 2016.

Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed. GAO-16-425. Washington, D.C.: May 19, 2016.

Department of Health and Human Services, Food and Drug Administration: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. GAO-16-299R. Washington, D.C.: December 16, 2015.

Federal Food Safety Oversight: Additional Actions Needed to Improve Planning and Collaboration. GAO-15-180. Washington, D.C.: December 18, 2014.

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