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# Produce Safety: Requirements, Implementation, and Issues for Congress

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## Produce Safety: Requirements, Implementation, and Issues for Congress

In the United States, fruits, vegetables, nuts, and sprouts continue to be associated with a series of foodborne illness outbreaks across the country, resulting in hundreds of illnesses and hospitalizations, as well as kidney failure and death. Many in Congress have expressed concern that foodborne illness outbreaks are occurring despite enhanced authorities and resources provided to the Food and Drug Administration (FDA) and state public health authorities following the 2010 enactment of comprehensive food safety legislation as part of the FDA Food Safety Modernization Act (FSMA; P.L. 111-353). FSMA amends the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.), which required FDA to develop produce safety standards for certain fruits, vegetables, nuts, and sprouts, as well as other rules to enhance food safety. To provide FDA with the means to implement FSMA, Congress has provided more than \$300,000,000 in FDA's base appropriation for FSMA since FY2011 (H.Rept. 115-232).

FDA published the Final Produce Safety Rule (PSR) in November 2015 to fulfill FSMA produce safety requirements. The PSR establishes science-based minimum standards to prevent microbial contamination of produce (fruits, vegetables, nuts, and sprouts) grown, harvested, packed, and held for human consumption. The PSR specifically applies to certain fruits and vegetables that are expected to be consumed without being cooked or otherwise prepared in a method that decreases the presence of harmful microbes.

FSMA gives FDA the authority to conduct surveillance inspections on farms. Through a cooperative agreement with the National Association of State Departments of Agriculture (NASDA), FDA shares in-person inspectional authority of domestic farms with states (foreign farms are inspected by FDA only); however, the autonomy of enforcement held by each state has eroded the ability of FDA and NASDA to collect, analyze, and communicate inspection results. Some in Congress have questioned whether implementation delays and inconsistent interpretation of PSR requirements between FDA and state inspectional authorities are adversely affecting produce safety. If FDA and NASDA were to build a central database, it could allow for consistent information sharing among state and federal authorities.

FDA has dispersed more than \$112 million to NASDA via the State Produce Implementation Cooperative Agreement Program (State CAP) in a package deal to conduct inspections and provide educational resources to farmers. In addition to the State CAP, FDA collaborates with other government and nongovernment partners to develop programs that foster PSR implementation through education. FDA's partnerships with organizations such as the U.S. Department of Agriculture's National Institute of Food and Agriculture (USDA-NIFA), Association of Food and Drug Officials (AFDO), and university extension services provide a scaffold to accomplish education and training goals established under PSR implementation.

Compliance dates for the FSMA rules are being phased in according to the sales of each business. Very small farms (those for which the average annual monetary value of produce sold during the previous three-year period is no more than \$250,000) generally have more time to comply with rule requirements than larger farms. Farms beneath the \$25,000 monetary threshold are exempt from the PSR and do not have to implement FSMA standards or maintain paperwork to prove their standing as exempt. In May 2019, FDA extended water quality-related compliance dates by an additional two years past their original compliance dates due to continued stakeholder feedback questioning the adequacy of water testing requirements. As of January 2020, all farms that grow produce subject to the PSR were to be in compliance with the requirements. Notwithstanding changes enacted as part of FSMA, large-scale foodborne illness outbreaks related to fresh produce continue to occur, according to FDA data.

As foodborne illness outbreaks continue, some question the effectiveness of FDA's food safety implementation of FSMA. FDA's repeated delays in fully implementing key FSMA produce standards point to several possible contributing factors. FDA's authority to conduct inspections on farms and annual reporting requirements is limited compared with its authority to carry out these activities in food facilities. FDA also has postponed compliance with certain key PSR requirements and has not fully implemented FSMA's traceability requirements for high-risk foods. Additionally, the lack of coordination over inspection data between FDA and state and local authorities, which often bear most of the responsibility for inspecting farms and food facilities within their jurisdictions, may lead to inconsistent implementation of rule requirements on farms. A future consideration for Congress could include expanding FDA's inspectional and reporting authorities on farms, thus limiting exemptions from the traceability rule. Congress could also consider authorizing FDA and states to build a unified farm registry and inspection database.

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## Introduction

The consumption of fresh and minimally processed produce—fruits, vegetables, nuts, and sprouts—has been associated with a series of foodborne illness outbreaks across the United States in recent years. The related symptoms can be severe, even life-threatening.<sup>1</sup> The Food and Drug Administration (FDA) received enhanced authorities to develop and implement food safety regulations from the 2011 FDA Food Safety Modernization Act (FSMA; P.L. 111-353).

Several of the regulations required by FSMA were to be proposed or finalized within one to two years after enactment (by January 2012 or 2013); however, final publication dates for many of these regulations were delayed until 2016 or beyond (see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*, by Renée Johnson ). Some rules saw further delays in implementing key provisions after finalization, prompting attention from some Members of Congress.<sup>2</sup>

The 111<sup>th</sup> Congress passed FSMA in response to changes in the global food system and an understanding of foodborne illness and its consequences. Signed into law on January 4, 2011, FSMA amended the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.) to expand FDA’s authority to establish prevention-focused, scientifically based standards applicable to farms that grow, harvest, pack, or hold fresh produce for human consumption in the United States. In 2015, FDA then published the Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption (the Produce Safety Rule, or PSR) to implement FSMA produce safety requirements.<sup>3</sup> Produce subject to the PSR include but are not limited to various crop categories, such as leafy greens, berries, melons, herbs, tree nuts, legumes, and root vegetables.

This report begins with a brief discussion of the U.S. produce industry. It then discusses key provisions of the PSR, implementation of the rule, and selected issues for Congress.

## Foodborne Illness Outbreaks

Although growers and distributors of domestic and foreign produce must comply with various layers of mandatory and voluntary food safety requirements, contaminated produce continues to cause foodborne illness outbreaks. Pathogens—bacteria, viruses, and other biological hazards—are the leading cause of foodborne illnesses. Pathogens may be found in foods of all kinds and often are first acquired at the farm (or harvest) level. Their presence in produce is of particular concern because produce is often consumed without cooking, which is one microbial “kill” step.

The Centers for Disease Control and Prevention (CDC) define a *foodborne disease outbreak* as occurring when two or more people get the same illness from the same contaminated food or drink.<sup>4</sup> Based on previous CDC outbreak investigations, microbial hazards associated with

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<sup>1</sup> See Centers for Disease Control and Prevention (CDC), “Foodborne Germs and Illnesses,” at <https://www.cdc.gov/foodsafety/foodborne-germs.html>.

<sup>2</sup> See, for example, Food Safety News, “Rep. DeLauro says she’s had enough with FDA’s delays in water quality enforcement,” February 15, 2019, at <https://www.foodsafetynews.com/2019/02/rep-de-lauro-says-shes-had-enough-with-fdas-delays-in-water-quality-enforcement/>.

<sup>3</sup> See Food and Drug Administration (FDA), “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” 80 *Federal Register* 74353, November 27, 2015 (hereinafter FDA, PSR Final Rule, 80 *Federal Register* 74353, 2015).

<sup>4</sup> See CDC, “Frequently Asked Questions: About the Foodborne Disease Outbreak Surveillance System (FDOSS),” at

produce include pathogenic (disease-causing) strains of Shiga toxin-producing *E. coli* (STEC), *Salmonella*, Norovirus or Norwalk-like virus, and *Listeria monocytogenes*. Other produce-related hazards have involved *Cyclospora cayatenensis*, Hepatitis A virus, *Shigella*, and *Cryptosporidium*. Microbial hazards may be introduced through agricultural and processing water (e.g., agricultural water used in production), soil amendments (such as manure and municipal biosolids), unhygienic practices by workers, unsanitary field and packing facility conditions, and produce transportation and distribution.<sup>5</sup> In 2015, FDA estimated that the total cost of illnesses linked to all items of produce is approximately \$2.5 billion annually.<sup>6</sup>

Since FSMA was enacted in 2011, several high-profile outbreaks have brought attention to effective food safety regulation and enforcement. Many of these outbreaks occurred after the PSR was published in 2015. **Table 1** summarizes selected recurring outbreaks of produce, currently subject to the PSR, that involve *E. coli*, *Salmonella* spp., *Cyclospora cayatenensis*, or *Listeria monocytogenes*, as reported by FDA and CDC from 2011 through 2020.

**Table 1. Selected Recurring Foodborne Disease Outbreaks, 2011-2020**

Year	Produce Commodity	Pathogen	Confirmed Illnesses	Hospitalizations (Deaths)
2020	Bagged Salad Mix	<i>Cyclospora cayatenensis</i>	701	38
	Sprouts (clover)	<i>E. coli</i> O103	51	3
2019	Basil	<i>Cyclospora cayatenensis</i>	241	6
	Salad Mix	<i>E. coli</i> O157:H7	10	4
	Romaine Lettuce	<i>E. coli</i> O157:H7	167	85
	Papaya	<i>Salmonella</i> Uganda	81	27
2018	Leafy Greens	<i>E. coli</i> O157:H7	25	9 (1)
	Leafy Greens	<i>E. coli</i> O157:H7	210	96 (5)
	Romaine Lettuce	<i>E. coli</i> O157:H7	62	25
	Vegetable Trays	<i>Cyclospora cayatenensis</i>	250	8
	Salad Mix	<i>Cyclospora cayatenensis</i>	511	24
	Sprouts (type unspecified)	<i>Salmonella</i> Montevideo	10	0
2017	Papaya	Various <i>Salmonella</i> strains	251	5 (1)
	Leafy Greens	<i>E. coli</i> O157:H7	25	9 (1)
2016 <sup>a</sup>	Cilantro (suspect)	<i>Cyclospora cayatenensis</i>	384	NR
	Sprouts (alfalfa)	<i>Salmonella</i> Reading and <i>Salmonella</i> Abony	36	7
	Sprouts (alfalfa)	<i>E. coli</i> O157	11	2
	Sprouts (alfalfa)	<i>Salmonella</i> Muenchen and <i>Salmonella</i> Kentucky	26	8

<https://www.cdc.gov/fdoss/faq.html>.

<sup>5</sup> See CDC, “How Food Gets Contaminated – The Food Production Chain,” at <https://www.cdc.gov/foodsafety/production-chain.html>.

<sup>6</sup> FDA, *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, Final Regulatory Impact Analysis*, pp. 53-54, at <https://www.fda.gov/media/94153/download>.

Year	Produce Commodity	Pathogen	Confirmed Illnesses	Hospitalizations (Deaths)
2015	Packaged Salads	<i>Listeria monocytogenes</i>	19	19 (1)
	Cilantro (suspect)	<i>Cyclospora cayatenensis</i>	546	21
	Cucumbers	<i>Salmonella</i> Poona	907	204 (6)
2014	Cucumbers	<i>Salmonella</i> Newport	275	34 (1)
	Sprouts (bean)	<i>Salmonella</i> Enteritidis	115	19
	Sprouts (bean)	<i>Listeria monocytogenes</i>	5	5 (2)
2013	Cilantro	<i>Cyclospora cayatenensis</i>	304	7
	Sprouts (clover)	<i>E. coli</i> O121	19	7
	Ready-to-Eat Salads	<i>E. coli</i> O157:H7	33	7
	Salad Mix, Cilantro	<i>Cyclospora cayatenensis</i>	631	49
	Cucumbers	<i>Salmonella</i> Saintpaul	84	17
2012	Spinach, Spring Mix	<i>E. coli</i> O157:H7	33	13
	Mangoes	<i>Salmonella</i> Braenderup	127	33
	Cantaloupe	<i>Salmonella</i> Typhimurium and <i>Salmonella</i> Newport	261	94 (3)
2011	Sprouts (clover)	<i>E. coli</i> O26	29	7
	Romaine Lettuce	<i>E. coli</i> O157:H7	58	33
	Cantaloupe	<i>Listeria monocytogenes</i>	147	143 (33)
	Cantaloupe	<i>Salmonella</i> Panama	20	3
	Papaya	<i>Salmonella</i> Agona	106	10
	Sprouts (alfalfa, spicy)	<i>Salmonella</i> Enteritidis	25	3

**Sources:** Congressional Research Service (CRS), using data from Food and Drug Administration (FDA), “Outbreaks of Foodborne Illnesses,” at <https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks-foodborne-illness>; and Centers for Disease Control and Prevention (CDC), “List of Selected Multistate Foodborne Outbreak Investigations,” at <https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html>.

**Notes:** Deaths appear in parentheses, if applicable.

NR = not reported.

- a. Beginning in 2016, key FDA Food Safety Modernization Act (FSMA; P.L. 111-353) rules applicable to fresh produce entering the distribution chain from farms, packinghouses, fresh-cut facilities, and mixed-type facilities went into effect. These include the Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption (PSR), Preventive Controls for Human Food rule (PCHF; 21 C.F.R. §117), Foreign Supplier Verification Program (FSVP; 21 C.F.R. §1), Intentional Adulteration rule (IA; 21 C.F.R. §121), Sanitary Transport of Food rule (ST; 21 C.F.R. §1). FSMA was enacted in 2011.

According to a 2019 study conducted by the U.S. Department of Agriculture’s (USDA’s) Economic Research Service (ERS), food retailers report that their food safety requirements have evolved as major foodborne illness outbreaks raise awareness of food safety risks. Many produce retailers participating in the study require more stringent food safety audits for produce perceived as high risk, such as lettuce and cantaloupe.<sup>7</sup> The majority of food retailers also require their

<sup>7</sup> Travis Minor et al., *Food Safety Requirements for Produce Growers: Retailer Demands and the FDA Food Safety*

suppliers to complete food safety audits for produce not covered by the PSR, such as potatoes. Some retailers further stated they would not buy or have stopped selling produce with a history of foodborne illness outbreaks, such as sprouts.

In response to recent high-profile outbreaks, collaborative efforts between industry groups, foreign governments, and FDA aim to identify and improve production practices most critical for produce safety beyond PSR requirements. For example, the 2020 Leafy Greens STEC Action Plan aims to advance work in three areas: (1) prevention, (2) response, and (3) addressing knowledge gaps.<sup>8</sup> The Fresh Express Blue-Ribbon Panel on the Prevention of *Cyclospora* Outbreaks in the Food Supply and the *Cyclospora* Task Force are two concurrent efforts to identify data gaps and research needs so that improved tools can be developed to detect, prevent, and control *Cyclospora* contamination of food.<sup>9</sup>

## Key Provisions of FDA's Produce Safety Rule

Congress passed FSMA to amend the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§301 et seq.), which governs foods under FDA's jurisdiction. As required by FSMA, FDA has developed and implemented mandatory food safety and traceability requirements for farmers, packers, and processors of domestically produced and imported products. Selected provisions that broadly address produce are shown in the text box titled "Selected Produce-Related FSMA Provisions," below.

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*Modernization Act*, U.S. Department of Agriculture (USDA), Economic Information Bulletin no. 206, April 2019, at <https://www.ers.usda.gov/webdocs/publications/92761/eib-206.pdf?v=2999.6>.

<sup>8</sup> FDA, *2020 Leafy Greens STEC Action Plan*, last updated March 2020, at <https://www.fda.gov/food/foodborne-pathogens/2020-leafy-greens-stec-action-plan>.

<sup>9</sup> See Fresh Express, *Fresh Express Releases Blue-Ribbon Panel Interim Report on the Prevention of Foodborne Cyclospora Outbreaks*, June 5, 2019, at <https://www.freshexpress.com/blue-ribbon-panel-report>; and Frank Yiannas and Monica Parise, M.D., "CDC Develop Robust Strategy to Prevent Illnesses Caused by Cyclospora, FDA," 2019, at <https://www.fda.gov/news-events/fda-voices/fda-cdc-develop-robust-strategy-prevent-illnesses-caused-cyclospora>.



### **Selected Produce-Related Provisions in FSMA (P.L. 111-353)**

#### **Inspections of Records (§101)**

- Allows the Food and Drug Administration (FDA) to inspect records related to the “manufacture, processing, packing, distribution, receipt, holding, or importation” of certain foods and feed.

#### **Registration of Food Facilities (§102)**

- Requires food facilities be subject to biennial registration renewal; FDA may suspend a facility’s registration in certain cases.

#### **Hazard Analysis & Risk-Based Preventive Controls (§103)**

- Requires FDA to establish mandatory preventive controls for food facilities, except for “small business” and “very small business.”

#### **Standards for Produce Safety (§105)**

- Requires FDA to establish mandatory minimum standards for the safe production and harvesting of fruits and vegetables, except for “small business” and “very small business.”

#### **Targeting of Inspection Resources (§201)**

- Requires FDA to identify high-risk facilities, increase the frequency of inspection of domestic and foreign facilities, identify and conduct inspections at ports of entry, and improve interagency coordination and cooperation.

#### **Tracking and Tracing Food, Records (§204)**

- Requires FDA to establish pilot projects to improve traceability of foods and establish additional recordkeeping requirements for certain “high-risk foods.”

#### **Surveillance (§205)**

- Requires the Centers for Disease Control and Prevention to enhance foodborne illness surveillance systems and conduct an assessment of state and local food safety and defense capacities.

#### **Foreign Supplier Verification Program (FSVP, §301)**

- Requires FDA to establish a program whereby importers provide assurances that each foreign supplier is in compliance with applicable food safety requirements.

#### **Authority to Require Import Certifications for Food (§303)**

- FDA may require certifications for imported food based on food safety risk.

#### **Inspection of Foreign Food Facilities (§306)**

- FDA may make arrangements and agreements with foreign governments to facilitate the inspection of foreign food facilities.

#### **Accreditation of Third-Party Auditors (§307)**

- Requires FDA to establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet the applicable food safety requirements.

For more information, see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

At the farm production level, FSMA principally affects produce growers by directing FDA to establish and enforce produce safety standards (P.L. 111-353, §105, 21 U.S.C. §350h). FDA finalized its produce safety regulation in 2015.<sup>10</sup> FDA’s PSR addresses certain routes of potential contamination, including

- water and soil amendments used in production,
- domesticated and wild animal intrusions into production areas,
- worker training and hygiene, and
- equipment and sanitation practices used in production.

<sup>10</sup> FDA, PSR Final Rule, 80 *Federal Register* 74353, 2015.

Notably, due to limitations of FDA authority, PSR requirements are intended to prevent microbial contamination of fruits and vegetables. The PSR does not include provisions to prevent chemical contamination of these products.

## Producer Compliance with FSMA Rules

The PSR covers fruits and vegetables, mushrooms, sprouts, peanuts, tree nuts, and herbs. FDA estimates that the regulation covers as many as 37,000 domestic produce farms and 285 sprout operations.<sup>11</sup> FDA further estimates PSR implementation will cost farms an average of approximately \$10,500 annually.<sup>12</sup> Foods not covered by regulation include foods that are rarely consumed raw,<sup>13</sup> foods that go to commercial processing, foods produced for personal consumption, and certain foods identified as low risk. Produce that undergoes certain minimal commercial processing, such as bagged salads and fresh-cut fruits and vegetables, are further covered by FDA's rule on preventive controls affecting food facilities (§ 103, 21 U.S.C. § 350g).

Other FSMA requirements affecting minimally processed produce facilities include records access (§101, 21 U.S.C. §350c), registration of food facilities (§102, 21 U.S.C. §350d), and inspections (§201, 21 U.S.C. §350j). FSMA requirements affecting foreign farms and imported produce include the Foreign Supplier Verification Program (FSVP) (§301, 21 U.S.C. §384a), import certifications (§303, 21 U.S.C. §381(a)), inspections of foreign food facilities (§306, 21 U.S.C. §384c), and accreditation of third-party auditors (§307, 21 U.S.C. §384d). Certain qualified farms and facilities are exempt from regulation depending on business size, among other factors (see “Modified Requirements and Qualified Exemptions”).

The compliance dates for FSMA rules are being phased in according to business size (**Table 2**). Very small farms (those for which the average annual monetary value of produce sold during the previous three-year period is no more than \$250,000) generally have more time to comply with rule requirements than larger farms. Farms below the \$25,000 sales threshold are exempt from the PSR,<sup>14</sup> and they do not have to implement FSMA standards or maintain paperwork to prove their standing as exempt. In May 2019, water-related compliance dates were extended an additional two years past their original compliance dates (84 *Federal Register* 9706) due to continued stakeholder feedback questioning the feasibility and cost involved with water testing requirements (see “Agricultural Water”). Farms beneath the \$25,000 monetary threshold are exempt from the PSR. These farms do not have to implement FSMA standards or maintain paperwork to prove their standing as exempt (see “Modified Requirements and Qualified Exemptions”).

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<sup>11</sup> FDA, PSR Final Rule, 80 *Federal Register* 74353, 2015, p. 74530. Estimates of domestic produce and sprout farms are from USDA, National Agricultural Statistics Service (NASS), *2012 Census of Agriculture*.

<sup>12</sup> Estimated average cost of implementation is approximately \$2,900 for very small farms; \$15,300 for small farms; and \$28,500 for medium and large farms. The average across the three farm sizes is approximately \$10,500 annually. See footnote 6.

<sup>13</sup> Listed at 21 C.F.R. §112.2(a)(1).

<sup>14</sup> 21 C.F.R. §112.4-5 describes Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption (Produce Safety Rule, or PSR) and monetary threshold values.

**Table 2. Selected PSR Compliance Dates**

<b>Business Size</b>	<b>Compliance Date for Sprouts</b>	<b>Compliance Date for Most Other Produce</b>	<b>Water-Related Compliance Date (Subpart E)</b>	<b>Compliance Date for Qualified Exemption Labeling</b>	<b>Compliance Date for Retention of Records Supporting a Qualified Exemption</b>
Businesses with Annual Produce Sales Over \$500,000	Jan. 26, 2017	Jan. 26, 2018	Jan. 26, 2022	Jan. 1, 2020	Jan. 26, 2016
Small (\$250,000-\$500,000)	Jan. 26, 2018	Jan. 28, 2019	Jan. 26, 2023	Jan. 1, 2020	Jan. 26, 2016
Very Small (\$25,000-\$250,000)	Jan. 28, 2019	Jan. 27, 2020	Jan. 26, 2024	Jan. 1, 2020	Jan. 26, 2016
Exempt (<\$25,000)			Not applicable		

**Source:** See FDA, “FSMA Compliance Dates,” at [https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-compliance-dates#Produce\\_Safety](https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-compliance-dates#Produce_Safety). Additional FSMA compliance dates also can be found at this site.

**Note:** PSR = Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption.

## Traceability and Surveillance

In FSMA, Congress also addressed food traceability (§204, 21 U.S.C. §2223) and surveillance (§205, 21 U.S.C. §2224). Traceability refers to the ability to fully trace the movement of food and ingredients through each specific stage of production, processing, and distribution and the ability to identify the origin of food and ingredients when a food or finished product is found to be unsafe. Full traceability often requires extensive recordkeeping, other types of traceback mechanisms, or both. FSMA directed FDA to establish pilot projects to improve its capacity to effectively and rapidly track and trace foods in the event of an outbreak and directed CDC to enhance foodborne illness surveillance systems (§205, 21 U.S.C. §2224). FDA’s traceability pilot projects were completed in 2012.<sup>15</sup> In addition to the pilot projects, FSMA directed FDA to designate high-risk foods that require additional recordkeeping to protect public health. Results from the pilot projects and the FSMA recordkeeping requirements were included as components of the FDA proposed traceability rule.

On July 13, 2020, FDA Commissioner Stephen Hahn announced the New Era of Smarter Food Safety Blueprint.<sup>16</sup> The blueprint outlines the approach FDA is to take over the next decade to usher in the New Era of Smarter Food Safety.

<sup>15</sup> See FDA, “Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Request for Comments and for Information,” 78 *Federal Register* 14309, April 4, 2013, at <https://www.federalregister.gov/documents/2013/03/05/2013-04997/implementation-of-the-fda-food-safety-modernization-act-provision-requiring-fda-to-establish-pilot>.

<sup>16</sup> FDA, “New Era of Smarter Food Safety Blueprint,” at <https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint>.

The blueprint has four core elements:

- Enhance tech-enabled traceability;
- Develop smarter tools and approaches for prevention and outbreak response;
- Address new business models and retail modernization to reduce contamination of food; and
- Foster the development of stronger food safety cultures.<sup>17</sup>

In October 2020, FDA created working groups dedicated to each of the four core elements and has begun identifying short-term goals to be accomplished by 2022.<sup>18</sup> As of February 2021, FDA had not yet finalized the traceability rule.

## **Produce Safety at FDA Prior to FSMA**

Although the PSR is the first federal regulation focusing on microbial food safety at the farm level, it is not the first effort to improve the safety of produce. Produce farms are subject to several layers of federal and state requirements. Commercial buyers (retailers, foodservice firms, and produce processors) also have demanded certain food safety practices from growers for years. Produce growers and grower organizations also are instrumental in raising food safety standards.

Starting in the late 1960s, FDA established current good manufacturing practices (cGMPs) in the *Code of Federal Regulations* (21 C.F.R. Part 110) to help ensure food manufacturing facilities would implement protocols to prevent food contamination.<sup>19</sup> Farms are exempt from these requirements. Drawing from cGMPs, the 1998 *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables* (good agricultural practices, or GAPs) established a collection of nonbinding GAPs that farms should implement to prevent produce contamination.<sup>20</sup> Prior to FSMA, state and industry-led produce safety programs were based on these recommendations.

State legislatures set requirements for farms based on GAPs, which often varied widely from state-to-state and commodity-to-commodity. However, USDA's GAP/Good Handling Practices (GHP) program provided a uniform nationally and internationally recognized assessment option for the food industry to ensure produce is grown and handled in a manner that prevents microbial contamination.<sup>21</sup> Produce farms that choose to participate in the GAP/GHP fee-for-service program pay a third-party GAP/GHP auditor to perform the assessment. Third-party auditors commonly come from organizations such as state departments of agriculture, university extensions, and consulting firms. The GAP/GHP audits have been updated to align with the PSR; however, both FDA and USDA maintain that the audits do not replace regulatory inspections to determine compliance with the rule.

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<sup>17</sup> FDA, "New Era of Smarter Food Safety Blueprint."

<sup>18</sup> FDA, *New Era of Smarter Food Safety Blueprint: The First 100 Days*, 2020, at <https://www.fda.gov/media/143346/download>.

<sup>19</sup> 21 C.F.R. §117 replaced 21 C.F.R. §110 on September 2015. See FDA, "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food," 80 *Federal Register* 55907, September 17, 2015.

<sup>20</sup> FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables>.

<sup>21</sup> USDA, "Good Agricultural Practices (GAP) & Good Handling Practices (GHP)," at <https://www.ams.usda.gov/services/auditing/gap-ghp>.

Industry-led food safety practices, in addition to federal standards, drive producers to participate in other voluntary auditing programs,<sup>22</sup> the requirements of which often extend beyond regulatory standards and increase market access. These standards commonly exist as public-private partnerships or buyer requirements. For example, the California and Arizona Leafy Greens Marketing Agreements (CA-LGMA and AZ-LGMA,<sup>23</sup> respectively) are collaborative efforts between state authorities and industry leaders who set commodity-specific guidelines to drive food production safety practices. Fresh produce growers and distributors must also meet food production safety standards set by individual customers. These standards include passing multiple audits, establishing microbial sampling protocols, and maintaining various records. As a result, fresh produce growers and distributors may need to comply with multiple layers of food safety requirements (see “FDA-USDA” for additional information on current voluntary programs).

## Farms Subject to the Produce Safety Rule

Produce farms must meet several criteria for the operation to be subject to PSR requirements, including the following:<sup>24</sup>

- Farms must be classified as a primary production or secondary activities farm.
- Farms must perform covered activities on covered produce.
- Farms must meet monetary threshold criteria.
- Produce must not be for personal/on-farm consumption (items used for this purpose are not subject to the PSR).
- Produce must not be intended for commercial processing where produce is cooked or receives processing that reduces microbes “of public health significance.”

Key definitions that appear in the PSR are described in the “Selected Definitions from the Produce Safety Rule (PSR)” text box.

### Selected Definitions from the Produce Safety Rule (PSR)

**Agricultural Water**—water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

**Biological Soil Amendment of Animal Origin**—a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term *biological soil amendment of animal origin* does not include any form of human waste.

**Covered activity**—growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of

<sup>22</sup> Popular auditing standards for fresh fruit and vegetable producers include those from Global Food Safety Initiative (GFSI), Safe Quality Food (SQF), and International Organization for Standardization (ISO). The audits are typically conducted by certified independent consultants. See, for example, GFSI, “Certification,” at <https://mygfsi.com/how-to-implement/certification/>; SQF, “How to Get Certified,” at <https://www.sqfi.com/how-to-get-certified/>; and ISO, “ISO 22000: Food Safety Management,” at <https://www.iso.org/iso-22000-food-safety-management.html>.

<sup>23</sup> See the California Leafy Greens Marketing Agreement (CA-LGMA) website at <https://lgma.ca.gov/> and the Arizona Leafy Greens Marketing Agreement (AZ-LGMA) website at <https://www.arizonaleafygreens.org/>.

<sup>24</sup> 21 C.F.R. §112.1-5 (Subpart A: General Provisions) describes requirements for farming operations to be subject to the PSR.

*farm* as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in §112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 117 of this chapter.

**Covered produce**—produce that is subject to the requirements of this part in accordance with §§112.1 and 112.2. The term *covered produce* refers to the harvestable or harvested part of the crop.

**Farm**—

(i) *Primary Production Farm*. A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term *farm* includes operations that, in addition to these activities,

(A) Pack or hold raw agricultural commodities;

(B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (i)(C)(2)(i) of this definition; and

(C) Manufacture/process food, provided that

(1) All food used in such activities is consumed on that farm or another farm under the same management; or

(2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of

(i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(ii) *Secondary Activities Farm*. A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in paragraphs (i)(B) and (C) of this definition.

**Mixed-type facility**—an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a *farm mixed-type facility*, which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

**Raw agricultural commodity**—21 U.S.C. §321(r)—The term *raw agricultural commodity* means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

For a full list of statutory definitions related to the PSR, see 21 C.F.R. §112.3.

The rule does not apply to primary production and secondary activities farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less. Such farms are considered to be exempt.

Produce subject to the PSR include but are not limited to various crop categories, such as leafy greens, berries, melons, herbs, tree nuts, legumes, and root vegetables. Rather than identify a wide variety of produce subject to the PSR, FDA specifically identifies an exhaustive list of



rarely consumed raw (RCR) produce that are exempt from the requirements.<sup>25</sup> The rule does not apply to

- produce that is not a *raw agricultural commodity* (RAC);<sup>26</sup>
- the following RCR produce:<sup>27</sup> asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts;
- food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed); and
- produce that is used for personal or on-farm consumption.

A primary production or secondary activities farm may be classified as a *mixed-type facility* if the business performs both farming activities and manufacturing activities. For example, a farm that grows and harvests berries destined for wholesale to a grocery distributor may also reserve a portion of those berries to make jam that is to be sold in a farmer’s market. Because this is a mixed-type facility, multiple regulations would apply, including the PSR, the Preventive Controls for Human Food (PCHF) rule,<sup>28</sup> as well as other federal, state, and local regulations. **Table 3** provides a summary of criteria that apply to primary and secondary activities farms. **Figure 1** shows FDA’s coverage and exemptions flow chart to help farm operators determine if their produce and operations are subject to the PSR.

## Modified Requirements and Qualified Exemptions

The PSR provides a qualified exemption and modified requirements for certain farms. To be eligible for a qualified exemption, a farm must meet two requirements.

1. The farm must have food sales averaging less than \$500,000 per year during the previous three years.
2. The farm’s sales to qualified end users must exceed sales to all others combined during the previous three years.

A qualified end user is either (1) the consumer of the food or (2) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away. A farm with a qualified exemption still must meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown, either on the label of the produce or at the point of purchase. These farms also are required to establish and keep certain documentation.

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<sup>25</sup> *Rarely consumed raw* (RCR) produce refers to fruits and vegetables that are almost always cooked before being consumed. RCR produce therefore, is intended to mean those produce commodities that are almost always eaten only after being cooked (i.e., heat treated in some form). The RCR produce list was developed using survey data from the National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA). FDA, *FDA Fact Sheet, Produce Safety Rule (21 CFR 112): “Rarely Consumed Raw” Produce*,” at <https://www.fda.gov/media/107445/download>.

<sup>26</sup> See “Selected Definitions from the Produce Safety Rule” textbox in “Farms Subject to the Produce Safety Rule.”

<sup>27</sup> RCR is an exhaustive list of produce that may be changed only by new rulemaking. 21 C.F.R. §112.1-2.

<sup>28</sup> 21 C.F.R. §117.

**Table 3. Selected Produce Safety Rule Farm Classifications**

Farm Type	Operational Structure	Farming Activities	Monetary Threshold	Qualified Exemptions
Primary Production	<ul style="list-style-type: none"> <li>One general physical location</li> <li>Under one management</li> </ul>	<ul style="list-style-type: none"> <li>Growing, harvesting, packing, holding raw agricultural commodities</li> <li>Raising animals</li> <li>Certain manufacturing activities</li> </ul>	<ul style="list-style-type: none"> <li>Farms with &gt; \$25k produce sales (three-year rolling basis, adjusted for inflation) subject to the Produce Safety Rule (PSR)</li> </ul>	<ul style="list-style-type: none"> <li>Farms with &gt; \$500k food sales (three-year rolling basis, adjusted for inflation) subject to modified requirements</li> </ul>
Secondary Activities	<ul style="list-style-type: none"> <li>Not located on a primary production farm</li> <li>Majority owned (&gt;50%) by the primary production farm where raw agricultural commodities are grown/harvested or animals are raised</li> </ul>	<ul style="list-style-type: none"> <li>Harvesting, packing, holding raw agricultural commodities</li> <li>Manufacturing activities allowed on primary production farms</li> </ul>	<ul style="list-style-type: none"> <li>Farms with &gt; \$25k produce sales (three-year rolling basis) subject to the PSR</li> </ul>	<ul style="list-style-type: none"> <li>Farms with &gt; \$500k food sales (three-year rolling basis, adjusted for inflation) subject to modified requirements</li> </ul>

**Source:** CRS using the PSR. See FDA, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” 80 *Federal Register* 74353, November 27, 2015 (hereinafter FDA, PSR Final Rule, 80 *Federal Register* 74353, 2015). Also available at FDA, “FSMA Final Rule on Produce Safety,” at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>.

**Notes:** Manufacturing may include activities such as drying, fumigating, and labeling if the activities do not destroy the intact nature of the produce commodity (e.g., slicing). See 21 C.F.R. §112.3. Produce sales calculations are not limited to produce subject to PSR requirements. Food sales calculations are not limited to produce sales but are based on all food sold.

### Withdrawal of a Qualified Exemption

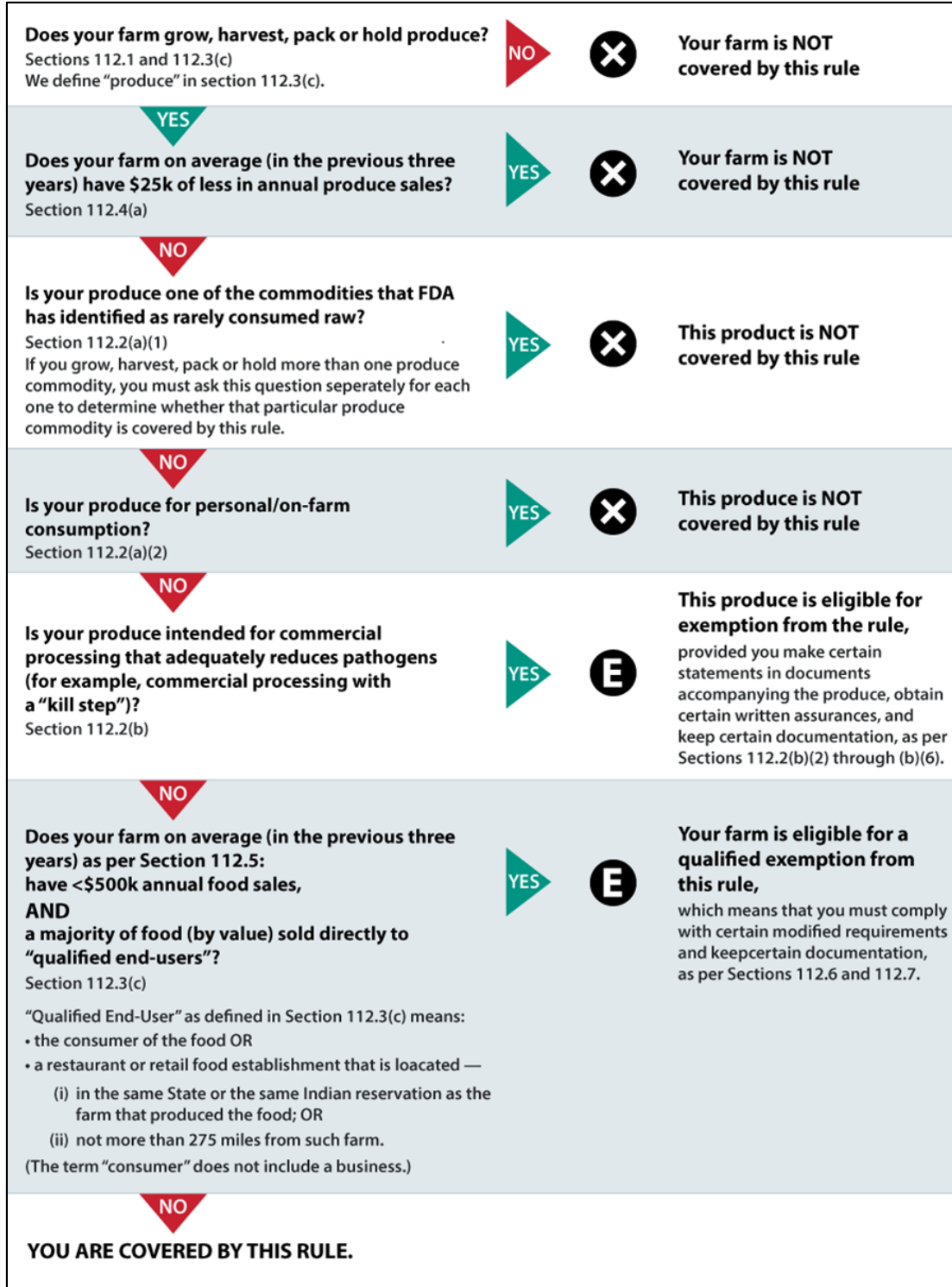
A farm’s qualified exemption may be withdrawn if there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm. A farm’s qualified exemption may also be withdrawn if FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm. The conduct or conditions in question must be material to the safety of the farm’s produce covered by the rule.

Before FDA issues an order to withdraw a qualified exemption, the agency may consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, or injunction. FDA also must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency. A withdrawn exemption may be reinstated if (as applicable)

- FDA determines that the outbreak was not directly linked to the farm, and/or
- FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.



Figure I. Coverage and Exemptions/Exclusions Flowchart



Source: CRS modified from FDA, *Coverage and Exemptions/Exclusions Flowchart*, at <https://www.fda.gov/media/94332/download>.

## Agricultural Water

FDA's produce safety regulations require all agricultural water to be safe and of adequate sanitary quality for its intended use.<sup>29</sup> Agricultural water, in part, includes water used during pre-harvest activities (e.g., irrigating, fertilizing, frost/scorch protection) and post-harvest activities (e.g., washing harvested produce, sanitizing tools and equipment, hand washing).<sup>30</sup> Agricultural water can be particularly risky when used during post-harvest activities, such as washing, if water coming into contact with produce is contaminated. Due to the potential for agricultural water to contaminate produce, agricultural water provisions of the PSR focus on water quality and testing. Many of the agricultural water recommendations originally published in the 1998 GAPs guide were made mandatory in the PSR. The PSR expanded on the number of water samples for testing, built upon risk profiles of different water sources, and set a no detectable *E. coli* standard for post-harvest water uses.

Water quality criteria are based on the presence of generic *E. coli*. *E. coli* are mostly harmless bacteria that live in the intestines of people and animals and contribute to intestinal health. However, eating or drinking food or water contaminated with certain types of *E. coli* can cause mild to severe gastrointestinal illness. Some types of pathogenic (illness-causing) *E. coli*, such as Shiga toxin-producing *E. coli* (STEC), can be life-threatening. PSR agricultural water standards aim to prevent contaminated water from contacting covered produce by requiring agricultural water testing to determine water quality.

There are two PSR numerical water quality criteria based on the presence of generic *E. coli*. The first of the criteria requires no detectable *E. coli* when agricultural water is used during activities where the water may come in contact with covered produce or food contact surfaces, such as during harvest or post-harvest activities. This criterion, for example, applies to water used for hand washing, commodity washing, and irrigating sprouts. The PSR's other numerical criteria apply to agricultural water that is directly applied to growing produce (other than sprouts). These criteria establish the maximum amount of *E. coli* allowed for agricultural water used to grow produce and are based on the average amount of generic *E. coli* and the variable quantity of *E. coli* in the waters.<sup>31</sup> Testing frequency is based on the type of water source. **Table 4** provides selected numerical microbial water quality criteria.

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<sup>29</sup> 21 C.F.R. §112.41-50 describes requirements for PSR, Subpart E: Agricultural Water.

<sup>30</sup> 21 C.F.R. §112.3 provides the *agricultural water* definition.

<sup>31</sup> The average amount of *E. coli* in agricultural water is known as the geometric mean (GM). The variable quantity of *E. coli* in agricultural water is known as the statistical threshold value (STV). Water quality can vary, for example, due to environmental changes, such as heavy rainfall. The GM and STV are intended to help farms understand the microbial quality of agricultural water over time and determine a long-term strategy for use of water sources for growing produce other than sprouts.

**Table 4. Selected Numerical Microbial Water Quality Criteria in the Produce Safety Rule**

Criteria	Application	Numerical Criteria for Generic <i>E. coli</i>	Agricultural Water Source to Which Numerical Criteria Apply
No detectable <i>E. coli</i>	Certain harvest and post-harvest uses of agricultural water in which the water may directly or indirectly contact covered produce or food contact surfaces	0 CFU <sup>a</sup> per 100 mL of agricultural water	Municipal water, <sup>b</sup> groundwater, treated surface water (untreated surface water is prohibited for this use)
Geometric mean (GM)	Agricultural water that is directly applied to growing produce (other than sprouts)	≤126 CFU per 100 mL of agricultural water	Municipal water, groundwater, treated surface water, untreated surface water
Statistical threshold value (STV)		≤410 CFU per 100 mL agricultural water	

**Source:** CRS using the PSR. FDA, PSR Final Rule, 80 *Federal Register* 74353, 2015; and FDA, “FSMA Final Rule on Produce Safety,” at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>.

**Notes:** The average amount of *E. coli* in agricultural water is known as the geometric mean (GM). The variable quantity of *E. coli* in agricultural water is known as the statistical threshold value (STV). Water quality can vary, for example, due to environmental changes, such as heavy rainfall. The GM and STV are intended to help farms understand the microbial quality of agricultural water over time and determine a long-term strategy for use of water sources for growing produce other than sprouts.

a. CFU = colony forming units; mL = milliliter.

b. Municipal water refers to water controlled, tested, and/or delivered by any federal, state, or local public works system.

FDA received extensive comments to the proposed PSR,<sup>32</sup> published in 2013 (78 *Federal Register* 3504), and the supplemental proposed PSR, published in 2014 (79 *Federal Register* 58434). Many of the comments expressed concern with financial burdens associated with implementing agricultural water standards, testing methodologies, and use of generic *E. coli* as an indicator of fecal contamination. According to FDA, after the final PSR was published in 2015, many stakeholders continued to assert during FDA farm visits and at industry gatherings across the country that the agricultural water regulatory scheme was too complex and too burdensome.<sup>33</sup> The agricultural water compliance dates (see **Table 2**) have been extended while the FDA considers how best to address concerns about the complexity of the agricultural water requirements and the practicality of implementing them across a wide variety of farms, water sources, and uses. The first compliance dates for large farms become effective on January 26, 2022.

Recent outbreaks of foodborne illnesses associated with the consumption of romaine lettuce and other leafy greens have highlighted the need for a viable option for treating agricultural water against foodborne pathogens (see **Table 1**). In July 2020, a new protocol was established in

<sup>32</sup> See, for example, comment letter from Roger Johnson, president of the National Farmers Union, to Dr. Margaret Hamburg, FDA’s food and drug commissioner, December 15, 2014, at [https://downloads.regulations.gov/FDA-2011-N-0921-1332/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2011-N-0921-1332/attachment_1.pdf); comment letter from Produce Marketing Association to FDA, December 15, 2014, at [https://downloads.regulations.gov/FDA-2011-N-0921-1331/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2011-N-0921-1331/attachment_1.pdf); and comment letter from Western Growers to FDA, December 15, 2014, at [https://downloads.regulations.gov/FDA-2011-N-0921-1409/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2011-N-0921-1409/attachment_1.pdf).

<sup>33</sup> See FDA, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E,” 84 *Federal Register* 9706, March 18, 2019, p. 9710.

collaboration with FDA and the U.S. Environmental Protection Agency (EPA) for developing and registering antimicrobial treatments for pre-harvest agricultural water, such as the water used in farm irrigation systems.<sup>34</sup> Companies can now use data developed under this protocol to support the EPA's registration of products that can treat agricultural water against foodborne bacteria. The protocol could provide farmers with a tool to help protect the safety of produce intended for consumers, such as romaine lettuce and other leafy greens. Although farmers are not required to treat their agricultural water, these treatments could help farmers keep their produce safe for consumption. Currently, no registered antimicrobial treatment products are authorized for use on agricultural fields or for treatment of irrigation water systems or ponds.

## Biological Soil Amendments of Animal Origin and Human Waste

The PSR requires farms to apply and handle Biological Soil Amendments of Animal Origin (BSAAs) in a manner that does not contaminate produce. For example, human waste is prohibited from use as a soil amendment, except when used in accordance with EPA requirements. General uses and hazards associated with BSAAs are described in the "BSAA Microbial Hazards" text box, below.

### BSAA Microbiological Hazards

Soil amendments are physical, chemical, or biological components mixed into topsoil to promote healthy plant growth. They function in numerous ways—for example, they may change the pH of soil or supply nutrients. Soil amendments made from animal sources, such as animal waste (raw manure) or compost made from animal-derived materials, including animal waste, animal carcasses, feathers, and bones, are referred to as biological soil amendments of animal origin (BSAAs). BSAAs may contain bacterial pathogens (e.g., *Salmonella* spp., *E. coli*) and various other pathogens, such as parasites (e.g., *Cryptosporidium parvum*), which may infect humans. BSAAs do not include any form of human waste; 21 C.F.R. §112.53 states that the use of human waste is prohibited for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 C.F.R. part 503, subpart D, or equivalent regulatory requirements.

Farms monitor soil nutrient and moisture levels to determine when to apply soil amendments (including BSAAs), which can come into contact with fruits or vegetables. The application method and timing can determine if BSAAs that contain raw, untreated materials or improperly treated materials could contaminate produce.

Material that does not contain any animal waste is far less likely to harbor these food safety hazards at microbial populations that reasonably can be expected to lead to severe adverse health consequences or death. FDA, therefore, concludes that the likelihood of contaminating produce by use of biological soil amendments that do not contain animal waste or human waste carrying human pathogens (e.g., yard trimmings, culled fruit and vegetables) is low. Thus, requirements in the Produce Safety Rule focus on BSAAs.

**Sources:** CRS, using various sources, including FDA, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 78 *Federal Register* 3576, January 16, 2013 (see 21 C.F.R. §112.53); and Jon Traunfeld and Ellen Nibali, *Soil Amendments and Fertilizers: Fertilizing Guidelines Included by Plant Group*, University of Maryland Extension, Home & Garden Information Center, 2013, p. 1.

The PSR does not require microbial testing of any BSAAs. Instead, it provides the microbial standards to which BSAA treatment processes must be validated.<sup>35</sup> Growers may use any treatment process or processes that have been validated to meet relevant PSR requirements

<sup>34</sup> FDA, "FDA Announces New Protocol for the Development and Registration of Treatments for Preharvest Agricultural Water," press release, July 30, 2020, at <https://www.fda.gov/news-events/press-announcements/fda-announces-new-protocol-development-and-registration-treatments-preharvest-agricultural-water>.

<sup>35</sup> 21 C.F.R. §112.55 describes biological soil amendments of animal origin (BSAA) microbial standards.

without the need to test the end products.<sup>36</sup> Growers may use one of the two methods stated in the PSR, or they may use another validated method.

The proposed BSAAO requirements received vast public input. FDA first proposed to establish 9-month or 45-day application intervals for BSAAOs depending on the treatment level and application method. After receiving public comments, FDA chose to

- remove application intervals for treated and untreated BSAAOs applied in a manner that does not, under any circumstance, contact the edible portion of the crop,<sup>37</sup> and
- postpone establishing an application interval for untreated BSAAOs applied in a manner where contact with the edible portion of the crop is unlikely but possible.

The application interval is postponed pending the results of a risk assessment by FDA and USDA. At the time of the final PSR's publication in 2015, FDA and USDA anticipated the risk assessment would be complete within 5 to 10 years.<sup>38</sup>

## Sprouts

Sprouts represent a special food safety concern because the conditions under which they are produced (time, temperature, water activity, pH, and available nutrients) are ideal for the growth of pathogens, if present.<sup>39</sup> Between 1996 and July 2016 in the United States, there were approximately 46 reported outbreaks associated with sprouts, accounting for 2,474 illnesses, 187 hospitalizations, and 3 deaths, including 2 documented outbreaks of *Listeria monocytogenes*.<sup>40</sup> In these outbreaks, epidemiological investigations often identified seeds used for sprouting as the most likely source of contamination. Poor sanitation and unhygienic practices at sprout operations also can contribute to sprout contamination. The PSR requires farms to implement practices specific to sprout operations.

PSR requirements specific to sprouts include, for example,<sup>41</sup>

- Taking measures to (1) prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, and (2) treat seeds or beans used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation).
- Testing of spent sprout irrigation water from each production batch of sprouts for certain pathogens. Sprouts cannot enter commerce until pathogen test results are negative.

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<sup>36</sup> 21 C.F.R. §112.54 describes BSAAO treatment processes.

<sup>37</sup> 21 C.F.R. §112.51-60 describes requirements for PSR, Subpart F: Biological Soil Amendments of Animal Origin and Human Waste.

<sup>38</sup> Five to ten years of the PSR publication date of November 27, 2015. See FDA, PSR Final Rule, 80 *Federal Register* 74353, 2015.

<sup>39</sup> National Advisory Committee on Microbiological Criteria for Food, *Microbiological Safety Evaluations and Recommendations on Sprouted Seed*, November 1999, at <https://pubmed.ncbi.nlm.nih.gov/10733245/>.

<sup>40</sup> FDA, *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*, Draft Guidance, January 2017, at <https://www.fda.gov/media/102430/download>.

<sup>41</sup> 21 C.F.R. §112.141-150 describes requirements for PSR, Subpart M: Sprouts.

- Testing the growing, harvesting, packing and holding environment for *Listeria* species or *Listeria monocytogenes*.
- Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.<sup>42</sup>

## Domesticated and Wild Animals

Domesticated animals (e.g., pets, livestock) and wild animals are a concern because they may harbor and spread human pathogens or be difficult to control in ways that contribute to contamination risks and can contaminate food or food contact surfaces.<sup>43</sup> The PSR requires produce production farms to take the necessary measures to identify and not harvest covered produce that is likely to be contaminated.

The PSR does not require farms to exclude animals from outdoor growing areas, destroy animal habitats, or clear borders around growing or drainage areas. At a minimum, all covered farms must visually examine the growing area for animal contamination and all covered produce to be harvested, regardless of the harvest method used. In addition, under certain circumstances, the rule requires farms to do additional assessments during the growing season and, if significant evidence of potential contamination by animals is found, take measures reasonably necessary to assist later during harvest. Such measures might include, for example, outlining the affected area with flags.

## Worker Health, Hygiene, and Training

Humans can carry a wide variety of pathogens (including *Hepatitis A virus*, *Salmonella* spp., *E. coli* O157:H7, and *Cyclospora cayatenensis*), which can be transferred onto fruits and vegetables and make other people ill if they ingest the contaminated produce. The PSR requires farm employees to practice good health and hygiene while handling food and food contact surfaces.<sup>44</sup> Personnel must use hygienic practices while handling covered produce and food contact surfaces to protect against such contamination.<sup>45</sup> This requirement applies both to personnel who handle covered produce and food contact surfaces and to others who work in the operation.

PSR requirements for health and hygiene include the following:

- Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, for example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces.
- Using hygienic practices when handling (contacting) covered produce or food-contact surfaces, for example, washing and drying hands thoroughly at certain times such as after using the toilet.

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<sup>42</sup> See FDA, “FSMA Final Rule on Produce Safety, Key Requirements, Sprouts,” at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>.

<sup>43</sup> 21 C.F.R. §112.81-84 describes requirements for PSR, Subpart I: Domesticated and Wild Animals.

<sup>44</sup> 21 C.F.R. §112.21-30, 31-33 describes requirements for PSR, Subpart C: Personal Qualifications and Training and Subpart D: Health and Hygiene.

<sup>45</sup> 21 C.F.R. §112.32 (a) describes hygienic practices workers must use per the PSR.



- Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.<sup>46</sup>

Farm workers who handle covered produce, food-contact surfaces, or both, as well as their supervisors, must be trained on the importance of health and hygiene and on other topics pertaining to their work duties. The PSR marks the first time FDA has required worker and supervisor training in a food regulation. Training may not be substituted with education or experience. At least one supervisor on the farm must successfully complete training on the standardized curriculum as delivered by the Produce or Sprout Safety Alliances or must successfully complete an equivalent course.

## **Equipment, Tools, Buildings, and Sanitation**

The PSR establishes standards related to equipment, tools, and buildings to prevent inadequate sanitation of these sources from contaminating produce.<sup>47</sup> This section of the rule covers, for example, greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities.

Measures required to prevent equipment, tools, buildings, and sanitation practices from becoming a route of contamination for covered produce and food contact surfaces include

- appropriate storage, maintenance, and cleaning of tools and equipment (including transport vehicles);
- appropriate placement and use of toilet and hand-washing facilities;
- control of pests;
- maintenance of adequate plumbing; and
- proper disposal of sewage and waste.

## **Federal and State Inspections**

Section 105 of FSMA authorizes FDA to coordinate with USDA and state authorities to perform activities to ensure compliance with the PSR. FDA's approach to compliance has centered on developing a strategy for inspections and training (see "Resources Supporting PSR Implementation" for training programs). To this end, FDA determined state regulatory authorities are to conduct most domestic produce farm inspections, and FDA is to conduct inspections in states without inspectional authority as well as on foreign farms. The National Association of State Departments of Agriculture (NASDA) is the main conduit for states to perform inspections. The association also disperses funds to state groups to perform inspections and provides training. Inspections performed by FDA or states are generally scheduled with the farm owner or operator in charge via a phone call. Unannounced inspections are rare but may occur in limited circumstances.<sup>48</sup>

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<sup>46</sup> See FDA, "FSMA Final Rule on Produce Safety, Key Requirements, Worker Training and Health and Hygiene," at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>.

<sup>47</sup> 21 C.F.R. §112.121-140 describes requirements for PSR, Subpart L: Equipment Tools, Buildings, and Sanitation.

<sup>48</sup> FDA, "What to Expect During a Regulatory Inspection," fact sheet, at <https://www.fda.gov/media/124328/download>.

The first major compliance date for large farms subject to the PSR, other than sprout operations (foreign and domestic), arrived on January 26, 2018; however, FDA delayed inspection of large farms until the spring of 2019. This action was intended to allow FDA and its state partners time to provide additional opportunities for education and outreach, such as through the On-Farm Readiness Review (OFRR) program.<sup>49</sup> FDA also asked states receiving funding to perform inspections as part of the State Produce Implementation Cooperative Agreement Program (State CAP) to begin routine inspections of large produce farms in spring 2019. Produce farm inspections were delayed again in March 2020 after FDA announced it would postpone all inspections due to the Coronavirus Disease 2019 (COVID-19) pandemic.<sup>50</sup> Inspections resumed in July 2020, and FDA and states continue to prioritize inspections in a manner that assures inspectors' safety. In FY2019 and FY2020, FDA and states conducted almost 1,000 large farm inspections and 1,400 OFRRs.<sup>51</sup>

## State Produce Implementation Cooperative Agreement Program

FSMA authorizes FDA to undertake examinations, inspections, investigations, and related food safety activities.<sup>52</sup> FSMA allows FDA to enter into cooperative agreements with states and territories (State CAP). In 2016, FDA awarded cooperative agreement funding to NASDA to implement or enhance state and territory produce safety programs.<sup>53</sup> NASDA further awarded funds to individual states based on the number of farms growing covered produce within the jurisdiction.<sup>54</sup> Some of the awards (referred to as Competition A) are related to state or territorial capacity building (covering state or territorial food safety infrastructure, education, technical assistance, and inventory resources). Pursuant to awards that include a state or territorial inspection, compliance, and enforcement program (referred to as Competition A/B), the state or territory conducts routine inspections (**Figure 2**). For states and territories not covered by Competition A/B agreements, FDA conducts routine inspections to assess compliance with the PSR.

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<sup>49</sup> The On-Farm Readiness Review (OFRR) program is a voluntary, nonregulatory review of food safety protocols performed at the request of individual farms. For more information, see National Association of State Departments of Agriculture (NASDA), "On-Farm Readiness Review," at <https://www.nasda.org/foundation/food-safety-cooperative-agreements/on-farm-readiness-review>.

<sup>50</sup> FDA, "Coronavirus (COVID-19) Update: FDA prepares for resumption of domestic inspections with new risk assessment system," press release, July 10, 2020, at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-prepares-resumption-domestic-inspections-new-risk-assessment-system>.

<sup>51</sup> FDA, *FY2021 Justification of Estimated of Appropriations Committees*, 2020, at <https://www.fda.gov/media/135078/download>.

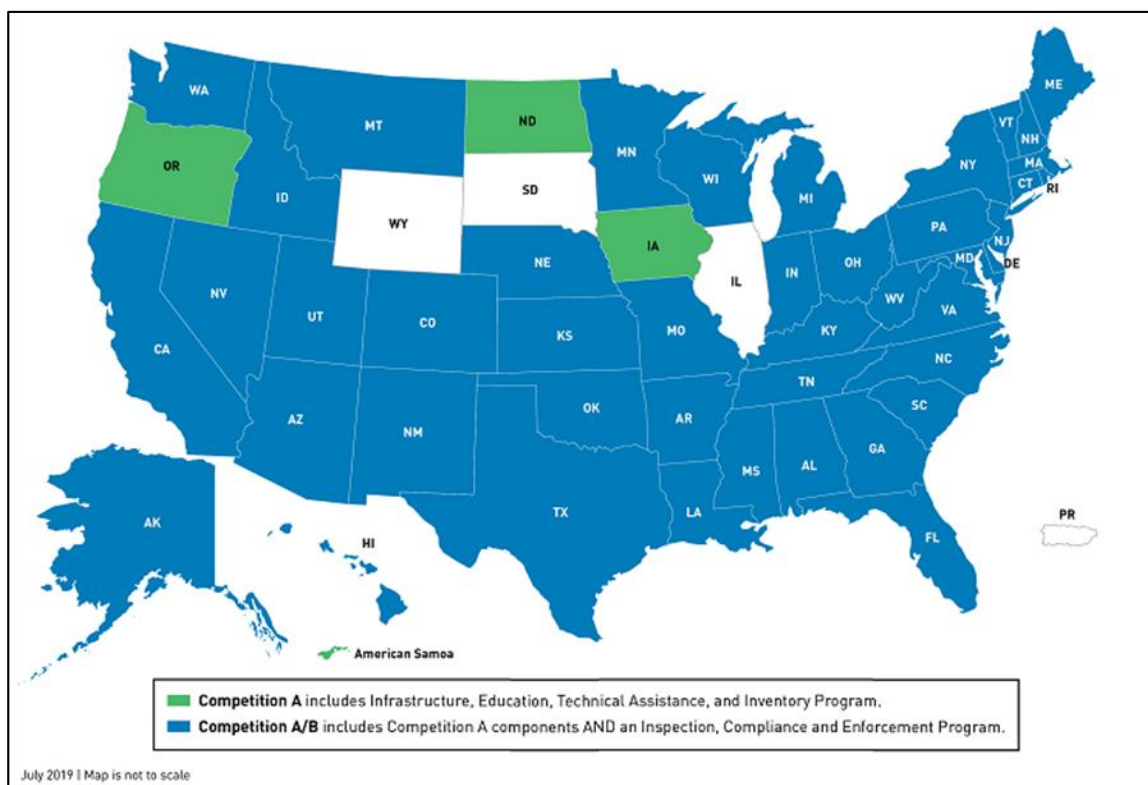
<sup>52</sup> FSMA, §210.

<sup>53</sup> FDA, "Funding Opportunity Announcement (FOA)," 2016, at <https://grants.nih.gov/grants/guide/pa-files/PAR-16-137.html>.

<sup>54</sup> U.S. states and territories are classified into five tiers of funding ceilings based on the number of farms growing covered produce within the jurisdiction. This tiered system establishes funding ceilings proportional to the applicant's jurisdictional produce volume.



Figure 2. Competition A Only and Competition A/B Map



**Source:** FDA, “State Produce Implementation Cooperative Agreement Program (State CAP),” last accessed November 2020, at <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/state-produce-implementation-cooperative-agreement-program-cap>.

**Notes:** As February 2021, states that appear in white do not participate in the State Produce Implementation Cooperative Agreement Program. FDA conducts routine inspections to assess compliance with the PSR in states and territories that appear in white and green. State authorities conduct routine inspections to assess compliance with the PSR in states that appear in blue.

The approach of FDA and NASDA to produce safety inspections gives autonomy to state and federal regulators to develop inspection priorities and data collection systems. In the states where the state department of agriculture conducts the inspection and the state has adopted (at a minimum) the authority to enforce the PSR requirements, that state will decide what enforcement action to take in the event of a violation. If the state has not adopted authority to enforce the PSR, the state department of agriculture would inform FDA of the violation, and FDA would determine the appropriate enforcement action. As a result, compliance and regulatory action may differ based on whether the state or FDA is the enforcing authority. Systems developed to track and to identify trends in inspection results are disjointed and do not communicate across state and federal lines (see the “Multi-jurisdictional Communications” section). NASDA supports building a central database for all food safety inspection data, which would allow states and FDA to have access to farm histories, evaluate sector-wide trends, and promote consistent enforcement.

The number of awards and final funding levels under the State CAP is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Funding amounts in future years will depend upon annual appropriations and awardee performance. The

total funding available for years one through four (FY2017-FY2020) amounted to approximately \$112 million.<sup>55</sup>

PSR standards apply equally to domestic and foreign farms. FDA conducts inspections of foreign farms; however, the number of foreign farms that export fresh produce to the United States outpaces the number of in-person farm inspections FDA can feasibly accomplish in a year. Compliance assessments for foreign farms subject to the PSR are covered by the Foreign Supplier Verification Program (FSVP). With respect to the PSR, FSVP requires importers to verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection as the produce safety regulations and to ensure that their suppliers' foods are not adulterated and are not misbranded with respect to allergen labeling.<sup>56</sup> Importers must establish and follow written procedures to ensure that they import foods only from approved foreign suppliers. Unapproved foreign suppliers can be used when necessary, on a temporary basis, if such suppliers successfully complete verification activities before importing foods. FDA began routine FSVP inspection of importers of produce from large farms in fall 2019.<sup>57</sup>

## **Enforcement Discretion of Certain Product Safety Rule Provisions**

In January 2018, FDA announced it did not intend to enforce certain provisions in four FSMA rules.<sup>58</sup> The announcement referred to *enforcement discretion*, which is a temporary policy guidance whereby FDA does not intend to enforce certain provisions of FSMA rules.<sup>59</sup> Enforcement discretion focuses, in part, on the “farm” definition and on written assurance requirements.

### **The “Farm” Definition**

The farm definition is a fundamental principle that the produce farming industry and regulators use to determine if a farm is subject to PSR requirements. When FDA uses enforcement discretion, the produce farming industry and regulators might not be able to determine which operations that perform farm-related activities are subject to the rule.

An operation must perform one or more specific activities (e.g., growing, harvesting, packing, holding, and limited manufacturing processes) to be considered a primary production farm. Secondary activities farms perform the same activities as primary production farms (except growing) and must be primarily owned by a primary production farm. However, some establishments fall outside of the current farm definition conduct activities that are typically conducted on farms (**Table 5**). For example, some operations that might otherwise qualify as

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<sup>55</sup> See FDA, “State Produce Implementation Cooperative Agreement Program (CAP),” at <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/state-produce-implementation-cooperative-agreement-program-cap>.

<sup>56</sup> See FDA, *Am I Subject to FSVP*, November 13, 2015, at <https://www.fda.gov/media/94281/download>.

<sup>57</sup> See FDA “FSVP and Produce Inspections,” at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fsvp-and-produce-inspections>.

<sup>58</sup> FDA, *Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry*, 2018, at <https://www.fda.gov/media/110023/download> (hereafter FDA’s Enforcement Discretion Guidance); and FDA, “Enforcement Discretion for Certain FSMA Provisions,” fact sheet, 2018, at <https://www.fda.gov/media/110052/download> (hereafter FDA’s Enforcement Discretion Fact Sheet).

<sup>59</sup> FDA’s Enforcement Discretion Guidance covers certain entities or activities covered by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal food rules (PC Human Food and PC Animal Food or CGMP & PC rules), Foreign Supplier Verification Programs rule (FSVP), and the PSR.

secondary activities farms do not because they do not meet the ownership requirement. In this situation, they would be regulated under PCHF.

**Table 5. Summary of Enforcement Policy with Regard to Human Food**

Description of facilities and activities conducted by the facilities	Does enforcement apply for human food preventive control requirements?	Does enforcement discretion apply for human food cGMPs? <sup>a</sup>
Facilities that would qualify as secondary activities farms except for the ownership of the facility	Yes	No, for farm-related activities conducted on produce RACs <sup>b</sup> Yes, for farm-related activities conducted on nonproduce RACs <sup>c</sup>
Facilities that would qualify as farms if they did not color RACs	Yes	No, for coloring of produce RACs Yes, for coloring of nonproduce RACs
Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that consists of only RACs that have been dried/dehydrated to create a distinct commodity such as dried beans	Yes	No, for produce RACs Yes, for nonproduce RACs

**Source:** FDA, “Enforcement Discretion for Certain FSMA Provisions,” fact sheet, 2018, at <https://www.fda.gov/media/110052/download>.

**Notes:**

- a. cGMPs = current good manufacturing practices.
- b. RACs = raw agricultural commodities.
- c. Eggs are examples of nonproduce RACs.

According to FDA, stakeholders have challenged the classification of establishments that both fall outside of the current farm definition and conduct activities that are typically conducted on farms. FDA recognized the “conundrum” created by “regulating identical facilities that pack or handle raw agricultural commodities sometimes under the Produce Safety Rule (PS) and sometimes under the Preventive Controls (PC) Rule” and implemented enforcement discretion while it reevaluates the farm definition.<sup>60</sup> As of February 2021, FDA has not set a target date for reevaluating the farm definition.

**Written Assurance Requirements**

FDA’s written assurance requirements intend to provide documentation to a manufacturer, processor, importer, or farmer that the food will be processed to control for hazards before the food reaches consumers. The PSR’s written assurance provisions specify,<sup>61</sup> in summary, that produce is eligible for an exemption from many of the requirements if it is to receive commercial processing that reduces harmful foodborne pathogens. Certain other conditions also must be met, including requirements for disclosure statements and written assurances similar to what is

<sup>60</sup> Letter from United Fresh Produce Association et al. to Michael Taylor, FDA’s deputy commissioner for Foods and Veterinary Medicine, and Dr. Stephen Ostroff, FDA Office of the Commissioner’s chief scientist, April 19, 2016, at <https://downloads.regulations.gov/FDA-2011-N-0921-19141/content.pdf>.

<sup>61</sup> 21 C.F.R. §112.2(b)(3).

required by PCHF and FSVP.<sup>62</sup> Industry feedback has identified that these provisions would cause stress to produce farms and distributors.<sup>63</sup> For instance, certain product distribution chains would require many more written assurances and resources to comply than FDA anticipated during the rulemaking process.

## Resources Supporting PSR Implementation

FSMA requires FDA to set standards and administer training and education programs for the employees of state, local, territorial, and tribal food safety officials.<sup>64</sup> To meet these goals, FDA collaborates with domestic and international organizations to increase the reach of PSR implementation assistance. These government, nongovernment, and private industry groups foster critical communication with farms to increase the availability of resources necessary to support education and compliance. FDA's partnerships with organizations, such as USDA's National Institute of Food and Agriculture (NIFA), the Association of Food and Drug Officials (AFDO), and university extension services provide a scaffold to accomplish education and training goals established as part of PSR implementation. Congress has provided more than \$300,000,000 in FDA's base appropriation for FSMA-related goals since FY2011 (H.Rept. 115-232).

## FDA-USDA Resources Supporting Produce Safety

In FY2019, the Food Safety Outreach Program expanded upon the FY2015 national infrastructure established by NIFA and FDA, known as the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Competitive Grants Program.<sup>65</sup> The purpose of the grant program is to train owners and operators of small businesses, including small and medium-sized farms, beginning farmers, socially disadvantaged farmers, small processors, or small fresh fruit and vegetable merchant wholesalers, as well as farms that lack access to food safety training and other educational opportunities.<sup>66</sup> Grants issued through this program are funding a National Coordination Center (NCC) and four Regional Centers (RCs),<sup>67</sup> which will be involved in two key components of training—facilitating training delivery and, in certain situations, facilitating curricula development targeted to specific audiences.

**Table 6** summarizes key cooperative agreements to help with the implementation of PSR-related education, training, and outreach.

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<sup>62</sup> FDA's Enforcement Discretion Fact Sheet.

<sup>63</sup> Consumer Brands Association (CBA) (formerly the Grocery Manufacturers Association [GMA]), "GMA Industry Impacts from Disclosure and Written Assurance Requirements," 2017, at <https://beta.regulations.gov/document/FDA-2011-N-0921-19136>.

<sup>64</sup> FSMA, §209.

<sup>65</sup> USDA's National Institute of Food and Agriculture (USDA-NIFA), "USDA-NIFA Food Safety Outreach Program," at <https://nifa.usda.gov/food-safety-outreach-program>.

<sup>66</sup> Several grants are issued through the FDA, USDA-NIFA grants program. The funding is made possible through NIFA's Agriculture and Food Research Initiative (AFRI) program. Congress established AFRI in the 2008 Farm Bill and reauthorized it in the 2018 Farm Bill. The program was reauthorized to be funded at \$700 million a year. The Consolidated Appropriations Act, 2019, funds AFRI at \$415 million. See H.R. 648; and USDA-NIFA, "Agriculture and Food Research Initiative (AFRI)," at <https://nifa.usda.gov/program/agriculture-and-food-research-initiative-afri>.

<sup>67</sup> See FDA, "FSMA Training," at [https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-training#Establishing\\_the\\_National\\_Coordination](https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-training#Establishing_the_National_Coordination).

**Table 6. Selected Key FDA Cooperative Agreements for Product Safety Rule Education, Training, and Outreach**

Organization	Program Objective
National Association of State Departments of Agriculture (NASDA)	Develop a set of best practices for implementation of the produce rule, including education and outreach activities to both regulators and industry
USDA Agricultural Marketing Service (AMS) and Cornell University	Establish the Produce Safety Alliance to develop the standardized curriculum for producers of fruits and vegetables other than sprouts
Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH)	Establish the Sprouts Safety Alliance to develop the standardized curriculum for sprout producers
University of Arkansas Indigenous Food and Agriculture Initiative (IFAI)	Advance food safety through outreach, education and training to Native American tribes
National Farmers Union via the Local Food Safety Collaborative	Enhance food safety through targeted outreach, education and training to local food producers and processors including beginning and socially disadvantaged farmers, traditional farmers, urban farmers, small farmers and processors, and other supply-chain participants.
University of Florida, Oregon State University, Iowa State University, University of Vermont and State Agricultural College	Establish regional centers in the Southern, Western, North Central and Northeast regions of the country charged with understanding and communicating the landscape of training opportunities available to target businesses in their region.
University of Maryland Joint Institute for Food Safety and Applied Nutrition (JIFSAN)	Coordinate and deliver international training programs

**Source:** CRS using FDA, "FSMA Training," at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-training>.

NASDA has played many roles in PSR implementation. In 2014, NASDA began a multiyear cooperative agreement to help implement the PSR.<sup>68</sup> As a part of the cooperative effort, NASDA established the State CAP (see "State Produce Implementation Cooperative Agreement Program") and developed a proposed NASDA Model Produce Safety Implementation Framework for states to consider as they prepare for PSR implementation.<sup>69</sup> NASDA has also developed an OFRR process,<sup>70</sup> in conjunction with the FDA and extension services, to offer a voluntary, nonregulatory opportunity to assess a farm's readiness for FSMA compliance. The majority of NASDA's funding recipients are operating education and outreach programming along with compliance and enforcement.

FDA is continuing cooperative agreements with the National Farmers Union and the University of Arkansas Indigenous Food and Agriculture Initiative (IFAI) to enhance food safety under

<sup>68</sup> FDA, *Developing a Coordinated National Produce Safety Program*, 2014, at [https://federalreporter.nih.gov/Projects/Details/?projectId=928912&ItemNum=NaN&totalItems=3846&searchId=b850241613a74a58962c0bd1a1edd5d4&searchMode=Smart&page=67&pageSize=50&sortField=lc&sortOrder=desc&filters=\\$Agency;FDA\\$ProjectType;p&navigation=True](https://federalreporter.nih.gov/Projects/Details/?projectId=928912&ItemNum=NaN&totalItems=3846&searchId=b850241613a74a58962c0bd1a1edd5d4&searchMode=Smart&page=67&pageSize=50&sortField=lc&sortOrder=desc&filters=$Agency;FDA$ProjectType;p&navigation=True).

<sup>69</sup> NASDA, *NASDA Model Produce Safety Implementation Framework*, updated 2019, at [https://s3.amazonaws.com/nasda2/media/NASDA-Model-Produce-Safety-Implementation-Framework\\_2-22-2019.pdf?mtime=20190906154302](https://s3.amazonaws.com/nasda2/media/NASDA-Model-Produce-Safety-Implementation-Framework_2-22-2019.pdf?mtime=20190906154302).

<sup>70</sup> See NASDA, "About On-Farm Readiness Review," at [https://www.nasda.org/foundation/food-safety-cooperative-agreements/on-farm-readiness-review#token=FFvWlvZzPLDbIonAziUjw8cJ\\_TPpbYL7](https://www.nasda.org/foundation/food-safety-cooperative-agreements/on-farm-readiness-review#token=FFvWlvZzPLDbIonAziUjw8cJ_TPpbYL7).



FSMA.<sup>71</sup> The National Farmers Union plans to conduct targeted outreach, education, and training to local food producers and processors, including beginning and socially disadvantaged farmers, traditional farmers, urban farmers, small farmers and processors, and other supply-chain participants, through the National Farmers Union Food Safety Collaborative Project.<sup>72</sup> The IFAI plans to conduct outreach, education, and training to Native American tribes.<sup>73</sup>

FDA, in collaboration with the Agricultural Marketing Service (AMS) of USDA and Cornell University, has established the Produce Safety Alliance (PSA).<sup>74</sup> FDA also established the Sprouts Safety Alliance (SSA) in collaboration with the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH).<sup>75</sup> Both PSA and SSA have developed and disseminated science- and risk-based training and education programs. Referred to collectively as "the Alliance courses," they provide produce farms with fundamental, on-farm food safety knowledge and equip them to comply with the PSR. FDA has recognized the PSA and SSA training materials as the standardized curricula that are consistent with the requirements of the PSR. Farms can fulfill the training requirement by either successfully completing the Alliance course appropriate for their farming operation or completing an equivalent course. FDA has published guidance on identifying alternate curricula.

## International Programs

The Produce International Partnership for Education and Outreach (PIP) is a joint effort among the University of Maryland Joint Institute for Food Safety and Applied Nutrition (JIFSAN), the PSA based at Cornell University, and multinational industry leaders to provide food safety training to the international community that satisfies the PSR-required training. PIP draws from existing cooperative agreement resources to support international outreach. PIP is responsible for translating the existing PSA curriculum and offering training to international audiences.<sup>76</sup> Additionally, PIP has an active role in collaborating with international industry associations,

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<sup>71</sup> See FDA, "FDA Announces New Round of Funding to Support FSMA Education, Training and Technical Assistance: Constituent Update," July 27 2020, at <https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-new-round-funding-support-fsma-education-training-and-technical-assistance>.

<sup>72</sup> The award for the local food producer cooperative agreement will be for \$1,000,000 for one year with the possibility of an additional year of support contingent upon satisfactory performance and the availability of federal funding. For more information, see National Farmers Union, "Local Food Safety Collaborative," at <https://nfu.org/farmsafety/local-food-safety-collaborative/>; and Department of Health and Human Services (HHS), "Local Food Producer Outreach, Education, and Training to Enhance Food Safety and FDA Food Safety Modernization Act (FSMA) Compliance," 2019, at <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-20-006.html>.

<sup>73</sup> The award for the tribal cooperative agreement will be for \$500,000 for one year with the possibility of an additional year of support contingent upon satisfactory performance and the availability of federal funding. See HHS, "Native American Tribes Outreach, Education, and Training to Enhance Food Safety and FSMA Compliance," 2019, at <https://grants.nih.gov/grants/guide/rfa-files/RFA-FD-20-004.html>.

<sup>74</sup> FDA and USDA do not publicly publish funding data for the Product Safety Alliance (PSA); however, based on articles from industry groups, PSA received roughly \$1,150,000 for a three-year partnership established in 2010. PSA continues to operate as a collaboration between Cornell University, FDA, and USDA to deliver training. See NSAC's blog, *USDA, FDA, and Cornell University form Produce Safety Alliance*, 2010, at <https://sustainableagriculture.net/blog/produce-safety-alliance/>; and the PSA web page at <https://producesafetyalliance.cornell.edu/>.

<sup>75</sup> Per 80 *Federal Register* 43095, FDA's cooperative agreement with Illinois Institute of Technology's National Center for Food Safety and Technology provides roughly \$5,000,000 to \$7,000,000 annually to support research, education, and outreach programs, including the Sprouts Safety Alliance.

<sup>76</sup> For more on the Produce International Partnership for Education and Outreach (PIP) program, see University of Maryland Joint Institute for Food Safety and Applied Nutrition (JIFSAN), "Program Description," at <https://jifsan.umd.edu/training/international/courses/pip/description>.

universities, government organizations, and others in the development and delivery of training programs that address the local and regional needs of foreign farms in complying with the PSR.

In an effort to enhance food safety across the southern border, FDA and Mexican authorities with regulatory oversight of farms, packinghouses, and food manufacturing facilities created the Food Safety Partnership (FSP). FSP establishes the intent to continue collaborations that strengthen food safety capabilities in each country. Signed in 2020, FSP prioritizes outbreak response, laboratory collaboration, foodborne illness prevention, outreach, and training.

FDA signed a systems recognition agreement in 2016 with the Canadian Food Inspection Agency (CFIA).<sup>77</sup> FDA's and CFIA's systems recognition involves a bilateral review of each country's domestic food safety regulatory system to determine if it has legal authorities and regulatory tools that together provide public health outcomes comparable to those provided by either FDA or CFIA. This puts both countries in a unique position of mutual reliance to deliver education, training, and outreach to farming communities, as well as to perform regulatory inspections per the PSR.

Although FDA and CFIA have a systems recognition agreement, Canada has taken a tough stance on lettuce imported from the United States. On October 2, 2020, CFIA announced new requirements for romaine imported into Canada from the United States.<sup>78</sup> Importers must hold a Safe Food for Canadians license and provide a Proof of Origin (state and county) for romaine lettuce and products containing romaine lettuce from outside of the California counties of Santa Cruz, Santa Clara, San Benito, and Monterey. If romaine is sourced from California or Arizona, the importer must source romaine only from those companies certified by the respective LGMA. Additionally, shipments of romaine sourced from the Salinas growing region (Santa Clara, Santa Cruz, San Benito, and/or Monterey counties) or romaine of unknown or undeclared origin must be accompanied by a certificate of analysis demonstrating that the product does not contain detectable levels of *E. coli* O157:H7.

## Considerations for Congress

As foodborne illness outbreaks continue, some have questioned the effectiveness of FDA's implementation of FSMA. Despite changes enacted as part of FSMA, the U.S. Government Accountability Office has regularly placed federal oversight of U.S. food safety on its biennial High Risk List since 2007,<sup>79</sup> and it has recommended that the United States take steps to "improve the federal food safety oversight system and address ongoing fragmentation."<sup>80</sup> In one instance involving the contamination event that led to three outbreaks of *E. coli* O157:H7 during the fall of 2019, the investigation report linked the outbreak strain to a fecal-soil composite sample collected near an animal production facility.<sup>81</sup> The samples were specifically collected

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<sup>77</sup> See FDA, "Frequently Asked Questions on Systems Recognition for Foreign Governments," at <https://www.fda.gov/food/international-interagency-coordination/frequently-asked-questions-systems-recognition-foreign-governments>.

<sup>78</sup> See Produce Marketing Association, "Canada Import Requirements for U.S. Romaine Lettuce: Q&A," at <https://www.pma.com/content/articles/canada-import-requirements-for-us-romaine-lettuce>.

<sup>79</sup> U.S. Government Accountability Office (GAO), *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP, March 6, 2019, at <https://www.gao.gov/products/GAO-19-157sp>.

<sup>80</sup> GAO, *A National Strategy Is Needed to Address Fragmentation in Federal Oversight*, GAO-17-74, January 2017, at <https://www.gao.gov/assets/690/682095.pdf>. For related background, see CRS Report RS22600, *The Federal Food Safety System: A Primer*.

<sup>81</sup> See FDA, "Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Three Outbreaks of *E. coli* O157:H7 During the Fall of 2019," at <https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-romaine-lettuce-implicated-three-outbreaks-e-coli>.

from public land immediately adjacent to the animal facility because federal and state inspectors did not have jurisdiction to collect samples directly from the cattle ranch. Legislation introduced in the 116<sup>th</sup> Congress would have authorized FDA to request access to concentrated animal feeding operations during foodborne illness investigations (H.R. 5415, S. 2958).

Several factors might have contributed to FDA's delays in fully implementing key FSMA produce safety standards. FDA's authority to conduct inspections on farms and annual reporting requirements are limited as compared with its authority to carry out these activities in food facilities. FDA also has postponed compliance with certain key PSR requirements and have not fully implemented FSMA's traceability requirements pertaining to high-risk foods in response to continued consideration of industry feedback. Additionally, the lack of coordination of inspectional data between FDA and state and local authorities may lead to inconsistent implementation on rule requirements on farms, as state and local authorities often bear most of the responsibility for inspecting farms and food facilities within their jurisdictions.

## Enforcement and Reporting

Operations that handle RACs may be subject to either PSR or PCHF based on factors such as the types of activities performed on RACs and on business ownership (see "Enforcement Discretion of Certain Product Safety Rule Provisions"). FDA's authority to conduct inspections on operations that perform similar activities differs. Farms that produce certain foods identified as high-risk for contamination may not fall within FDA's more stringent requirements for inspection frequency and reporting.

For example, Section 105 of FSMA authorizes FDA to coordinate with USDA and states to perform activities to ensure compliance with the PSR. Section 201 of FSMA requires FDA to identify and prioritize inspections of *high-risk food facilities*, which does not include farms.<sup>82</sup> Facilities that handle high-risk foods and may be subject to traceability requirements, including leafy greens, tomatoes, and melons. Since farms subject to the PSR are not defined as facilities, FDA does not have authority to apply critical inspection frequency and annual reporting requirements of FSMA's Section 201 to farms. Congress could revisit FDA's enforcement capabilities on farms and consider whether to strengthen reporting requirements through additional authorizations, appropriations, or oversight.

## Traceability of High-Risk Foods

Section 204 of FSMA requires FDA to designate foods for which additional recordkeeping requirements are appropriate and necessary to protect public health.

On September 23, 2020, FDA published the Requirements for Additional Traceability Records for Certain Foods proposed rule (traceability rule).<sup>83</sup> The rule proposes to establish additional traceability recordkeeping requirements for persons that manufacture, process, pack, or hold foods the agency has designated for inclusion on the FTL.<sup>84</sup> The proposed rule would exempt, in part, farms (and the farm activities of farm mixed-type facilities) that are not subject to the PSR

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<sup>82</sup> For purposes of Section 201, the term *facility* means a domestic facility or a foreign facility that is required to register under 21 U.S.C. §350d. Per 21 U.S.C. §350d, facility does not include farms. Section 201 further sets facility inspection frequencies, and it amends 21 U.S.C. §393 annual reporting to Congress.

<sup>83</sup> FDA, "Requirements for Additional Traceability Records for Certain Foods: Proposed Rule," at <https://www.regulations.gov/document?D=FDA-2014-N-0053-0056>.

<sup>84</sup> FDA, "Food Traceability List," at <https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>.



because they have less than \$25,000 in average annual produce sales. A potential public health concern about this proposed rule is that there are no restrictions for where produce from exempt farms may be sold. For example, if a farm exempt from PSR requirements sells cucumbers to a distributor who comingles produce from several other farms during repacking, the contaminated cucumbers can potentially cross-contaminate other cucumbers from farms that followed PSR requirements. One alternative Congress could consider to prevent potential contamination from comingling would be to require farms to meet two criteria to be exempt from the traceability rule:

- less than \$25,000 average annual sales of produce sold during the previous three year period, adjusted for inflation (currently proposed); and
- greater than 50% of annual produce sales to qualified end users as defined in 21 C.F.R. §112.3.<sup>85</sup>

## Multi-jurisdictional Communications

Domestic farm inspections are generally conducted by state authorities. Most states have either adapted the requirements of the PSR into their state laws or perform inspections on behalf of FDA. Upon the conclusion of farm inspections, FDA inspectors provide a Produce Farm Observation Form 4056. FDA and NASDA have agreed that states are to have the option to provide Form 4056 or to choose an alternate method to deliver feedback. Because the FDA form is optional for states, there is no central repository to aggregate inspectional findings. Also, farms are not required to register with FDA per the Bioterrorism Act of 2002, as is required of food manufacturing facilities.<sup>86</sup> FDA and states are generally unable to develop a farm inventory to accurately identify farms; track and identify trends in inspectional results; and provide consistent, region-specific responses to business questions and concerns.<sup>87</sup> This may result in inconsistent application of rule requirements, potentially hazardous produce from unknown farms entering the food supply, and missed opportunities for program improvement. Congress could consider the costs and potential food safety benefits of authorizing FDA to develop a farm registry and unified inspection database in cooperation with states.

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<sup>85</sup> Per 21 C.F.R. §112.3, *qualified end user*, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in §1.227) that is located: (1) In the same State or the same Indian reservation as the farm that produced the food; or (2) Not more than 275 miles from such farm.

<sup>86</sup> FDA, “Registration of Food Facilities and Other Submissions,” at <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions>.

<sup>87</sup> GAO, *FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule*, GAO-18-85, November 2017, at <https://www.gao.gov/assets/690/688596.pdf>.

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