

## MEMORANDUM via Email

**TO:** Clients and Other Interested Parties

**December 1, 2015**

**RE:** Overview of FDA's Final Rule to Implement FSMA's Standards for Produce Safety

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On November 27, 2015, the Food and Drug Administration (FDA) published its final rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption ("Produce Safety Final Rule" or "Final Rule") to implement the Standards for Produce Safety set forth in Section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which was created by Section 105 of the FDA Food Safety Modernization Act (FSMA).<sup>1</sup>

FDA issued a proposed rule to implement the Standards for Produce Safety provisions in January 2013, followed by a supplement to the proposal in September 2014.<sup>2</sup> Although the Final Rule clarifies and refines many concepts and provisions, the final regulations generally are consistent with the proposal and the supplement.

The Produce Safety Final Rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. The Final Rule sets standards regarding agricultural water; biological soil amendments; sprouts; domesticated and wild animals; worker training and health and hygiene; and equipment, tools and buildings, among other things. We discuss each of these requirements in further detail below.

The Final Rule is effective January 26, 2016. Covered farms generally have 2 years from the effective date to comply with the Final Rule, i.e., January 26, 2018. Small businesses (those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three-year period) must comply within 3 years, i.e., January 26, 2019. Very small businesses (those

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<sup>1</sup> The final rule was published in the Federal Register on November 27, 2015. *See* Final Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354 (Nov. 27, 2015), available at: <http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>.

<sup>2</sup> Proposed Rule: 78 Fed. Reg. 3504 (Jan. 16, 2013); Supplement: 79 Fed. Reg. 58434 (Sept. 29, 2014).

with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three-year period) must comply within 4 years, i.e., January 26, 2020. Each of those categories of covered farms will have an additional two years to comply with certain agricultural water requirements. Compliance dates for covered activities involving sprouts are sooner: three years for very small businesses, i.e., January 26, 2019; two years for small businesses, i.e., January 26, 2018; and one year for all other farms, i.e., January 26, 2017.

## **I. Key Differences Between Proposed Rule and Final Rule**

Throughout the Final Rule – and as discussed in detail in the preamble to the rule – FDA has added clarity to various provisions in response to stakeholder comments. Nevertheless, the core components of the Produce Safety Final Rule are substantially similar to those expressed in the proposal and the supplement. Although it is not an exhaustive description of the differences between the proposal and the final rule, we note certain key changes/clarifications below:

- The definition of the term “farm” and the terms used in the definition now conform to the definition of the same term in the final human preventive controls rule (21 C.F.R. part 117) and the final animal preventive controls rule (21 C.F.R. part 507).
- The definition of the term “farm” now includes offsite packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms) for the purposes of application of the Produce Safety Rule, provided that specified ownership criteria are met.
- FDA has revised the list of examples of fruits and vegetables that are subject to the Final Rule and the list of exempt commodities.
- In lieu of the proposed requirement to train workers at the beginning of each growing season, the Final Rule requires that periodic training must be conducted at least once annually.
- The Final Rule withdraws proposed waiting periods between application of untreated biological soil amendments of animal origin and harvest, but the agency has deferred its decision on an appropriate minimum application interval until it conducts a risk assessment and research to supplement the science on an appropriate interval.

## **II. Summary of Requirements in the Produce Safety Final Rule**

Although a detailed description of all requirements in the Final Rule is beyond the scope of this summary memorandum, below we provide a synopsis of key requirements and definitions intended to implement the rule.

### **A. Application of and Exemptions to the Produce Safety Final Rule**

#### **1. Application (21 C.F.R. § 112.4)**

Farms subject to the Produce Safety Final Rule must comply with all of its applicable requirements when conducting a “covered activity” on “covered produce.” The term “farm” is

defined by the introduction of two new terms, “primary production farm” and “secondary activities 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:

- (1) pack or hold raw agricultural commodities;
- (2) 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 as described below, and
- (3) manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same management; or any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of the following: 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); treating 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 packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation).

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 (RACs), provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs 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. FDA added the secondary activities farm definition to allow offsite packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms) to be within the definition of the term “farm” and thus governed by the Produce Safety Rule, provided that the ownership criteria are met.

A “mixed-type facility” is defined as “an establishment that engages in both activities that are exempt from registration under Section 415 of the FD&C Act and activities that require the establishment to be registered. A subset of “mixed-type 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. Such a facility is likely to be subject to the Produce Safety Rule and the hazard analysis and risk-based preventive controls set forth at 21 C.F.R. part 117.

To be a “covered farm,” the farm must perform a “covered activity” on “covered produce.” The term “covered produce” is produce within the meaning of the Produce Safety Final Rule that is also a RAC. The Final Rule lists a number of examples of covered produce.<sup>3</sup> In addition, FDA clarifies that “covered produce” refers to the harvestable or harvested part of the crop.

A “covered activity” is defined, in part, as 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 RACs and only to the extent that such activities are within the definition of the term “farm.”

## 2. Exemptions

The Produce Safety Final Rule contains a number of exemptions and limitations. The Final Rule does not apply to:

- Specified types of produce that are rarely consumed raw (Section 112.2(a)(1)).<sup>4</sup>
- Produce that is used for personal or on-farm consumption (Section 112.2(a)(2)).
- Produce that is not a RAC (Section 112.2(a)(3)).

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<sup>3</sup> I.e., fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and mixes of intact fruits and vegetables (such as fruit baskets).

<sup>4</sup> I.e., specifically the produce on the following exhaustive list: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

- Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., via a “kill step”)<sup>5</sup> as long as certain disclosures are made and written assurances are received, with appropriate documentation (Section 112.2(b)).
- Farms that have an average annual value of produce sold during the previous 3-year period of \$25,000 or less (Section 112.4).

In addition, a qualified exemption and modified requirements apply to farms that meet two requirements: (1) the farm must have food sales averaging less than \$500,000 per year during the previous 3 years; and (2) the farm’s sales to qualified end-users (i.e., consumers and retail food establishments, if they are sufficiently close to the farm) must exceed sales to others.

#### **B. Agricultural Water (21 C.F.R. §§ 112.41-112.50)**

FDA finds that agricultural water is a potential route of contamination of produce and that poor agricultural practices related to water can lead to contamination and subsequent illness even where the potential for contamination is relatively low. Accordingly, FDA has imposed a number of requirements on agricultural water.

As a threshold issue, the term “agricultural water” is defined as water that is intended to, or is likely to, contact the harvestable portion of covered produce or food-contact surfaces. All such water must be safe and of adequate sanitary quality for its intended use. The Final Rule also establishes requirements for inspection, maintenance, and other actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding covered produce.

Section 112.44(a) of the Final Rule sets forth requirements for the microbial quality of agricultural water that is used for specific purposes and requires periodic analytical testing of such water. Agricultural water used for sprout irrigation water, in direct contact with covered produce or food contact surfaces, or for washing hands during or after harvest may not contain any detectable generic *Escherichia coli* in a 100 milliliter test sample. If agricultural water is found to be not safe or of adequate sanitary quality for its intended use or does not meet the Section 112.44(a) microbial quality requirements, its use must be immediately discontinued. The water and its distribution system cannot be used until the farm either (1) reinspects the system, identifies conditions responsible for the contamination, makes necessary changes, determines those changes are effective, and ensures the water meets the Final Rule’s requirements; or (2) treats the water as set forth in Section 112.43 (treatment of agricultural water).

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<sup>5</sup> Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of 21 parts 113 (low acid canned food), 114 (acidified food), or 120 (juice HACCP), treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products.

Under Section 112.44(b), a less stringent standard applies to agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method. In that case, the water may contain some colony forming units of *E. coli* within the limits specified in the Final Rule. If the agricultural water does not meet the microbial quality criteria required under Section 112.44(b), the farm must “as soon as practicable and no later than the following year,” discontinue the use of the water, unless it does one of the following: (1) Allow potentially dangerous microbes to die off in the field by using a specified time interval between the final irrigation and harvest, but the farm may do this for no more than four consecutive days; (2) allow for potentially dangerous microbes to die off between the harvest and the end of storage, or to be removed during commercial activities such as washing; (3) reinspect the system, identify conditions responsible for the contamination, make necessary changes, determine those changes are effective, and ensure the water meets the Final Rule’s requirements; or (4) treat the water under Section 112.43.

The Produce Safety Final Rule provides for a testing exemption for water sourced from public water supplies, under certain specified conditions, and water treated according to requirements set forth at Section 112.43. However, if a farm chooses to treat agricultural water to meet the requirements of the Final Rule, it must establish measures related to those treatment methods and monitor their effectiveness.

The Final Rule also requires specified records to be kept regarding agricultural water, including, inspection findings, water testing results, scientific data or information relied on to support the adequacy of water treatment methods, treatment monitoring results, scientific data or information relied on to support microbial die-off or removal rates or any permitted alternatives to requirements, time intervals or log reductions applied, and corrective actions.

### **C. Biological Soil Amendments (21 C.F.R. §§ 112.51-112.60)**

The Produce Safety Final Rule also establishes requirements for the use of biological soil amendments of animal origin. The Rule sets forth requirements for determining the status of a biological soil amendment of animal origin as treated or untreated and, depending on that status, specific requirements for their handling, conveyance, and storage.

A biological soil amendment of animal origin is considered treated if it has been treated as set forth in Section 112.54. A biological soil amendment of animal origin is considered untreated if it has not been treated under Section 112.54 or, if so treated, it has been contaminated after treatment or combined with certain specified substances.

All biological soil amendments of animal origin must be handled, stored and conveyed such that they do not become a potential source of contamination. Treated biological soil amendments of animal origin must be handled, stored and conveyed such that they do not become contaminated by an untreated biological soil amendment.

In the Proposed Rule, FDA proposed waiting periods between application of untreated biological soil amendments of animal origin and harvest (“application intervals”). The Final Rule

withdraws the application intervals, but the agency has deferred its decision on an appropriate minimum application interval until it conducts a risk assessment and research to supplement the science on an appropriate interval.

In addition, the Produce Safety Final Rule prohibits the use of human waste for growing covered produce, except sewage sludge biosolids used in compliance with U.S. Environmental Protection Agency regulations.

The Final Rule also requires specified records to be kept regarding biological soil amendments of animal origin. For a treated biological soil amendment of animal origin received from a third party, a farm must have documentation (such as a Certificate of Conformance) at least annually that: (1) the process used to treat the soil amendment is a scientifically valid process that has been carried out with appropriate process monitoring; and (2) the soil amendment has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin. For a treated biological soil amendment of animal origin produced onsite, a covered farm must establish and maintain documentation that process controls (for example, time, temperature, and turnings) were achieved.

**D. Growing, Harvesting, Packing, and Holding Activities (21 C.F.R. §§ 112.111-112.116)**

Immediately prior to and during harvest, covered farms must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. At a minimum, this requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.

Covered farms may not distribute “dropped covered produce”; that is, covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground, crops that grow on the ground, or produce that is intentionally dropped to the ground as part of harvesting.

Covered produce must be packed in a manner that prevents the formation of *Clostridium botulinum* toxin, if it is a known or reasonably foreseeable hazard. Covered farms must use food-packing material that is adequate for its intended use, which includes being: (1) cleanable or designed for single use; and (2) unlikely to support growth or transfer of bacteria. In addition, covered farms that reuse food-packing material must ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

For covered farms that grow, harvest, pack or hold produce that is covered produce, as well as produce that is not covered produce, they must keep the two categories of produce separate and adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using the food contact surfaces for covered activities on covered produce.

**E. Sprouts (21 C.F.R. §§ 112.141-112.150)**

The Produce Safety Final Rule applies additional rules to sprouts, as the agency finds sprouts present a special concern with respect to human pathogens compared to other covered produce. However, the sprouts regulated do not include soil- or substrate-grown sprouts harvested without their roots.

Under the Produce Safety Final Rule, beans and seeds used to grow sprouts must meet a number of requirements that mandate that covered farms:

- establish measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards;
- take steps if they know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen;
- visually examine seeds and beans, and packaging used to ship them, for signs of potential contamination; and
- treat seeds or beans that will be used to grow sprouts – or cause them to be treated – using a scientifically valid method to reduce microorganisms of public health significance.

Covered farms must grow, harvest, pack, and hold sprouts:

- in a fully-enclosed building;
- with food contact surfaces that are cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts;
- under a testing regime (as specified in Section 112.144);
- under a written environmental monitoring plan (as specified in Section 112.145) and, if *Listeria* species or *L. monocytogenes* is detected in the growing, harvesting, packing, or holding environment, certain actions must be taken (as specified in Section 112.146); and
- under a written sampling plan to test spent sprout irrigation water or sprouts for pathogens (as specified in Section 112.147) and, if a pathogen is detected, certain actions must be taken (as specified in § 112.148).

The Final Rule also requires specified records to be kept regarding sprouts, including records regarding the following:

- documentation of the treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans;
- a written environmental monitoring plan;
- a written sampling plan for each production batch of sprouts;
- documentation of the results of all analytical tests conducted for purposes of compliance with the Final Rule’s provision on sprouts;

- any analytical methods used in lieu of the methods that are specified in Sections 112.152 (testing for *Listeria monocytogenes*) and 112.153 (testing of sprout irrigation water); and
- documentation of actions taken when seeds or beans may be contaminated (Section 112.142(b) and (c)), actions taken when environmental tests are positive for *Listeria monocytogenes* (Section 112.146), and actions taken when spent sprout irrigation water or sprouts test positive for a pathogen (112.148).

**F. Domesticated and Wild Animals (21 C.F.R. §§ 112.81-112.84)**

The Produce Safety Final Rule also requires farms to take measures against potential contamination from domesticated and wild animals. These requirements apply when a covered activity takes place in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce. The requirements do not apply when a covered activity takes place in a fully-enclosed building or to fish used in aquaculture operations.

The Final Rule requires covered farms to assess areas used for a covered activity for evidence of potential contamination of covered produce during the growing season. Under Section 112.83, if significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), a covered farm must (1) evaluate whether the covered produce can be harvested in accordance with the requirements of Section 112.112 (bar to harvesting covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard) and (2) take measures reasonably necessary during growing to assist the farm during harvest when it must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. Although Section 112.83 and Section 112.112 contain similar language, it is important to note that Section 112.112 applies immediately prior to and during harvest, while Section 112.83 applies during the growing season.

FDA regulations clarify that the exclusion of wild animals from areas that are used for covered activities is not to be construed to allow the “taking” of threatened or endangered species in violation of the Endangered Species Act and that the regulations do not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat, or otherwise clear farm borders around outdoor growing areas or drainages.

**G. Worker Training and Health and Hygiene (21 C.F.R. §§ 112.21-112.33)**

Under the Produce Safety Final Rule, all personnel who handle covered produce or food contact surfaces, and their supervisors must receive adequate training, as appropriate to the person’s duties, upon hiring, and at least once annually thereafter. The training must include (1) principles of food hygiene and food safety; (2) the importance of health and personal hygiene for all personnel and visitors; and (3) the standards established in the Produce Safety Rule that are applicable to the employee’s job responsibilities. Persons who conduct harvest activities for covered produce must also receive training relevant to those activities as specified in the Final Rule. In addition, at least

one supervisor or “responsible party” of a covered farm must successfully complete food safety training acceptable to FDA.

The Final Rule requires covered farms to establish measures related to hygienic practices and measures against contamination of produce by persons. Covered farms must develop hygienic practices for farm personnel, including, personal cleanliness, avoiding contact with animals other than working animals, taking appropriate steps to minimize the likelihood of contamination when in contact with working animals, washing hands thoroughly after specified activities, and maintaining gloves in an intact and sanitary condition, among other measures.

In addition, covered farms must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (e.g., communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea). Farms must make visitors aware of measures to protect against contamination by people and ensure that they comply with those measures. Finally, covered farms must make toilet and hand-washing facilities accessible to visitors.

The Final Rule also requires specified records to be kept regarding worker training, including records that document required training of personnel, including the date of training, topics covered, and the persons trained.

#### **H. Equipment, Tools and Buildings (21 C.F.R. §§ 112.121-112.140)**

The Produce Safety Final Rule also imposes requirements on equipment, tools and buildings. Equipment and tools subject to the Final Rule are those that are intended to, or likely to, contact covered produce and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. FDA provides the following examples of tools and equipment: knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce.

Under the Final Rule, equipment and tools are subject to a number of requirements, including: (1) installation to facilitate cleaning of the equipment and of all adjacent spaces and (2) storage and maintenance to protect covered produce from becoming contaminated and to prevent them from attracting and harboring pests.

Buildings subject to the Final Rule include: (1) any fully- or partially-enclosed building used for covered activities and (2) storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials). Generally, buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces and covered farms must implement measures to prevent contamination of covered produce and food contact surfaces.

Covered farms must also implement measures for buildings regarding domesticated animals, pest control, toilet and hand washing facilities, disposal of sewage and trash, plumbing, and animal excreta control.

The Final Rule also requires specified records to be kept regarding equipment, including, records documenting the date and method of cleaning and sanitizing of equipment used in: (1) growing operations for sprouts; and (2) covered harvesting, packing, or holding activities.

**I. Records (21 C.F.R. §§ 112.161-112.167)**

The Produce Safety Final Rule also imposes general recordkeeping requirements, in addition those specific recordkeeping requirements in each subpart – e.g., Subpart C—Personnel Qualifications and Training; Subpart E—Agricultural Water; Subpart F—Biological Soil Amendments of Animal Origin and Human Waste; Subpart L—Equipment, Tools, Buildings, and Sanitation; and Subpart M—Sprouts.

Records can be stored either onsite or offsite, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite at the covered farm if they are accessible from an onsite location.

Generally, records must be kept at least 2 years past the date the record was created. Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with Sections 112.5 (exemption based on average monetary value of all food sold and direct farm marketing) and 112.7 (records required for Section 112.5), must be retained as long as necessary to support the farm’s status during the applicable calendar year. Records related to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

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We will continue to monitor and report on FDA’s activities to implement the Produce Safety Final Rule and other FSMA related activities.